

**DEVELOPMENT OF AN OPEN-SOURCE 3-D PRINTABLE
SURGICAL INSTRUMENTS MADE FROM
ABS/PLA PLASTIC**

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**UNIVERSITI TEKNIKAL MALAYSIA MELAKA
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**DEVELOPMENT OF AN OPEN-SOURCE 3-D PRINTABLE
SURGICAL INSTRUMENTS MADE FROM
ABS/PLA PLASTIC**

This report is submitted in accordance with requirement of the University Teknikal Malaysia Melaka (UTeM) for Bachelor Degree of Manufacturing Engineering (Hons.)

by

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APPROVAL

This report is submitted to the Faculty of Manufacturing Engineering of Universiti Teknikal Malaysia Melaka as a partial fulfilment of the requirement for Degree of Manufacturing Engineering (Hons). The member of the supervisory committee are as follow:

.....
(Dr. Zulkeflee Bin Abdullah)

ABSTRAK

Penjagaan kesihatan dan perubatan merupakan antara sektor yang memandang berat potensi teknologi pencetakan tiga dimensi (3D) dan dijangka merevolusikan penjagaan kesihatan. Di zon perang seperti Gaza, peralatan and sumber perubatan adalah amat terhad and mahal disebabkan ekonomi yang lemah, konflik yang berterusan dan sekatan-sekatan akibat peperangan. Tujuan kajian ini adalah untuk membangunkan alat pembedahan yang boleh dicetak tiga dimensi secara terbuka yang diperbuat daripada plastik ABS/PLA. Pencetak tiga dimensi boleh digunakan untuk membuat instrumen pembedahan yang penting dari dalam zon perang dimana instrumen pembedahan ini amat terhad. Model CAD 3D instrumen pembedahan terdiri daripada pemegang pisau cukur, retractor, pemegang jarum, hemostat dan forsep tisu diubah suai dan dibangunkan menggunakan perisian CAD Solidworks. Dalam proses perancangan instrumen pembedahan, beberapa pengubahsuaian reka bentuk diperlukan untuk menangani perbezaan sifat antara ABS/PLA dan keluli tahan karat dimana ABS/PLA pasti lebih lemah daripada keluli tahan karat dari segi kekuatan. Kemudian, instrumen pembedahan ini dicetak secara tiga dimensi menggunakan mesin FDM. Untuk proses pasca-pemprosesan, kertas pasir digunakan untuk meningkatkan kualiti permukaan hasil cetakan. Sebelum instrumen pembedahan dicetak secara tiga dimensi menggunakan FDM, model 3D CAD instrumen pembedahan dianalisis dengan menggunakan FEA untuk menentukan kekuatan strukturnya. Kemudian, wawancara dilakukan dengan pakar bedah mengenai ergonomik dan fungsi instrumen pembedahan yang dicetak. Keputusan FEA menunjukkan bahawa rekabentuk instrumen pembedahan adalah boleh laksana and wawancara dengan pakar bedah memberikan respon yang positif. Hasil wawancara mendedahkan bahawa pemegang pisau cukur, retractor dan forsep tisu adalah berfungsi dan memerlukan sedikit penambahbaikan. Namun, hemostat dan pemegang jarum memerlukan penambahbaikan yang banyak dari segi rekabentuk and bahagian engsel.

