COMPARATIVE STUDY OF STENT PERFORMANCE UNDER COMBINED LOADING

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Special Dedication

To my beloved father, mother, family, supervisor and friends,

May Allah S.W.T hopefully simplified all matters in our life,

Thank you.

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In the name of Allah, Most Gracious and Most Merciful, I start this thesis. I would like to take this opportunity to express my deep gratitude and appreciation to those people who had helped me to complete this journey, without their support, this achievement would not have been possible. In life there is only one direction worth going and that is the future. Thinking of gratitude, the first that comes to my mind is my supervisor, Associate Professor Ir. Ts. Dr. Al Emran bin Ismail. He believed in me for all these years, guiding me through all the struggles I had to face with extreme patience and confidence during my M.Eng degree. I was extremely lucky to have Dr. Norihan Ibrahim as my co-supervisor, who cared about my work and guided me throughout this study with patient.

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ABSTRACT

A coronary artery stent is a medical device used to treat coronary artery disease. In the long term, there is a chance of restenosis, or stent fracture. Stainless steel, which has excellent mechanical properties, is the most common material for conventional stents. Because of their high yield stress and ductility, stainless steel stents can be safely extended. Stainless steel stents are permanent in the body and can cause complications. These studies, however, address the behaviour of stents under single and combined loading in terms of stress and strain. A new stent is constructed and tested under this loading. Computational analysis can be used to determine mechanical performance, anticipate possible problems, and direct stent optimization. As a result, preliminary evaluation using numerical methods enables a more in-depth analysis of some aspects of mechanical performance. In this thesis, six different stent designs (Palmaz, AVE S660, Bx Velocity, Multilink, Express and NIR) were evaluated. Best stent design in term of stress would be selected and then structure of the stent would be optimized. In Explicit numerical analysis, the deformation of the designs was simulated using ANSYS under internal pressure. AVE S660 stent shown most reaction as it shrinks to the middle while the highest and lowest von Mises stress is 352MPa and 190MPa for NIR and Express stent, respectively. The mechanical performance of a new design stent based on the previous evaluations was investigated in this study under single and combined loading.

ABSTRAK

Stent arteri koronari adalah alat perubatan yang digunakan untuk merawat penyakit arteri koronari. Untuk jangka masa panjang, terdapat kemungkinan akan berlaku restenosis atau keretakan pada stent. Keluli tahan karat, yang mempunyai sifat mekanikal yang sangat baik, adalah bahan yang selalu digunakan untuk stent konvensional. Kerana tekanan dan kemuluran hasil tinggi, stent keluli tahan karat dapat bertahan dengan selamat. Stent keluli tahan karat akan kekal di dalam badan dan boleh menyebabkan komplikasi. Analisis pengkomputeran dapat digunakan untuk menentukan prestasi mekanikal, mengantisipasi kemungkinan masalah, dan pengoptimuman stent secara langsung. Hasilnya, penilaian awal menggunakan kaedah berangka membolehkan analisis yang lebih mendalam dijalankan berkaitan prestasi mekanikal. Dalam tesis ini, enam reka bentuk stent yang berbeza (Palmaz, AVE S660, Bx Velocity, Multilink, Express dan NIR) diuji. Reka bentuk stent yang terbaik akan dipilih dan kemudian struktur stent akan dioptimumkan. Dalam analisis berangka menggunakan kaedah Explicit, pengembangan struktur disimulasikan menggunakan ANSYS di bawah tekanan. Stent AVE S660 menunjukkan reaksi paling ketara ketika ia menyusut ke tengah sementara tekanan von Mises tertinggi dan terendah masing-masing adalah 352MPa dan 190MPa untuk stent NIR dan Express. Prestasi mekanikal untuk reka bentuk stent yang baru diuji dalam kajian ini di bawah beban tunggal dan gabungan. Stent di bawah lenturan dan kilasan dengan tekanan mempunyai tekanan tertinggi iaitu 483MPa.

