THE FEASIBILITY STUDY OF IMPLANT MANUFACTURING USING THREE-DIMENSIONAL PRINTING AND SILICONE MOLDING

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by

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LIST OF ABBREVIATIONS

2D	Two-dimensional
3D	Three-dimensional
3DP	Three-dimensional printing
AAOS	American Academy of Orthopedic Surgeons
ABS	Acrylonitrile butadiene styrene
ASTM	American Society for Testing and Materials
BIS-GMA	Bisphenol A-glycidyl
CAD	Computer aided design
CAM	Computer aided manufacturing
C-C	Carbon-Carbon
CH_3	Carbon atom bonded to three hydrogen atoms
CNC	Computer numerical control
Co-Cr-Mo	Cobalt Chromium Molybdenum
CP-Ti	Commercially pure titanium
Cr-Ni-Cr-Mo	Chromium Nickel Chromium Molybdenum
CT	Computer tomography
DIY	Do it yourself
FDM	Fused deposition modeling
HA	Hydroxyapatite
Hg-Ag-Sn	Mercury Silver Tin
HUSM	Hospital Universiti Sains Malaysia
ISO	International Standards Organization
KKTM	Kolej Kemahiran Tinggi MARA
LOM	Laminated object manufacturing

MJS	Multiphase jet solidifications
MRI	Magnetic resonance imaging
MRT	Magnetic resonance tomography
MVA	Motor vehicle accidents
Ni-Ti	Nickel Titanium
NMR	Nuclear magnetic resonance
OPSM	Orthotics, prosthesis and special materials
PEEK	Polyetheretherketone
PET	Positron emission tomography
PET	Polyethylene terephthalates
PMMA	Polymethyl methacrylate
PMMA/HA	HA-reinforced PMMA
PTFE	Polytetra fluoroethylenes
Pt-Ir	Platinum Iridium
PVC	Polyvinyl chlorides
RE	Reverse engineering
RM	Rapid manufacturing
RP	Rapid prototyping
RT	Rapid tooling
RTV	Room temperature vulcanizing
SERC	Science and Engineering Research Centre
SGC	Solid ground curing
SLM	Selective laser melting
SLS	Selective laser sintering
SPECT	Single-photon emission computed tomography

STL	Stereolithography or standard tessellation language
Ti-13Nb-13Zr	Titanium Niobium13 Zirconium13
Ti-Al-Nb	Titanium Aluminum Niobium
Ti-Al-V	Titanium Aluminum Vanadium
Ti-Mo-Zr-Fe	Titanium Molybdenum Zirconium Iron
UHMWPE	Ultra high molecular weight polyethylene
UK	United Kingdom
US	Ultrasonic processes
USA	United States of America
USB	Universal serial bus
USM	Universiti Sains Malaysia
UTHM	Universiti Tun Hussein Onn Malaysia
UTM	Universal testing machine

LIST OF SYMBOLS

%	Percentage
°C	Degree Celsius
σ	Tensile stress
σ_f	Flexural stress
ε	Strain
μm	Micrometer
$\sum$	Summation
Δl	Difference between original length and final length
£	Great British Pound
A	Cross-sectional area
cm	Centimeter
cm^2	Square centimeter
E	Tensile Young's modulus or elastic modulus
E_B	Breaking energy
E_f	Flexural Young's modulus or bending modulus
g	Gram
GBP	Great Britain Pound
g/cm^3	Gram per cubic centimeter
h	Hour
I_s	Impact strength
J	Joule
J/m	Joule per meter
kg	Kilogram
kg/m^3	Kilogram per cubic meter

kN	Kilo Newton
l	Final length
l_0	Original length
L	Distance over which the surface deviations are measured
L	Span length
m	Slope of the initial straight line of stress and strain graph
ml	Milliliter
mm	Millimeter
mm/min	Millimeter per minute
mm/s	Millimeter per second
MPa	Megapascal
MYR	Malaysian Ringgit
N	Newton
P	Load applied
psi	Pounds per square inch
R_a	Average roughness
USD	United States Dollar
t	Thickness
w	Width
y	Vertical deviation from nominal surface or absolute value

