UNIVERSITI PUTRA MALAYSIA

STENT STRENGTH IMPROVEMENT THROUGH THE UTILIZATION OF SELECTIVE LASER MELTING TECHNOLOGY

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By

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The invention of Metal Additive Manufacturing or known as Selective Laser Melting has opened a wide application of field such as biomedical devices, automotive and Oil & Gas, Aerospace and Consolidation of parts, and in certain area where stronger parts can be produced. Furthermore, the Selective Laser Melting (SLM) has been known to produce new net shape and intricate design which cannot be achieved through conventional processing. In this research, the problem statement of laser cuts stent has been addressed to overcome the constraint of laser cutting by enhancing with the SLM technology. The additively manufactured stent is consisting of seven (7) type design where the purpose was manufacturability through SLM technology by utilizing the strut, diameter, height, and angle. A set of default parameter with the laser power of 200 Watt, with the hatching distance of 0.14mm, layer thickness of 0.02mm and scanning speed of 800mm/s has been applied through a series of different type of additive stent. The tolerances or shrinkage of the stent are also achieving a good result because the dimensional accuracy reaches closely to 0.5% shrinkage (±70 μm) of diameter and 0.03% (±30 μm) for the height. Result from testing method also shown that, where all seven (7) AM stents showed better performance compared with conventional stent due to the placement of strut hoops in all connectors with highest stiffness was 1.44 N/mm (in axial) and 0.75 N/mm in radial during compression load. Whereas the flexural test showed a better stiffness in the value of 0.44N/mm. The heat treatment stent was then compared with the As-built stent where there is significant increase on compression test (2.04 N/mm). While the Flexural Test showed the decrease of stiffness (0.36 N/mm), but still the acceptance rate was better compared to the commercial stent in the market. The Clinical test (Cytotoxicity test) also showed promising result where all the additively manufactured stent showed 100.3% viability cells.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

PENINGKATAN KEKUATAN STENT MELALUI PENGGUNAAN TEKNOLOGI LEBUR LASER TEPILIH

Oleh

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Penciptaan Pembuatan Aditif Logam atau dikenali sebagai Teknologi Lebur Laser Terpilih (SLM) telah membuka aplikasi bidang yang luas seperti peranti bioperubatan, automotif dan Minyak & Gas, Aeroangkasa dan Penyatuan bahagian, dan di kawasan tertentu di mana bahagian yang lebih kuat boleh dihasilkan. Selain itu, Teknologi Lebur Laser Terpilih (SLM) telah diketahui menghasilkan bentuk bersih baru dan reka bentuk rumit. Dalam penyelidikan ini, kenyataan masalah pemotongan laser stent telah ditangani untuk mengatasi kekangan pemotongan laser dengan meningkatkan dengan teknologi SLM. Stent yang dihasilkan secara aditif terdiri daripada tujuh (7) jenis reka bentuk di mana tujuannya adalah pembuatan melalui teknologi SLM dengan menggunakan strut, diameter, ketinggian dan sudut. Satu set parameter lalai dengan kuasa laser 200 Watt, dengan jarak penetasan 0.14mm, ketebalan lapisan 0.02mm dan kelajuan pengimbasan 800mm / s telah digunakan melalui satu siri jenis stent tambahan yang berbeza. Toleransi atau pengecutan stent juga mencapai hasil yang baik kerana ketepatan dimensi mencapai hampir 0.5% pengecutan (±70 μm) diameter dan 0.03% (±30 μm) untuk ketinggian. Hasil daripada kaedah ujian juga menunjukkan bahawa, di mana semua tujuh (7) Stent AM menunjukkan prestasi yang lebih baik berbanding dengan stent konvensional kerana penempatan gelung strut dalam semua penyambung dengan kekakuan tertinggi adalah 1.44 N / mm (dalam paksi) dan 0.75 N / mm dalam jejari semasa beban mampatan. Manakala ujian lenturan menunjukkan kekakuan yang lebih baik dalam nilai 0.44N/mm. Stent rawatan haba kemudiannya dibandingkan dengan stent yang dibina as di mana terdapat peningkatan yang ketara pada ujian mampatan (2.04 N/mm). Walaupun Ujian Flexural menunjukkan penurunan kekakuan (0.36 N/mm), tetapi kadar penerimaan masih lebih baik berbanding stent komersial di pasaran. Ujian klinikal (Ujian

Cytotoxicity) juga menunjukkan hasil yang menjanjikan di mana semua stent yang dihasilkan secara aditif menunjukkan 100.3% sel daya maju.