ABSTRACT

Healthcare and medical are among the sectors that greatly utilized the potential of 3-D printing and expected to revolutionize the health care. In the war zone such as Gaza strip, medical equipment and resources are limited and unaffordable due to economic turndown, persistent conflict, and blockades. The aim of this study is to develop an open-source 3-D printable surgical instruments made from ABS/PLA plastic. The 3-D printer can be used to make essential surgical instruments from inside war zone where these surgical instruments are very limited. The 3D CAD model of the surgical instruments consist of scalpel handles, retractor, needle driver, hemostat and tissue forceps were modified and developed using Solidworks CAD software. In the process of designing the surgical instruments, some design modifications were needed to address the difference of properties between PLA and stainless steel which PLA is definitely weaker than stainless steel in term of strength. Then, these surgical instruments were fabricated using FDM machine. For post-processing process, sandpapers are used to improve the surface quality of the final printed parts. Before the surgical instruments were fabricated using FDM, the 3D CAD model of the surgical instruments was analyzed using FEA in order to determine its feasibility. Then, interviews were conducted with the surgeons regarding the ergonomic and functionality of the printed part. FEA result shows the designs of the surgical instruments are feasible and received positive feedbacks from surgeons through interview. From interview, the surgeons revealed that 3-D printed scalpel handle, retractor and tissue forceps are functional and require little improvements. The 3-D printed surgical instruments that have hinged design such hemostat and needle driver need redesign and improvements on the hinge area and overall design.

DEDICATION

Special dedication to my beloved parents, siblings and friends
for giving me moral support, money, cooperation, encouragement and also understandings
to complete this final year project.

Thank You So Much & Love You All Forever.

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LIST OF ABBREVIATIONS

ABS	Acrylonitrile Butadiene Styrene
CAD	Computer-Aided Design
CATIA	Computer Aided Three-Dimensional Interactive Application
CDC	Centers for Disease Control
CNC	Computer Numerical Control
DLP	Digital Light Processing
EDM	Electric Discharge Machining
FDM	Fused Deposition Modelling
FEA	Finite Element Analysis
FEM	Finite Element Modelling
FTMK	Faculty of Information & Communication Technology
FYP	Final Year Project
MoH	Minister of Health
PLA	Poly lactide
SLA	Stereolithography
SLS	Selective Laser Sintering
STL	Stereolithography
UTeM	Technical University of Malaysia Malacca
2-D	Two-Dimensional
3-D	Three-Dimensional

LIST OF SYMBOLS

HB	Brinell Hardness Number
°C	Degree Celcius
GPa	Gigapascal
g/cm ³	Gram Per Cubic Centimetre
MPa	Megapascal
mm	Millimeter
N	Newton
N/m ²	Newton per Square Metre
%	Percent
pH	Power of Hydrogen
HR B	Rockwell B

CHAPTER 1

INTRODUCTION

This chapter describes the background of study, problem statement, objectives of study, scope of study and significance of study. The background of study focuses on the potential of 3-D printing, also known as additive manufacturing or rapid prototyping in the recent years and its roles in medical industries, particularly to surgical instrument design. The problem statement reveals the application of 3-D printing technologies in fabricating surgical instruments inside the war zone such as Gaza strip where the supply of surgical instruments is limited and unaffordable due to blockades, economic downturn and persistent conflict (Haria, 2017). In addition, the scope of study emphasizes the focus and limitation of the study. At the end of this chapter, the significance of study is discussed.

1.1 Background of Study

In the early to mid-1980's, 3-D printing technology was invented and has developed drastically over the few decades after the patent was expired as well as the cost of the technology is getting cheaper (George et. al., 2016). Generally, 3-D printing can be categorized into three main variants which are stereolithography (SLA), fused deposition modelling (FDM) and selective laser sintering (SLS). Each 3-D printing technology has its own uniqueness in term of its fabrication method from digital data to solid object. The SLA invented by Charles Hull was the earliest form of 3-D printing in the early 1980's (Hull, 1984). In SLA, liquid curable photopolymer and an activating laser are employed to form solid parts in a layered manner. The company named 3-D Systems was later founded by Hull and he developed the STL file which is used to render digital files into a physical embodiment. In the late 1980's, the founder of the company Stratasys, S. Scott Crump invented fused deposition modelling (FDM) (Crump, 1992). FDM works by extruding

spooled printing material through a heated nozzle onto a build platform. SLS is the third main variant of 3-D printing which invented by Dr. Carl Deckard and Dr. Joseph Beaman in 1987 (Beaman & Deckard, 1990). In SLS, the plastic powder is melted/sintered with a laser in a layered manner to form the solid parts.