KAJIAN KEBOLEHLAKSANAAN PEMBUATAN IMPLAN MENGGUNAKAN PENCETAK TIGA-DIMENSI DAN PENGACUAN SILIKON

ABSTRAK

Implan telah digunakan sebagai rawatan untuk pemulihan anggota badan manusia buat sekian lama. Pada masa kini, teknologi pencetak tiga-dimensi (3DP) memberi peluang kepada proses pembuatan dalam aplikasi perubatan dan menjadi satu teknologi yang berpotensi dalam pembuatan implan. Keterbatasan prosedur pembuatan implan sekarang adalah bahan sedia ada yang digunakan dalam proses 3DP tidak diluluskan dari segi perubatan untuk implan. Selain daripada kos pembuatan yang agak tinggi, masa dan proses intensif kerja untuk mencapai model dengan kualiti yang lebih baik dalam kemasan permukaan dan ketepatan anatomi. Sifat dan ciri-ciri implan adalah sangat penting untuk dipertimbangkan. Kekasaran permukaan implan juga perlu dipertimbangkan kerana bahan digunakan mesti menyesuaikan diri dan bergabung ke dalam tisu sekeliling selepas pengimplanan. Dalam kajian ini, dua kaedah pembuatan yang berbeza, dengan menggunakan bahan serasi biologi dicadangkan sebagai alternatif yang lebih baik daripada kaedah konvensional sebelumnya bagi menghasilkan produk langsung implan dan boleh digunakan secara langsung dalam bidang perubatan. Bahan *Polymethyl methacrylate* (PMMA) telah digunakan dalam kajian ini kerana bahan ini telah biasa digunakan secara komersial dan menjadi pilihan oleh pakar bedah dalam aplikasi perubatan. Kaedah pertama yang dicadangkan ialah pembuatan langsung oleh 3DP menggunakan pencetak 3D kos rendah, yang dipanggil *MakerBot Replicator*. Filamen PMMA digunakan dalam kaedah ini. Kaedah kedua adalah alat pantas tidak langsung iaitu pengacuan silikon dengan menggunakan *vacuum casting*. Implan dihasilkan dengan mereplikasi pola induk menggunakan pengacuan silikon di dalam ruang vakum. Selepas fabrikasi implan, analisis mengenai kajian kebolehlaksanaan antara kedua-dua kaedah fabrikasi ini di mana sifat mekanikal, sifat topologi (kekasaran permukaan), masa pembuatan dan kos pembuatan dikaji. Keputusan sifat mekanik implan yang dihasilkan oleh 3DP hampir memenuhi keperluan tulang manusia berbanding dengan implan yang dihasilkan oleh pengacuan silikon. 3DP menghasilkan kekasaran permukaan yang tinggi iaitu 6 kali lebih tinggi daripada pengacuan silikon dan mempunyai potensi untuk peratusan tinggi perlekatan sel. Berbanding dengan pengacuan silikon dan kaedah konvensional pembuatan implan, masa pembuatan oleh 3DP adalah 65% jauh lebih pendek dan kos pembuatan adalah 57% lebih rendah. Keputusan menunjukkan bahawa kedua-dua kaedah pembuatan boleh dilaksanakan dalam pembuatan implan. Namun. 3DP memberikan lebih banyak kelebihan dan menjadikannya lebih mudah untuk digunakan dalam pembuatan implan dan fabrikasinya dengan mengambil kira kos, masa dan manfaat daripada pembuatan implan yang disesuaikan untuk pesakit tertentu. 3DP boleh membuka jalan untuk teknologi yang lebih canggih dan memberi sumbangan besar dalam bidang perubatan.

Kata kunci:

Aplikasi perubatan; Implan perubatan; Pencetak tiga-dimensi; *MakerBot Replicator*; Pengacuan silicon; *Vacuum casting*; PMMA; Sifat mekanikal; Sifat topologi; Masa pembuatan; Kos pembuatan.