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LIST OF ABBREVIATIONS

MAM	Metal Additive Manufacturing
SLM	Selective Laser Melting
3D CAD	3-Dimensional Computer Aided Design
SEM	Scanning Electron Microscope
CoCrMo	Cobalt Chromium Molybdenum
Ti6Al4v	Titanium alloy
SS316L	Stainless Steel 316L alloy
HIP*ing*	Hot Isostatic Pressing
AFM	Atomic force microscopy
LPBF	Laser Powder Bed Fusion

CHAPTER 1

INTRODUCTION

1.1 Metal Additive Manufacturing

Metal Additive Manufacturing (MAM), or Selective Laser Melting (SLM), is a new technology where it uses a fiber laser for fabrication. The laser melts a feedstock (metal powder) layer by layer within variable thickness, and the powder solidifies to produce a fully dense component. The technology has been used comprehensively in many sectors, such as medical product, aerospace, tooling, and automotive sectors, can be found as early as the 1990s. The technology is used to build a complex object through three-dimensional computer-aided design (3D CAD) models without the use of special tools or jigs in the likes of subtractive processes, such as Computer Numerical Control (CNC) machining or laser cutting.Two (2) researchers from a university in the United Kingdom (UK) has created an invention, where they successfully produced patient-specific 3D-printed vascular stents using a technology called Micro Continuous Liquid Interface (Micro CLIP) from specialized polymer [1]. In 2017, two (2) researchers from Italy Polytechnics also worked on the same subject but with a different technique application, which is the SLM technique, to produce a metal stent [2]. New research published by one of the universities in United States of America (USA) illustrates a possible improvement in the use of medical stents, demonstrating the successful use of a completely biodegradable magnesium-alloy tracheal stent that avoids some of the risks posed by more traditional material [3]. Either prototyping or product development, SLM technology has penetrate through aerospace sector, medical devices, automotive sector, and tooling industry. SLM has been used to create a full dense part, directly from 3D STL data [4]. SLM is also used where all the parts which cannot be produced by conventional manufacturing, such as bulk deformation (casting) or subtractive (cutting tool) technique. One of the best cases involved the production of a porous structure made by titanium alloy (Ti-6Al-4V) possessing different sizes of pores and joint pore structures. This intricate structure with high rigidity and strength has already been produced together with additive manufacturing (AM) and powder metallurgy techniques [4]. Nowadays, a lot of industry player, in the likes of automotive (for retrofitting), hospitals, and aerospace industry (spare parts), fully adopting SLM technology [5].

1.1.1 Stenting

A stent has gain tremendous growth for nearly 2 decades, where all three (3) types of stents, which is bare metal (BMS) stents, biodegradable (BDS) stents and drug eluting (DES) stents and have been implanted to the patients with heavy complication of artery disease. Stents are a device used to treat narrowed or weakened arteries in a patient’s body. This small device helps surgeons expand arteries during surgery due to the build-up of fats that block the blood flow inside arteries, which is the epidemic of heart failure [6]. Stents are utilized to widen up arteries and help to reduce the risk of heart attack caused by the build-up of plaque. Stent positioning and length or diameter usually depend on the surgeon's expertise and skills. If a stent incorrectly fit, it could loose and went to the other section of the human body and cause catastrophic implication to the patient. Stents are designed using various metals, such as stainless steel, cobalt-chromium alloy, and recently, using nitinol. A stent that fits accurately is always an issue, although different sizes are available. The physician must guess the stent size for a good fit to keep the blood vessel open. However, there is no optimal solution because every human is different, and the results are highly dependent on the physician's experience. There are cases where a physician tries to place a stent into a patient's blood vessel, but the stent fits poorly. This condition might be due to indifferent geometry in the patient's blood arteries, such as a miss orientation path that can disturb the flow of blood, causing the stents to fracture. This will create additional issue for patients who use drugs as a supplement (reduce blood clots), normally carried out to patients with stents. It can be expected that the probability of these complications can be minimized by producing a stent with the correct geometrical and biological necessity.The application of AM or 3D printing technology produces personalized coronary stents. In stent manufacturing, the diameter of the diseased coronary is measured, and 3D reconstruction is conducted based on the coronary angiography imaging data. A personalized stent is produced for each patient according to the diameter, length, and morphological characteristics of the target vessel that suits the lesion. The use of AM can minimize the supply chain by shortening the current manufacturing process from six steps: rolling, tubing, turning, laser cutting, heat treatment, and polishing) to only three steps (3D printing, heat treatment, and polishing).

