UNIVERSITI TEKNIKAL MALAYSIA MELAKA

Faculty of Manufacturing Engineering

ADDITIVE MANUFACTURING IN MEDICAL APPLICATION, A COMPARATIVE STUDY BETWEEN CONVENTIONALLY MADE PROSTHESIS (PYLON) AND FUSED DEPOSITION MODELING PROSTHESIS (PYLON)

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MOHAMMAD AIZRULSHAH BIN KAMARUDDIN

A thesis submitted
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I declare that this thesis entitled " Additive manufacturing in medical application, a comparative study between conventionally made prosthesis (pylon) and fused deposition modelling prosthesis (pylon)" 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.

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APPROVAL

I hereby declare that I have read this dissertation/report and in my opinion, this dissertation/report is sufficient in terms of scope and quality as a partial fulfillment of Master of Manufacturing Engineering (Manufacturing System Engineering).

Signature : ....

Supervisor Name : DR SHAJAHAN BIN MAIDIN

Date : 22/3/17

DEDICATION

To my beloved parents

Hj Kamaruddin Hj Idris

Hjh Aisah Abu Bakar

To my loving wife

Azlinda Mohamad

And to my kids

Muhammad Izzu Syahmi

Maryam Kayyisah

Azra Sufiyyah

ABSTRACT

Prosthesis is an important device in helping amputee to recover from traumatizes experience. Prosthesis is an expensive device and not all amputees afford to own one, especially in the third world country. The specialized method of fabrication and needed highly skilled technician to produce the prosthesis contributed to the high price. The short life cycle of the prosthesis doesn't match with the high cost of ownership. The advancement of manufacturing technologies gives birth to additive manufacturing, a manufacturing process that did not use any tooling or molding. With additive manufacturing process, it is possible to produce low cost prosthesis due to the nature of the process. Additive manufacturing excels in producing low volume with high customizable product. The objective of this project is to compare between conventionally made HDPE prosthesis with ABS additive manufactured prosthesis. The comparison was done using statistical analysis focusing on the pylon in term of impact energy with print time and weight as the secondary proof. The study found that by comparing the impact energy between the HDPE and the fabricated ABS samples, 4 of the samples impact energies exceed the HDPE prosthesis. The print time and weight of the samples help to determine which FDM parameter of the print is the best. Comparing the weight of both the HDPE and FDM prosthesis specimen, it was found the FDM exceeds the weight of the HDPE prosthesis sample but it is not significant. The hardness test also concluded that the FDM prosthesis has high HR numbers. The result of the master report shows that it is possible to produce prosthesis pylon using FDM process.

ABSTRAK

Prostesis merupakan alat yang penting dalam membantu mereka yang telah kehilangan atau cacat anggota. Ianya membantu dan memudahkan mereka dalam melakukan aktivit seharian. Prostesis adalah alatan yang teramat mahal dan bukan semua pesakit mampu memilikinya terutama bagi penduduk dunia ketiga. Proses fabrikasi yang unik dah hanya mereka yang memnpunyai kepakaran yang tinggi boleh menghasilkan prostesis dan ini menyebabkan harga prostesis menjadi mahal. Jangka hayat prostesis yang singkat menjadikan ianya tidak sepadan dengan kos pemilikan yang tinggi. Kemajuan dalam bidang teknologi pembuatan telah melahirkan kaedah Pembuatan Tambahan "Additive Manufacturing", satu proses pembuatan tanpa acuan. Dengan proses Pembuatan Tambahan, ia adalah tidak mustahil untuk menghasilkan prostesis yang berkos rendah. Ini kerana proses Pembuatan Tambahan cemerlang dalam menghasilkan produk dalam jumlah rendah dan boleh diubah suai mengikut permintaan. Objektif projek ini adalah untuk membandingkan antara prostesis yang dihasilkan dengan menggunakan proses pembuatan konvensional dengan mengunakan bahan HDPE dengan prostesis yang dihasilkan menggunakan proses Pembuatan Tambahan menggunakan bahan ABS. Perbandingan ini dilakukan dengan menggunakan analisis statistik histogram tertumpu pada tenaga hentakan (impact energy), masa pembuatan dan juga mengambil berat specimen serta kekerasan sebagai bukti sekunder untuk mengukuhkan lagi keputusan. Kajian mendapati bahawa dengan membandingkan tenaga hentakan di antara HDPE dan sampel ABS, terdapat 4 sampel yang mempunyai tenaga hentakan yang tinggi melebihi prostesis HDPE. Masa pembuatan dan berat sampel membantu untuk menentukan parameter FDM yang terbaik. Perbandingan berat kedua-dua HDPE dan spesimen prostesis FDM, mendapati sampel FDM mempunyai berat melebihi berat sampel HDPE tetapi ia tidak ketara. Ujian kekerasan juga membuat kesimpulan bahawa prostesis FDM mempunyai nombor HR yang tinggi. Hasil daripada laporan ini menunjukkan bahawa ia adalah tidak mustahil untuk menghasilkan pylon prostesis menggunakan proses FDM.