3-D printing has existed for over three decades, but this technology has never gained the attention of both technology experts and the public until the recent years. With the expiration of the last major patent for FDM in 2009, 3-D printer could be produced without infringing on intellectual property and eventually boost up the interest and investment in 3-D printing technologies (Lancker, 2015). This last major patent expiration in 2009 has brought the 3-D printing technologies to the new era and further unlocked the endless potentials of the technologies, whether at an industrial, local or personal level. It is undeniable that 3-D printing carries a numerous of benefits that simply outperform conventional methods of manufacture in many aspects (Attaran, 2017). One of the benefits is the high customization which allows parts to be fabricated according to individual need and preferences. Small batches of customised products are relatively low cost compared to conventional mass production methods. 3-D CAD models can be directly produced using 3-D printer without the requirement of tools and moulds, therefore costs related to assembly processes can be eliminated. Another benefit of 3-D printing is the ability to fabricate high complexity product. Basically, 3-D printing is capable to produce any novel and complex structures like free-form enclosed structures and channels, and lattices (Attaran, 2017).

The potential of 3-D printing is unlimited as it is applicable in every sectors and industries in the world. Some of the major applications of 3-D printing are healthcare and medical, aerospace, automotive, jewellery and many more. Healthcare and medical are among the sectors that greatly utilized the potential of 3-D printing and expected to revolutionize the healthcare (Schubert et. al., 2013). The use of 3-D printing in the medical industry has been increased dramatically. In medical uses for 3-D printing, there are several broad categories that can be organized, including fabrication of tissue and organ, customized prosthetics, implants, and anatomical models, and pharmaceutical research related to drug dosage forms, delivery, and discovery (Klein et. al., 2013). The application of 3-D printing in medicine industry has a lot of benefits, including the customization and personalization of medical products, drugs, and equipment, increased productivity, cost-

effectiveness, the democratization of design and manufacturing and enhanced collaboration (Schubert et. al., 2013). One of the successful examples of 3-D printing in medical industry is the Glia medical project founded by Dr. Tarek Loubani from Canada (Jackson et. al., 2017). This project addresses the problem of scarce supplies in Gaza's Al-Shifa hospital. The project provides free and open-source 3-D printable medical equipment made from ABS/PLA plastic to those who most require it. Dr. Tarek Loubani has successfully designed and fabricated a 3-D printed stethoscope which found to be as effective as the actual one (Jackson et. al., 2017). Besides that, there are numerous of relatively new companies that are the leader in innovating 3-D printed medical devices such as Clear Correct LLC, MedShape Inc, Oxford Performance Materials (OPM), Renovis Surgical Technologies Inc and many more (Stafford & Chau, 2008). However, this market is still in its early stage, but the expectations of successfully using 3-D printing technology in the medical industry are high. In 2012, 3-D printing market in the medical segment was only \$11 million, but as the cost of the technology is getting cheaper, the market is expected to reach \$1.9 billion in 2025 (Lux Research, 2013). It is strongly believed that recent advances in 3-D printing technology may be applicable to surgical instrument design. As the evidence, a set of functional surgical instruments was first successfully fabricated by Kondor et. al. using a FDM machine from Stratasys. The advantages of 3-D printed surgical instruments are customisation and can be easily modified according to a clinician's preference (Kondor et al., 2013).

The aim of this study is to develop an open-source 3-D printable CAD drawing of surgical instruments which can be fabricated using ABS/PLA plastic. Solidworks software is used to design the surgical instruments and will be 3-D printed using FDM machine. These 3-D printed surgical instruments will be further tested for its feasibility and usability.

