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A Methodology For Coronary Stent Product Development: Design, Simulation And Optimization

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A Methodology for Coronary Stent Product Development: Design, Simulation and Optimization

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Biographical Sketch

Anweshana Vaizasatya was born on December 2, 1985, in India. She received a Bachelor of Engineering degree in Mechanical Engineering (Specialization in Production) from Osmania University in 2007 and a Master of Science degree in Industrial & Systems Engineering from Northern Illinois University in 2009. She began matriculation towards the Ph.D. in Industrial & Systems Engineering Department of North Carolina Agricultural & Technical State University (NCA&T) in 2010. She worked as an operations intern at Cook Medical Endoscopy during summers 2011 & 2012, and obtained intensive knowledge on design and manufacturing of medical devices.

Dedication

Dedicated to Sri Samartha Sadguru

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First of all, I would like to thank Him for giving me zeal, courage, and resources to attend the school all these years.

I am kindly grateful to my advisor Dr. Zhichao Li, who has guided me all these years in my research and professional development skills; also, for his patience, incredible suggestions and financial resources. I truly appreciate being afforded this opportunity which enhanced my engineering knowledge into medical science applications.

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Abstract

Coronary stents are slotted tubes made of metals, alloys, or polymers. They are deployed in human arteries, which are blocked by calcified plaque, to keep the arteries open and allow the blood to flow with ease. Coronary stents have been proven as an effective treatment device for heart diseases such as acute myocardial infarction.

Design plays an important role for coronary stents to perform the clinical functions properly. Various parameters such as materials, structures, dimensions, and deployment methods etc., need to be considered in the design of coronary stents. There are numerous studies on design of coronary stents and many significant manufacturing methods have been reported in the past two decades. However, there is no comprehensive methodology for the product development of coronary stents in terms of design, simulation, and manufacturing.

The objective of this research is to develop a methodology for coronary stents product development that focuses on design, simulation, and manufacturing. The methodology brings together insights from numerous engineering design disciplines with the aim of making coronary stent development more flexible and more cost-efficient

The product development methodology for coronary stents is executed through modeling and analyzing stent designs with details of design, simulation, and optimization methods. Three innovative stent designs are modeled using engineering design software (SolidWorks) and mechanical performances are simulated, evaluated, and optimized with the help of advanced engineering simulation software (ANSYS). In this study, the performance of stents based on stress, strain, and total deformation during deployment are analyzed and compared with commercially available optimal design i.e., Cypher (J & J Co.) stent, which acts as a benchmark design.

CHAPTER 1

Introduction

1.1 Coronary Stents

Nowadays, interventional cardiology is one of the medical treatments highly performed by cardiologists. It is a minimally invasive treatment to allow proper functioning of the heart, arteries and veins. Atherosclerosis is a heart disease treated by interventional cardiology. In atherosclerosis, a plaque which is a composition of fat, cholesterol, fibrin, and calcium develops on the inner walls of the arteries (Liang, 2005) as shown in Figure 1.

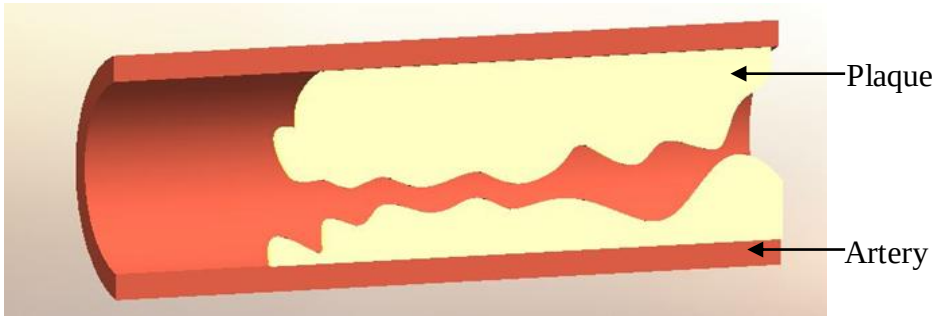


Figure 1. Cross sectional view of coronary artery with lesion.

The plaque forms a blockage and impedes the flow of blood which leads to myocardial infarction i.e., heart attack (Chua, 2004 a). In medicine, the blockage is treated by expanding a balloon or inserting a stent or combination of both procedures at the clogged site. Based upon the medical devices such as the balloon and stent used on the catheter, the treatments are further specified as balloon angioplasty and stent deployment procedures (Trozera, 2003). Both of these procedures are practiced to expand the passage in the arteries and veins for the blood to flow with ease.