1.1.2 Stent materials

Various materials and techniques have been used to produce stents (e.g., BMS, DES, and BDS) with their respective advantages and disadvantages. DES are more popular than BMS because DES have a flexibility material to reduce the passive ion release that can affect patients in the long term. Nowadays, many researchers have begun to explore the possibility of commercializing BDS using polylactic acid (PLA) and polymethyl methacrylate (PMMA), where the devices can dissolve in a human body in a certain period. Stents need to fulfil several requirements before they can be used for implants. These include strength, elastic modulus, resistance towards corrosion, and good biocompatibility. Stents available in the market nowadays use several types of materials, consisting of stainless steel 316L, nickel-titanium alloy (nitinol), titanium alloy (Ti-6Al-4V), and other metal alloys. Nitinol or known as shape memory alloy (SMA) has been developed extensively due to its ability to change shape according to the temperature and environment, besides possessing high strength and biocompatible. The feedstock such as SS316L, 181 Ta, NiTi, CoCrMo, and Ti6Al4V are a type of metal alloy which are commonly used to produce a stent. A stent must have several requirements, such as highly resistance to corrosion, excellent modulus of elasticity, good biocompatibility and finally radio opacity enabled for detection of scanned image during angioplasty. In this thesis, medical-grade ASTM F75 cobalt-chromium-molybdenum (CoCrMo) alloy was chosen due to its excellent strength and biocompatibility, thus making it the only outstanding material among to its classes. Stainless steel has excellent characteristics (e.g., strength and corrosion resistance). However, due to its relatively low cyclic loading (fatigue life), other materials must be assessed as an alternative to stainless steel. One research study has been done to compare two (2) types of material: SS316L and Ti-6Al-4V, where Ti-6Al-4V has better fatigue lifetime than stainless steel (316L) as a hip implant [7]. Whereas another study has been made where the average number of cycles to failure for the titanium rod models was 12840 while the CoCr rod models failed at a significantly higher, 58351 cycles (fatigue tested with 700N at 4 Hz until failure) [8]. Thus, it can be concluded that the cobalt-chromium has better tendency to sustain a longer lifetime compared to stainless steel or titanium alloy. In this case, Cobalt-chromium-molybdenum superalloy was chosen as the material of investigation, which is in conformity with F75 medical grade and meets the specification of ISO 5832-4. This superalloy is also comparable to the casting of conventional cobalt-chromium. This material is extensively used in metal additive manufacturing machines and widely accepted in biomedical applications (hip replacement, osseointegration) and dental prosthetics [9]. Cobalt-chromium alloys possess radial strength with excellent elastic modulus and capable of producing very fine thin-wall structure without compromising the strength of the material. Cobalt-chromium alloy has been known to have less biocompatibility issues; thus, it is suitable for biomedical applications. The alloy has better strength either in axial or radial force (load), highly flexural, and radio opacity [10].