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LIST OF SYMBOLS AND ABBREVIATIONS

$D^{shortest}$	-	Shortest distance
E	-	Young's modulus
F	-	Applied load vector
I	-	Internal force vector
K	-	Stiffness matrix
M	-	Mass matrix
U	-	Displacement vector
σ_y	-	Yield strength
σ_u	-	Ultimate Tensile Strength
σ_m	-	Mean stress
σ_a	-	Cyclic stress
ρ	-	Density
ω_{max}	-	Cumulative eigenvalue
BRS	-	bioresorbable stents
CAD	-	Computer-Aided Design
CAE	-	Computer-Aided Engineering
Cd	-	dilatational wave speed
FEA	-	Finite Element Analysis
LC	-	element dimension
UAE	-	Ultimate Tensile Strength

CHAPTER 1

INTRODUCTION

1.1 Background of Study

Intravascular stent insertion has been a common practice in vascular disease treatment. There are over 100 different types of stents in the market and hospitals around the world (Stoeckel et al., 2002). Stents can be categorised into the cylinder, loop, and mesh types depending on their unique cell designs. To adapt to the performance and adaptability requirements, the geometric cells could be in closed or open instances. A stent is collapsed to a small width and placed over an inflatable catheter before deployment. The stent is then moved into the area of vein blockage and expanded by inflatable swelling. The structure of a stent involves considerable plastic distortion and nonlinear contacts from a mechanics standpoint. As a result, understanding the stresses and strains faced by a stent during operation is critical to effectively use stenting breakthrough. Finite element analysis (FEA) has been widely used in numerical investigations of mechanical behaviour (strains, stresses, deformation, stiffness, and flexibility).

Hardening of the blood vessel due to an atheromatous plaque called atherosclerosis would lead to the blockage or narrowing of the blood pathway inside a vessel (Li & Kleinstreuer, 2007). Imitating atherosclerosis causes the process to become slower after the development of the initial plaque. When the arterial wall becomes weak, an aneurysm could be identified as the main reason that causes the enlargement of an artery. Although there are no symptoms at all, it could lead to fatal complications due to a ruptured aneurysm. An aneurysm is the weakness of the artery wall that causes the artery to bulge or swell up. Most cases of aneurysms do not show symptoms and are not perilous. But, for a severe stage, without precaution, an aneurysm would rupture and lead to internal bleeding and is life-threatening. Individuals' chances of experiencing and rupturing an aneurysm differ from each other. The development of an aneurysm is due to an unhealthy lifestyle, particularly smoking. That is why rupture of aneurysm needs surgical treatment. Doctors take this as a serious case as they are life-threatening.

1.2 Problem Statement

Long-term fatigue failure might occur because of stent failure due to a high number of arterial dilations caused by cardiac pressure (Azaouzi et al., 2013). Because of the high plastic deformation during balloon expansion, damage or micro-cracks caused by stress concentration at surface irregularities are one of the key causes of fatigue failure of balloon-expandable stents. A wide range of research is needed to study the performance of stents during stent implantation to decrease the rates of stent failure. As the number of people dying from cardiovascular diseases rises, this study is critical. Many patients prefer stent operation to open-heart surgery because it is performed in safer conditions and could theoretically treat lethal vascular diseases. However, most of these studies use stent alone or inside the blood vessel to evaluate it clinically or numerically (Stoeckel et al., 2002; Li & Kleinstreuer, 2007; Azaouzi et al., 2013)

These studies, however, address the behaviour of stents under single and combined loading in terms of stress and strain. A new stent is constructed and tested under this loading. The stent must exert enough radial force on the diseased coronary artery's wall to restore the vessel lumen to a near-normal diameter while somehow scaffolding the vessel and avoiding artery collapse in the coming years. Low elastic recoil, conformability, high visibility, and ease of delivery are all desirable performance characteristics. The latter is a complicated parameter that is influenced by the stent's versatility.

1.3 Objectives

The main objectives of this research are as follows:

i. To compare the mechanical performance of existing designed stents.
ii. To propose a new design of stent based on previous analysis of stent performance.
iii. To investigate the stent mechanical behaviour under single and combined loading of new stents.