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ABSTRACT

Implant has been used as a treatment for the restoration of the human body for a long time. Nowadays, three-dimensional printing (3DP) technology provides opportunity to the manufacturing process in medical applications and become a potential technology in implant manufacturing. The limitation of the current implant manufacturing procedure is the existing materials used in 3DP process are not medically approved for implant. Apart from relatively high production cost, time and work intensive process to achieve model with better quality in surface finish and anatomical accuracy. The properties and the characteristics of the implant are very important to be considered. The surface roughness of the implant needs to be considered as the material must adapt to and blend into the surrounding tissue after implantation. In this research, two different manufacturing methods by using biocompatible material are proposed as improved alternative of the previous conventional method in order to produce direct product of implant and can be used directly in medical field. Polymethyl methacrylate (PMMA) material used in this study as the material is already commercially established and most preferred by surgeons in medical application. First proposed method is direct production by 3DP using a low cost 3D printer, called MakerBot Replicator. PMMA filament was used in this method. The second method is indirect rapid tooling (RT) which is silicone molding by using vacuum casting. The implant was produced by replicating the master pattern using silicone molding under vacuum chamber. After the implant fabrication, the analysis on the feasibility study between both fabrication methods in which mechanical properties, topological properties (surface roughness), production time and production cost were investigated. The results of mechanical properties of implant produced by 3DP barely meet human bone requirement as compared to implant produced by silicone molding. 3DP produces high surface roughness which is 6 times higher than silicone molding and has potential for high percentage of cell attachment. As compared to the silicone molding and the conventional method of implant manufacturing, the production time by 3DP is 65% much shorter and the production cost is 57% lower. The results show that both manufacturing methods are feasible to apply in implant manufacturing. However, 3DP provides more advantages and make it more feasible to apply in implant manufacturing and fabrication taking into accounts the cost, time and benefit of highly customized implant for specific patient. 3DP can pave the ways to more advanced technology and gives great contribution to the medical field.

Keywords:

Medical application; Medical implant; Three-dimensional printing; MakerBot Replicator; Silicone molding; Vacuum casting; PMMA; Mechanical properties; Topological properties; Production time; Production cost.

CHAPTER ONE

INTRODUCTION

1.1 Introduction

This chapter consists of six sections which provide general ideas of this research. First section is research background which contains theoretical foundations related to the research and elaboration of research planning. Second section is problem statements and next is research objectives. Then, research hypotheses, scope of research and thesis outlines are illustrated in this chapter.

1.2 Research background

In many medical cases where implant is needed, it is common practice traditionally, to produce implant by cutting metal pieces, usually stainless steel or Titanium, or sometimes bovine bones to be fitted into patients in place of damaged bones, as temporary bridging structure or permanent replacement. The conventional techniques where traditional fabrication like sawing, cutting or bending in the workshop to fit varying patient sizes are time consuming and in only roughly estimated dimensions. This often created misfit on patients, leading to problem like premature implant loosening and excessive wear over a period of time leading to prolong uncomfortable living for patient. Implant cannot be easily and accurately customized according to unique size and lifestyle of individual patient. The recent development manufacturing technology, namely three-dimensional printing (3DP) offers the opportunity to improve medical implant fabrication.

3DP technology is a promising and powerful technology that can potentially improve and revolutionized field of medical science (Bagaria *et al.*, 2011b). 3DP technology can fabricate models with complex geometric forms, making it very suitable for reproducing the intricate of the human body (Raos *et al.*, 2005). By conventional method of casting or handcrafting, the fabrication of customized implants to fit everyone is challenging and in many cases, it is impractical to accomplish because of high cost and tight timeline (Frank *et al.*, 2008). By using layer-based nature of 3DP technologies, the creation of complex freeform shapes is very feasible, hence allowing customization to fit each patient.