1.1.2 Stent designs

Design of the stent is according on the strut dimensions and stent thickness. This research purposedly to carry out to find a property of stents by additive manufacturing based on designs, mechanical properties, and clinical studies. A study applied thin struts to avoid restenosis (blocked artery after surgery) [11]. The thickness of strut was the main issue for diameter reduction in arteries after surgery procedures [12]. Research was conducted to evaluate the implication of thinner struts, and the results listed out where thinner struts had a lower probability of restenosis, and stent design was a factor for late lumen loss after binary restenosis [11]. The selected stent design needs to be checked for dimensions after fabrication because shrinkage affects the SLM accuracy especially on the end products. One of the research projects commented that the number of design porosity contribute to shrinkage compared to the full dense [13]. A full dense part is one of the prime focuses to the implant area. Therefore, a stent through SLM must have the same or better specifications with other manufacturing techniques, such as bulk deformation or subtractive manufacturing. The grain structure, tensile strength, and ductility are better compared to conventional cobalt chromium [13]. The properties of strength, and ductility of Nickel alloys increased with increasing Chromium composition [14]. The stents must comply with the rules of so-called Design for Additive Manufacturing, in the likes of angle, overhang, holes and length of walls. Specific SLM parameters have been developed to give a better density to weight ratio, which influences energy density. Energy density was determined for optimization, leading up to 99.9% for cobalt-chromium alloy [15]. The stent density can be improved through secondary processing, which is called Hot Isostatic Pressing (HIP*ing*). HIP*ing* is a process of heat treatment characterized by using high concentration inert gas (argon) pressure through a sealed vat, where the common lead time is according to the stipulated time setting. The direct advantage of HIP is that the process can merged porosity inside, thus resulting for a better specification [16]. The demand for implants biocompatibility is important because a lot of issues happened after post-surgery. The stents need to undergo in vivo and in vitro studies before being used and acceptable for implants during surgery. This specific evaluation is called cytotoxicity measurement, which assesses viability of the cells [17]. Commercially stents are consisted with different type of design and diameter. A new developed tracheal stent was explained by one of a researcher with good results [18]. The model, which consist of "D" shape surface with a flexible geometry which permitted the stent location during respiratory, are choose for this assessment (Figure 1.1). The researcher proposed the use of a tool to alter the stent specification according to the artery size of the patient. The design parameters that can be modified are the height, diameter, thickness, and length. All design parameters can be saved and modified in a Microsoft Excel file for patient [18]. Customization of implants is costly and consumed a lot of time [19]. To search a technology that can manufacture specific customize parts through a software design while reducing a time cost consuming is interesting. Additive Manufacturing came out as a standard technology to produce customized implants faster and cheaper. The Fused Deposition Manufacturing (FDM) technology were utilized to manufacture a silicone because of the cheaper costs and to focus and utilize the entire manufacturing process. The first study was done using the Fused Deposition Manufacturing (FDM) machine and commonly type silicone. Beginning through a CAD design and fabrication developed by Melgoza et al. [18], a stent was successfully printed. The stent had the same characteristics as the imposed model. Therefore, after adjustments concerning the manufacturing path strategy, it could be said that the FDM machine was better to fabricate the product. Later, the FDM machines were used to fabricate high grade silicone stents. But, because of their material properties, the study was failure. Either alteration of the feedstock composition or the method of different technologies is essential to process the silicone materials.

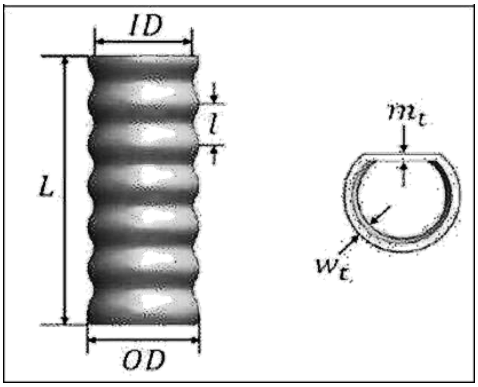

Figure 1.1: General dimensions of specific implant stent [18]

1.2 Problem Statement

Metal additive manufacturing (MAM) is a technology that potentially to substitute or compliments areas of manufacturing processes. A lot of researchers and engineers have conducted studies to understand laser cutting for manufacturing stents. However, comparatively fewer efforts have been made to investigate SLM for stents by additive manufacturing. Controlling the design rules and parameters requires study to overcome the obstacles below:

1. Conventional laser cutting has a defect, such as heat-affected zones where it produces a heat area where it could result in fracture when the stent is expanded due to brittleness [20].
2. Laser cut stent create a dross, where a molten material flows to the bottom edges of the parts [20].
3. Laser cut stent also occurred Recast. Recast is occurred because the harden of the molten materials on the edges. The surface is usually harder than the original materials and is highly brittle which can cause to formation of crack [20].
4. Back wall damages happened by the laser beam with molten particles transferred to the opposite of side wall [20].
5. Oxidation always occurred during laser cut materials. Oxidation can make a stent tend to fail during manufacturing. [21].
6. Laser cutting of tubing starts by exposed a laser beam on a focused spot on the tubing. The spot is melted and is preferably vaporized, by the laser beam. Once the laser beam burns through the side wall of the tubing, the beam will usually continue to strike the opposite side wall of the tubing and may begin to vaporize, the opposite side wall of the tubing. This undesirable burning or vaporization of the opposite sidewall is called 'burn through' and can result in the weakening of opposite sidewall. In some cases, burn through may result in the stent workpiece being discarded [21].
7. Laser cut stent is a thermal process which will lead to thermal damages. To overcome the thermal damages, the following postprocessing

techniques are applied: pickling, etching, annealing and electropolishing which raise the manufacture cost and could affect the mechanical properties of the stents [22].