1.4 Scope of Study

The scope of this study is to use Finite Element Analysis (FEA) to compare the performance of various stent designs. The design is simulated using ANSYS software. Two different types of simulation methods are used, which are Implicit and Explicit. For the Implicit simulation method, selected previous research of stent under single loading is simulated, while for Explicit, a new stent is simulated to observe its fracture due to single and combined loading. The result is validated with the previous study. Lastly, a new design of stents is proposed based on the performance of the existing design. All these studies are based on the numerical analysis and there is no experimental works conducted.

1.5 Significance of Study

Previous research has been conducted on stent designs to study their performance. The present study aims to prevent failure during the implantation of a stent to prevent restenosis. As the failure occurs, a second angioplasty or minor surgery is needed to open blocked arteries and restores normal blood flow. Aneurysm might also happen, weaken the artery wall, and cause an abnormally large bulge that results in rupture of the arteries and internal bleeding. The findings of this research are greatly beneficial to society considering that stent design and optimization play important roles in engineering and biomedical. The greater manufacturing and clinical demands with science and technology backgrounds justify the need for more effective and lifechanging approaches for patients. Thus, the results of this study could be used as guidance for future research on what should be emphasized by engineers to improve stent performance. For researchers, this study could help them uncover critical areas in the biomedical field that many researchers have not been able to explore. Lastly, a new learning process might be discovered.

CHAPTER 2

LITERATURE REVIEW

2.1 Chapter Overview

Significant technological advances have been created in the last 20 years, and new devices for coronary mediations have been reviewed. Stents, for example, have recently improved common procedures by offering a convincing and secure method in dealing with analyses that occur during inflatable angioplasty. Previous judicial studies have shown that open tubes, tempered steel, and balloon-expandable stents significantly reduce restenosis rates in specific sores (Negro et al., 1994). As a result of the multidisciplinary efforts put into stent science, new designs, as well as various materials and coatings, have been proposed to further improve the execution of these prostheses. Angioplasty with stenting, in which a balloon with a stent is inserted into the vessel, is one of the most common treatments for atherosclerosis (Rogers et al., 1999). During the stent placement process, the plaque or artery could be damaged. To keep this occasion, a comprehension mechanical procedure is deemed required.

2.2 Background of Stent Design

Stents are tubular intravascular devices inserted into blood vessels to keep them structurally opened. Stents might be used to keep blood vessels open immediately following intravascular procedures, reducing the risk of restenosis (Negro et al., 1994). More than one million percutaneous surgeries are conducted each year around the world, and the use of coronary stents in interventional approaches has risen from 10% in 1994 to over 80% in current practices (Kandzari et al., 2002). Stent advancement has increased steadily since the first generation of stents, with enhanced versatility and deliverability of stents extending the use of coronary stenting to a variety of injury morphologies and clinical settings (Kandzari et al., 2002).

Antonio Colombo presented the high-weight strategy for stent deployment in 1993. It was the high-pressure deployment, and the antithrombotic treatment has fundamentally brought down the recurrence of thrombosis occurrences. This prompted a wide utilization of stents, and following quite a long while of examination, they ended up being the almost perfect answer for ischaemic coronary illness (Azaouzi et al., 2013). Early research show that stent-based drug conveyance for restenosis prevention has overwhelmingly positive results. The functions of these stents are influenced by the designs, delivery-vehicle materials, and drug properties. Coil or hybrid stent models are inferior to stainless steel stents with tubular and multicellular designs. Different stent structures have a significant impact on acute and chronic results. Other older designs combine coil and tubular devices, making them more versatile and suitable for tortuous vessels (Hara et al., 2006).

Bioceramic adipoyl or coated stents, radioactive stents, biodegradable stents, and drug-eluting stents are just a few of the latest revolutionary stent designs being developed (Kandzari et al., 2002). The investigation on the relationship between a stent and its matching equipment, especially the balloon of the stent itself extends, and other biomechanical behaviours, are, however, limited. Initially, several animal studies and clinical applications have shown that different stent designs have different clinical outcomes (Kastrati et al., 2000).