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First and foremost, I would like to take this opportunity to express my sincere acknowledgement to my supervisor Dr. Shajahan bin Maidin from the Faculty of Manufacturing Engineering Universiti Teknikal Malaysia Melaka (UTeM) for his essential supervision, support and encouragement towards the completion of this Master Report

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Special thanks to all my peers, my mother, beloved father and siblings for their moral support in completing this degree. Lastly, thank you to everyone who had been to the crucial parts of realization of this project.

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HR yang tinggi. Hasil daripada laporan ini menunjukkan bahawa ia adalah tidak mustahil untuk menghasilkan pylon prostesis menggunakan proses FDM.

CHAPTER 1

INTRODUCTION

This chapter discusses briefly the project background, problem statement, objective and scope of a comparative study between conventionally made prosthesis and 3D printed prosthesis

1.1 Background of study

The prosthesis is a necessity for any amputee in order to recover from any traumatic experience either due to accident or disease. Currently, there are many methods used in the fabrication of prosthetic limb and the process is different from the manufacturer or fabricator and material type used. The usual material used for fabricating the prosthetic limb either polymer or aluminium and for the high end user, the prostheses are made from carbon fiber. The fabrication of the prosthetic is a time consuming and expensive process. Every prosthetic is individually fabricated for each patient. With the advancement of manufacturing process came additive manufacturing. Additive manufacturing is a process where the parts or product is built layer by layer without conventional tooling. This method of manufacturing could revolutionize the process of manufacturing prosthesis where it will reduce the manufacturing time and increase the customization factor. This report will cover the possibility and benefit of using additive manufacturing, focusing on fused deposition modelling in producing prosthetic limb. The possibility is the reduction of cost, time and the increase of the customization factor of the prosthetic limb. The most important characteristic to be investigated is the ability of FDM printed prosthesis to outperform the conventional HDPE made prosthesis. This master project will use Charpy impact experiment to find the impact energy and compared it between the FDM and HDPE specimen.

1.2. Problem statement

Additive manufacturing (AM) is a highly versatile manufacturing process with huge possibilities in producing high quality end product without using conventional manufacturing method. AM, typically known as 3D printing, is currently being promoted as the spark of a new industrial revolution. The technology allows one to make customized products without incurring any cost penalties in manufacturing as neither tools nor models are required(Weller, Kleer, & Piller, 2014). One of the areas that are not widely explored is in the manufacturing of prosthetic limb using additive manufacturing. The current method producing the prosthetic limb involves casting, molding and machining and this method is expensive and it is not a onetime cost because the prosthetic deteriorate when use. The price of a new prosthetic limb is anywhere from $5000 to $50000 depending on the quality and it will withstand 3 to 5 years of wear and tear(Gillian 2013). Furthermore the prosthetic limb needed to be custom fit for each individual and this will add more to the cost. Using additive manufacturing the manufactured prosthesis can be tailor made for each individual either adult of children. Yet the possibility of the AM manufactured prosthesis to outperform the conventionally made prosthesis is under question. That's the question that this master project will try to uncover.