1.2 Problem Statement

In the war zone such as Gaza strip, medical equipment and resources are limited and unaffordable due to economic turndown, persistent conflict and blockades (Jackson et. al., 2017). Medecins Sans Frontières revealed that most of its burns treatment and surgical operations are performed on children under 16. To make it worse, even bringing medical equipment into Gaza through either Egypt or Israel is no longer a good alternative anymore (Jackson et. al., 2017). According to Dr. Hassan Khalaf who is Deputy Health Minister in Gaza, he stated that many health services have stopped and it is expected to be out of control because Gaza is currently lack of essential medicines and supplies needed (Murphy, 2017). For the last five years, organ transplant patients, as well as routine surgeries needed patients have been suffering due to the Israeli-led, internationally-backed siege of the Gaza Strip (Murphy, 2017). Medical supplies and equipment are under the bans list following the democratic elections in 2006 that brought Hamas to power. This has further severed the quality of healthcare in Gaza. According to Pietro Dionisio (2016), he stated that the percentage of outdated medical equipment in Gaza is close to fifty percents and the average wait for spare parts is approximately 6 months. In 2014, the MoH Central Drug Store in Gaza reported that an average of 47 percent of medical disposables (424 of 902 items) and 26 percent of medicines on the essential drug list (124 of 481 items) were at or near zero stock for MoH facilities. To address the issue of insufficient medical equipment, Dr. Tarek Loubani from Canada founded the Glia medical project in Gaza's Al-Shifa hospital which provides free and open-source 3-D printable medical equipment made from ABS/PLA plastic to those who need it. Their first project has successfully designed a 3-D printed stethoscope and it is found to be effective as the actual one at the much lower price (Haria, 2017). Figure 1.1 shows the Glia project stethoscope on a self-assembled printer.



Figure 1.1 Glia project stethoscope on a self-assembled printer
(Source: 3-D Printing Industry)

3-D printing technology is not something new in medical industry as it has been applied in medicine industry since the early 2000s, when first 3-D printed dental implants and custom prosthetics were fabricated using this technology. Therefore, this study focused on developing an open-source 3-D printable CAD drawing of surgical instruments which can be fabricated using ABS/PLA plastic. The 3-D printer can be used to make essential surgical instruments from inside war zone where these surgical instruments are very limited.

1.3 Objectives of Study

This study attempts to achieve the following objectives:

1. To develop an open-source 3-D printable CAD drawing of surgical instruments which can be fabricated using ABS/PLA plastic.
2. To investigate the feasibility and design process of the 3-D printed surgical instruments.

1.4 Scope and Limitation of Study

This study focuses on developing an open-source 3-D printable CAD drawing of surgical instruments which can be fabricated using ABS/PLA plastic. There are five types of surgical instruments that will be involved in this study which are scalpel handles, retractor, needle driver, hemostat and tissue forceps. Other surgical instruments will not be mentioned in this study. All 3-D CAD modelling of these surgical instruments will be designed using Solidworks software and 3-D printed using FDM machine. The material used to fabricate these surgical instruments are limited to Acrylonitrile butadiene styrene (ABS) and Polylactide (PLA). Finite element analysis (FEA) will be carried out on these surgical instruments by using Solidworks simulation. In addition, interview with surgeons will be conducted to investigate the functionality and design of the 3-D printed surgical instruments.

1.5 Significance of Study

The outcome of this study is potentially contributing several benefits to the following parties:

a) Medical Industry

This study may introduce to the medical industry about using 3-D printing technologies to fabricate surgical instruments in the future. The surgical instruments fabricated using traditional method may be replaced with 3-D printing technology as it has more advantages such as low cost, high customization and many more.

b) The Country In The Midst of War

This study may help the country in the midst of war such as Gaza strip to solve the problem of insufficient surgical instruments. As surgical instruments are very limited in the war zone, 3-D printing can be used to fabricate these surgical instruments from inside war zone.

c) Academic institutions

Academicians and students of universities can use this study for research, teaching and learning activities.