2.3 Classifications of Stent

The method of expansion (self-expanding or balloon-expandable), the composition (stainless steel, cobalt-based alloy, tantalum, nitinol, inert coating, active coating, or biodegradable), and the configuration of stents are all categorized as mesh structure, coil, slotted tube, ring, multi-design, or custom design.

2.3.1 Material of Stent

Metallic, mass, and surface properties, structure, and science are all extremely important factors to consider when creating an ideal stent. Self-extending stents must be set up from metals with adequate flexibility so they could be compacted and extended and held adequate spiral band quality to avoid vessel force or conclusion once set up (Burns et al., 2009). Based on Table 2.1, stainless steel is much weaker than Co-Cr. Radial strength against the plaque of the artery is maintained due to the stent struts as Co-Cr has better density. A stent’s capability needs to be considered when designing the stents to meet the attributes. Table 2.2 indicates that Cobalt alloys are more capable in terms of having higher strength, visibility in medical imaging, and flexibility. However, stainless steel stents are more capable to minimize the recoiling of stent struts.

Table 2.1: Comparison of CoCr stents versus 316L stainless steel stent (Wu & McCarthy, 2012)

Advantage	Material (CoCr)	Material (316L SS)	Reason of preference
Strength	Stronger	Lower strength	Maintain good radial strength
Density	Denser	Smaller density	Design thin stent struts with good radiopacity
MRI-compatible	More MRI-compatible	Not MRI-compatible	Material is non-ferromagnetic, has good biocompatibility

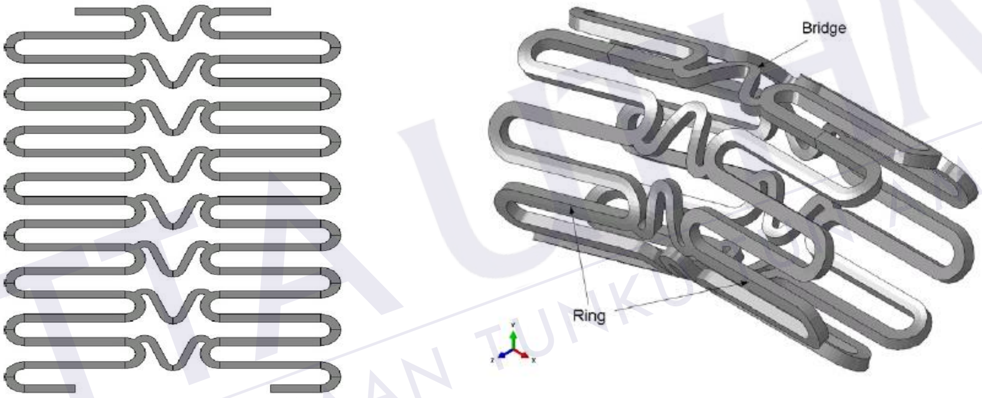
2.3.2 Balloon Expandable Stent

A balloon-expandable stent is a tubular, mesh-like tube that is extended within a diseased (stenosis) artery fragment to restore blood flow and hold the vessel open after angioplasty (Azaouzi et al., 2013). The designs of balloon-expandable stents have two major constituents, categorised as ring components and interfacing components or bridges as shown in Figure 2.1. Most balloon-expandable stents are delivered using treated steel material that plastically deforms during the construction of an inflatable balloon. After being delivered, balloon-expandable stents experience up to 20%–30%

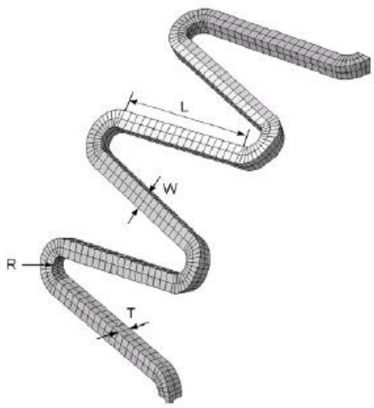
plastic strain. Except for a small backfire caused by the adaptable piece of the distortion, the stent maintains its form after the inflatable balloon is crumpled.