8. The manufacturing cost is slightly higher for conventional stents in the market, which paves the way for stent by additive manufacturing as a viable alternative [22].
9. In a conventional process, a standard-sized stent is used for all patients. Thus, surgeons sometimes need to assume the exact size of airways during angioplasty. In AM, a custom and specific-sized stent can be produced according to the patient, leading to shorter time for implants and saving lives [23].
10. The materials for commercialized stents are comparatively weaker than the average AM materials, which have higher strength.
11. In general, the manufacturing process of conventional needs to undergo several processes, such as rolling, tube forming, laser cutting, and heat treatment. Meanwhile, AM only needs powder metallurgy to process the infinite shape and design without tooling. This will be a huge advantage compared to conventional methods in terms of lead time and time to delivery.
12. SLM are relatively superior compared to manufacturing process. In this context, it produced complex parts with acceptance geometrical accuracy thus allowing the freedom to manufacture patient-specific products.
13. Additive manufacturing has a very rough surface. The part needs to be smooth to be advantageous during an angioplasty procedure. The needs of electrochemical polishing will be addressed in methodology and result will be evaluate based on the outcome.

This research can be associate as a novelty to fill the gap especially on characteristics, behavior, and properties in SLM studies, especially in the development of stents. The research of SLM stents is crucial to understand each characteristic and properties. Based on the latest publication, two article of metallic stents by additive manufacturing is published, but the number of testing and specific parameters are very limited [2][24]. The mechanical properties, secondary processing, and clinical studies were not considered in the development of stents by additive manufacturing.

1.3 Objectives of the study

To overcome the problems, the setting objectives are listed:

1. To create a stent design and shape using additive manufacturing technique via selective laser melting processing
2. To apply the secondary processing, such as surface polishing and heat treatment
3. To analyze the performance of mechanical properties, such as compression, flexural strength, hardness, and tensile strength

4. To investigate the effect of material usage in in vitro (cytotoxicity test) for better understanding via the biocompatibility study.

As previously mentioned, this research aims to determine the mechanical properties of the design model and to determine suitable methods for enhancing the surface finish and characteristics of stents by additive manufacturing.

1.4 Significance of the study

The significance of evaluating SLM processing can be summarized as follows:

1. Understanding the design model for a complex, undercut, and intricate stent using the AM technique via DFAM.
2. Enhancing the mechanical properties of stents by additive manufacturing by studying several characteristics, such as compression, flexural strength, and hardness.
3. Modifying secondary processing, such as surface roughness and heat treatment, so that the process is more compatible with commercialized stents in the market

1.5 Scopes of the study

This study was conducted between 2015 and 2020 in conformity with the following scopes:

1. The research fundamentally focused on the stent design of various struts and undercuts with similar length and diameter.
2. The processing was executed using a high-powered SLM machine (EOSINT M280) with standardized parameters, such as laser power, hatching distance, layer thickness, and scanning speed.
3. The stent specimen was held and oriented at 90° to reduce the overall support during fabrication (ASTM ISO/ASTM52910-18).
4. The material used was cobalt-based superalloy (CoCrMo), which meets the ASTM F75 standard.
5. The cytotoxicity test (Clinical Testing) was performed according to the laboratory requirement to reduce external contamination (ISO 10993-5).
6. The heat treatment and polishing procedures were conducted to improve the overall shape and performance of the stents by additive manufacturing.

1.6 Organization of the thesis

This thesis has five chapters. Chapter 1 focused to the introduction on Metal Additive Manufacturing (MAM), Selective Laser Melting (SLM), stenting, and related materials. The problem statement is identified, objectives developed, the significance of the study, and the scopes and limitations of the study are subsequently described. Chapter 2 consists of the literature review that focuses on related issues, mechanical processing, and selective laser melting parameters. Chapter 3 discusses the methodology, while Chapter 4 focuses on results and analysis by comparing the experimental outcome to obtain different characteristics of commercialized stents and stents by additive manufacturing. Finally, Chapter 5 concludes the thesis, and the novelty contributions are addressed. The additional suggestions for future works are addressed as well.

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