1.3. Objective

The objectives of the project are:

1. To 3D print the prosthesis pylon using fused deposition modeling method with different shell thickness and infill density percentage.
2. To test the printed prosthesis pylon using an Impact Charpy test
3. To compare the standard lower limb prosthesis pylon with the 3D printed lower limb prosthesis pylon

1.4. Scope

The scope of the report only covers the study of passive lower limb prosthesis without any mechanical and electronic assist. This master project also will be covering the 3D printing process focusing on fused deposition modelling process and parameter to fabricate the lower limb prosthesis. The conventional fabrication method only listed and explains in the literature review.

The FDM printer used in the master project is manufactured by WINBO with build volume of 210mm x 150mm x 150mm. The printer is equipped with a dual print nozzle with the diameter of 0.4mm and a heated bed that can be temperature control. The slicer software use in the master project is MakerBot Desktop that has been developed by MakerBot Industries USA.

The filament material selected for the project is ABS (Acrylonitrile Butadiene Styrene) is a thermoplastic resin commonly used for injection molding applications with the filament diameter of 1.75mm.

Further information will be covered in the Chapter 3 methodology

CHAPTER 2

LITERATURE REVIEW

This chapter consists of the information gathered regarding the master project title, which is the comparative study between conventionally fabricated lower limb prosthesis and 3D printed lower limb prosthesis. The information collected and compare from previous research.

2.1 Prosthesis

Prosthesis is an artificial device, manufactured to replace missing body parts. Prosthesis is already being used since before century, but due to technology development, the prosthesis change from mere wooden peg into a complex and complicated robotic artificial limb. War is the major contributor and accelerated prosthesis development historically, the impulse to create functional replacement limbs has grown in parallel with the number of living amputees, whose ranks ballooned following periods of military conflict, especially the American Civil War and World War I (Hunter Oatman 2012).Figure 2.1 shows a mid-19 century prosthesis made from leather for the limb and strap, steel frame for its structural rigidity and articulation.

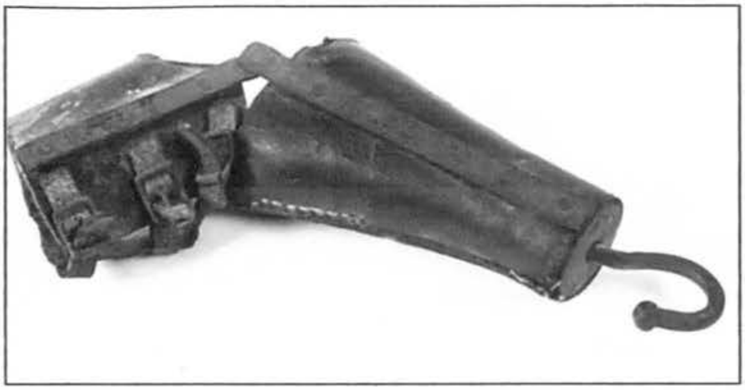

Figure 2.1: A mid-19 century artificial limb made from leather, wood and iron. (Macrea 2011)

The prosthesis is divided into two main categories which are; passive and active prosthesis. A passive prosthesis is a prosthesis that functions without external power; it is only driven by the wearer movement. Passive lower and upper body prostheses, sometimes called conventional or body-powered prostheses, are generally driven by gross body movements (Brooker 2012). They store energy in an elastic element during the beginning of a step and release it at the end in order to move the body forwards (Geeroms 2011). Figure 2.2 shows the controlled energy storing and release (CESR) foot developed in the Michigan University, where (A) is the controlled energy storing and release (CESR) prototype, (B) showing the schematic design of the energy storing and release system, (C) the energy storing and release sequence (Collins & Kuo 2010).