The manufacturing of medical models such as implant using 3DP technology begins with the acquisition of three dimensional shape data of both internal and external human body structures using medical scanners such as Computer Tomography (CT) and Magnetic Resonance Tomography (MRT), which are commonly used in medical imaging to obtain anatomical information. The data from medical imaging is then used for the production of 3D physical object by using CAD/CAM system, in a 3DP apparatus. Although 3DP technology has been around since the last 15 years, it is relatively new in medical field. The use of 3DP in medical is not satisfactorily high, despite the potential benefits.

Implant is used as treatment for the restoration of the human body that has been lost due to traumatic injuries and non-traumatic events. In recent years, some of the biomaterial used in implant manufacturing to fill the defect includes bioceramics, biopolymers, metal and composites. Titanium and polymeric materials such as polymethyl methacrylate (PMMA) and polyetheretherketone (PEEK) are the most preferred by surgeons in medical applications because of their excellent mechanical properties and biocompatibility (Rahim *et al.*, 2015b). Most implants are just simple models that only give approximate fit to the patients. By referring to the previous and recent studies, the material of polymethyl methacrylate, (PMMA) was proposed in this research. This is because PMMA material is already established and mostly used in medical implant by researcher from previous and recent studies (Teo *et al.*, 2016).

A research on biocompatible implant manufacturing was carried out, including the analysis of the PMMA material as potential material for implant. The proposed solutions of implant manufacturing process are divided into two different processes; direct printing using 3DP and indirect production using Rapid Tooling (RT). In direct printing using 3DP, implant material must be printable and also biocompatible. A low cost 3DP machine (MakerBot Replicator 2X) based on fused deposition technology where solid filament is fused, was used in 3D printing. For indirect implant fabrication using rapid tooling, silicone molding was used where a 3D physical model of the implant (also known as the master pattern) from any material is first produced using 3D printer, then used in subsequent silicone molding process to replicate the implant in the form of actual biocompatible material. The feasibility of the two methods for implant manufacturing is assessed based on the results of analysis in characterization of material, topological properties, production time and production cost.

1.3 Problem statements

There are 6.3 million fractures each year in the United States, according to the AAOS (American Academy of Orthopedic Surgeons). In addition, the costs associated with these fractures are extremely expensive. In fact, there were more than 500,000 bone graft procedures performed in the USA in 2005 and charged about USD 2.5 billion (Stevens *et al.*, 2008). That means the costs related to the fractures are too expensive. In medical data reported in Hospital Universiti Sains Malaysia (HUSM) between 2007 and 2011, 447 patients had experienced maxillofacial (jaws and face region) fractures (Pohchi *et al.*, 2013). 85% of the maxillofacial fractures were caused by the motor vehicle accidents (MVA) and followed by falls (5%), fight and assaults (4%), sports related injuries (3%), industrial accidents (2%) and others (1%). This showed MVA was the main factor of the maxillofacial fractures reported in HUSM.

In early implant production, the conventional manufacturing procedures are milling, casting and injection molding (Raos *et al.*, 2005). Milling can be used to produce surgical instruments with low material cost (Petzold *et al.*, 1999). Implant production cost by milling is lower than in the 3DP process (Raos *et al.*, 2005). However, the geometric accuracy is poor, which is (±1.5 mm) (Petzold *et al.*, 1999). Before this, modifying implants into a desired shape, size and fits should be done by shaving pieces of metal and plastic using scalpels and drills or sometimes surgeons need to perform bone graft surgeries (Ventola, 2014), which can be time consuming for the whole process of implant production.

Nowadays, the use of 3DP technology in medicine is already known. Unfortunately, it is not satisfactory high since it is a relatively young field, and has wide potentials to be reached (Silva *et al.*, 2014). Currently in Malaysia, the craniofacial implant that used by oral maxillofacial surgeon is mostly imported from overseas and the cost can be varies depends on the material, size and complexity of defects, but generally very high. In medical, CT scan or MRT are commonly used imaging techniques for diagnostic purpose before medical team and the patient can decide the next best treatment. CT and MRT data are only 2D virtual images of different layers of patient’s anatomy, as such are difficult to comprehend. With 3DP, such 2D data may be printed in 3D physical form allowing for better assessment of the disease. This can be extended to implant design and fabrication where CT or MRT data can be