Table 2.2: Comparison of physical and mechanical properties of selected biomaterials (AL-Mangour, Mongrain, & Yue, 2013)

Required attribute	1st Generation Alloy	2nd Generation Alloy	
	Stainless Steel (316L)	Cobalt Chromium(L605)	Cobalt Nickel (MP35N)
Visibility	Capable	More Capable	More Capable
Strength	Capable	Capable	Capable
Minimized Recoil	More Capable	Less Capable	Less Capable
Flexibility	Capable	Capable	Capable



(a) A 2-dimensional stent layout (b) Stent design



(c) Bridge of stent

Figure 2.1: Balloon expandable stent design and bridge (Azaouzi et al., 2013)

2.3.3 Self-Expanding Stent

Self-expanding stents are widely used to treat occlusions in endovascular arterial lumens, such as blood vessel narrowing caused by cholesterol plaque build-up. Figures 2.2 and 2.3 display self-expanding stents made of nickel-titanium alloy with mesh-like tube structures (Nitinol). Biocompatible and fatigue properties along with the super elastic and shape memory properties of Nitinol are the reasons why it has been extensively used in medical applications (Azaouzi et al., 2012). During an operation, Nitinol is very useful as its properties help to reduce stent damage.

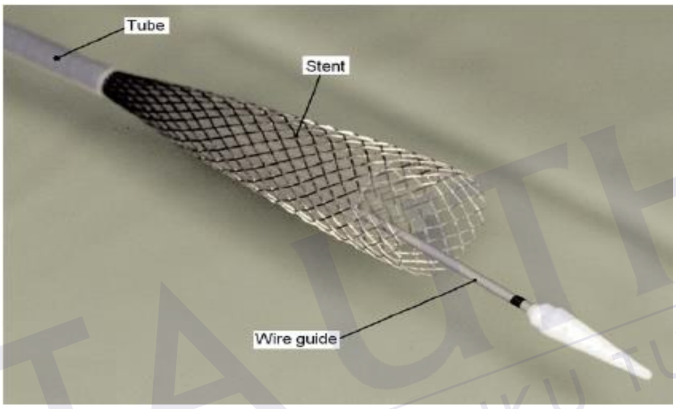
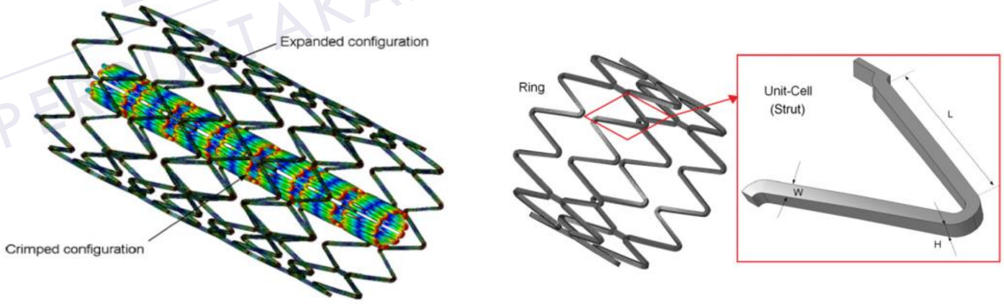


Figure 2.2: Self-expanding stent (Azaouzi et al., 2012)



(a) Self-expanding Nitinol stent (b) Ring unit cell model

Figure 2.3: Nickel-titanium alloy self-expanding stents (Azaouzi et al., 2012)

2.3.4 Raw Material Form of Stents

As shown in Table 2.3, stents could be made of sheet, wire (round or flat), or tube. Wire or tube has been used to make most balloon-expandable and self-expanding stents. The BSC/Medinol ‘NIR,' the Navius ‘ZR1,' the EndoTex ‘ratcheting' stent, and

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