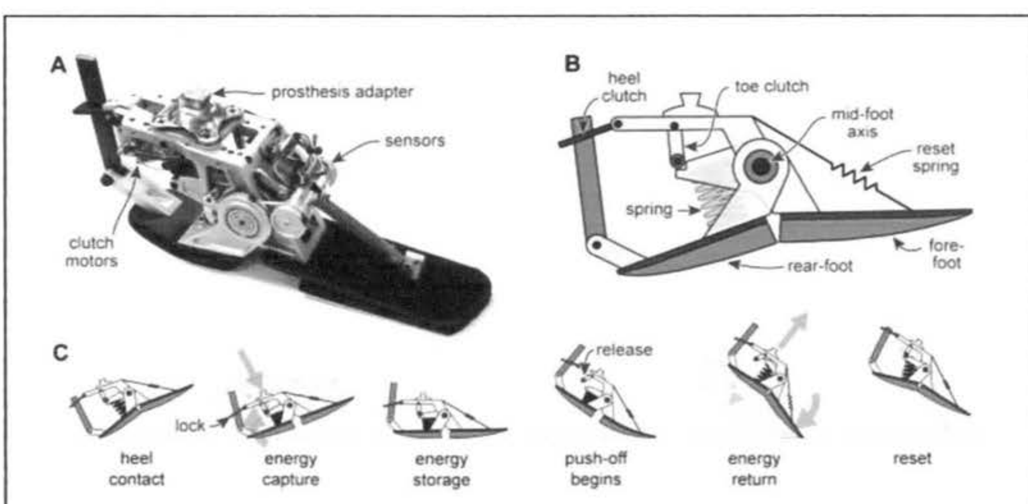

Figure 2.2: Controlled energy storing and release (CESR) foot

An active prosthesis is an artificial limb that is using external power to generate motion from a servo and sensor. An active prosthesis is one that uses an additional energy supply for motion and control over and above that provided by muscle power from the user (Brooker 2012).Active prostheses move on their own thanks to a battery-operated motor and this solves the problem of a passive prosthesis which is locomotion speed reduction, non-natural gait, and fatigue. Active prostheses help reduce the fatigue and improve the user posture (Duvinage et al. 2011). Two main categories of active prostheses exist to date: first, devices which controlled by the movements of other healthy parts of the body and secondly, devices equipped with a myoelectric control system. Advanced technique concerned with the detection, processing, classification, and application of myoelectric signals to control human-assisting robots or rehabilitation devices (Asghari Oskoei & Hu 2007). Figure 2.3 shows Ossur Proprio Foot which is the most advanced prosthetic foot that is currently available in the market. It uses an electric motor to adjust the orientation of the foot during the swing phase of walking, to clear the ground and able to auto adjusts when walking in irregular terrain to avoid tripping. Just recently, the device has evolved with a brain-controlled functionality using surgically implanted myoelectric sensors on residual muscle tissue of the amputees (Thapa 2015). Just recently, the device has evolved with a brain-controlled functionality using surgically implanted myoelectric sensors on residual muscle tissue of the amputees (Thapa 2015).

Figure 2.3: Ossur Proprio Foot

2.1.1 Categories of artificial limb

2.1.1.1. Transradial Prosthesis

Transradial prosthesis is an artificial limb that replaces an arm missing below the elbow. Two main types of prosthetics are available. Cable operated limbs work by attaching a harness and cable around the opposite shoulder of the damaged arm, passive prosthesis. The other form of prosthetics available is myoelectric arms an active prosthesis. These works by sensing, via electrodes, when the muscles in the upper arm move, causing an artificial hand to open or close. Figure 2.4 shows a high-end transradial prosthesis covered with light brown rubber to mimic the human skin and electronic motor and sensor for its motion.

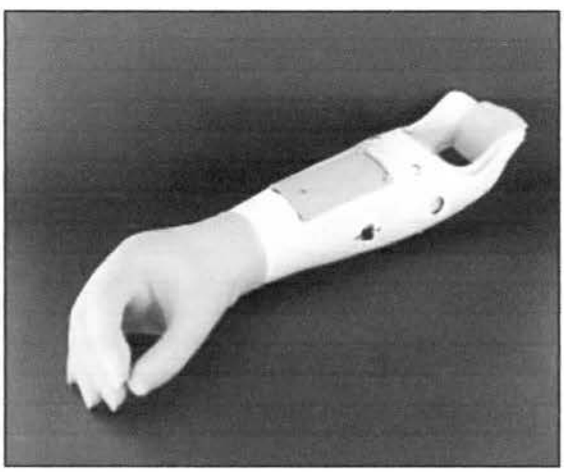

Figure 2.4: Transradial Prosthesis (courtesy: Centre of Prosthetics and Orthotics Inc.)

2.1.1.2. Transhumeral Prosthesis

Transhumeral prosthesis is an artificial limb that replaces an arm missing above the elbow. Transhumeral amputees experience some of the same problems as transfemoral amputees, due to the similar complexities associated with the elbow movement. This makes mimicking the correct motion with an artificial limb very difficult. Figure 2.5 shows the prosthesis for people who missing their limb to the shoulder. The chest plate houses the muscle sensor for triggering the electronic motor inside the arm, upper arm for motion and hand for the gripping action.

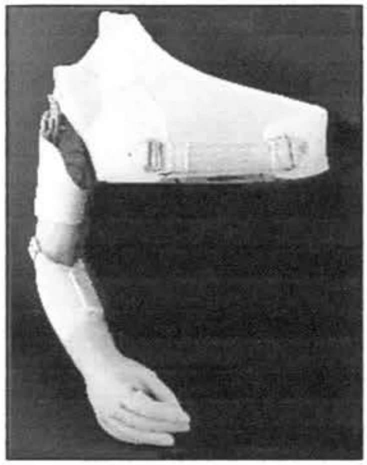

Figure 2.5: Transhumeral Prosthesis (courtesy: Centre of Prosthetics and Orthotics Inc.)

2.1.1.3. Transtibial Prosthesis

Transtibial prosthesis is an artificial limb that replaces a leg missing below the knee. Transtibial amputees are usually able to regain normal movement more readily than someone with a transfemoral amputation, due in large part to retaining the knee, which allows for easier movement. Figure 2.6 shows the transhumeral prosthesis made from a single sheet of polymer material. The prosthesis only has basic function, with the articulation point at the knee only.

Figure 2.6: Transtibial Prosthesis (courtesy: Dynamics O&P. Inc.)

2.1.1.4. Transfemoral Prosthesis

Transfemoral prosthesis is an artificial limb that replaces a leg missing above the knee. Transfemoral amputees can have a very difficult time regaining normal movement. In general, a transfemoral amputee must use about 80% more energy to walk than a person with two whole legs. This is due to the complexities in movement associated with the knee. In newer and more improved designs, after employing hydraulics, carbon fibre, mechanical linkages, motors, computer microprocessors, and innovative combinations of these technologies to give more control to the user. Figure 2.7 shows a high-end Transfemoral prosthesis that is made from composite (foot), aluminium (pylon or shank) and polymer for the socket. The prosthesis uses a mechanical device for knee articulation.

Figure 2.7: Transfemoral Prosthesis (courtesy: Dynamics O&P. Inc.)

There are multiple types of prosthesis being used and produce, this master project only study the fabricating of the lower transtibial prosthesis pylon.

2.2. Additive Manufacturing (AM)

AM is the extension of rapid prototyping and it is the latest technology in manufacturing. The name implies the method use where the part is built by adding layer upon layer of materials unlike the subtractive conventional method. AM processes were first presented to the public in 1987. AM processes are based on the fundamental concept of building up parts layer on layer; that is, the part is built up additively by generating individual layers