The stent deployment procedure is implemented in the following steps as demonstrated by Figures 2 and 3:

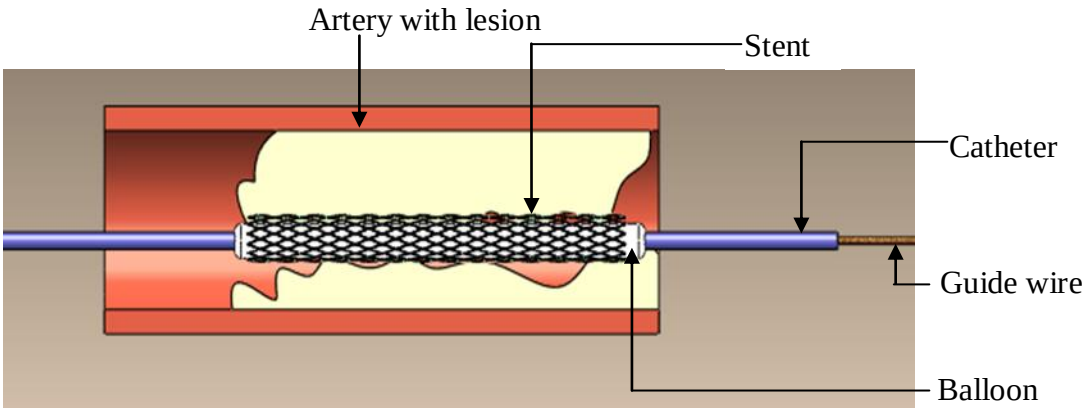


Figure 2. Catheter loaded with balloon stent.

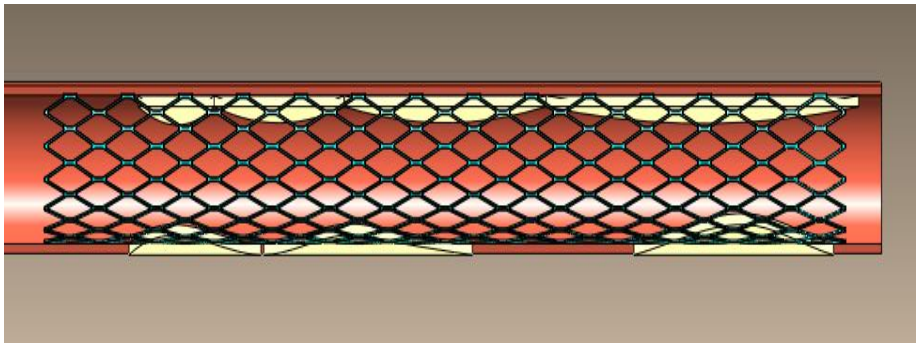


Figure 3. Stent deployed inside the blocked artery.

1) A guide wire is passed through the afflicted site.
2) A balloon with crimped stent loaded on catheter is inserted through a guide wire and passed to the site (Lally, 2006).
3) The balloon is expanded with 20 atm (Maguire, 2005) pressure to expand and deploy the stent at the blockage area to make the passage open.
4) The expanded stent remains at the blockage inside the artery, while the catheter with balloon and guide wire is removed (Lim, 2004).

Stents are one of the medical devices widely used to treat cardiovascular diseases. It is reported that these medical devices command a huge market which accounts for $30 billion as of 2007 and was expected to reach $40 billion by 2012 (Bergman et al., 2010). Every year about 2

million people are treated with coronary stents (Anonymous (a), 2010) in the world. According to a medicine market report, coronary stents accounted for about $7.1 billion in 2011 and will increase to $10.6 billion by 2016 (Anonymous (b), 2012).

1.2 Technical Trends and Challenges

Coronary stents were first introduced in 1986, since then researchers have developed many different stents with various materials, designs and manufacturing methods (Liang, 2005). Technically speaking, they can be classified into different types according to medical applications, deployment methods, materials, forms, patterns, coatings, manufacturing methods, and other aspects. For instance, coronary stents can be classified as Balloon Expandable Stents (BES) and Self Expandable Stents (SES) according to deployment methods and materials. BES's are deployed using a balloon as shown in Figure 2. The materials used for BES's are tantalum, stainless steel, platinum, cobalt-chromium, etc., (Stockel, 2002). SES's expand themselves inside the artery at a temperature of 37^0C (Venkatraman et al., 2006). Nitinol is considered as a self-expandable stent material which is made of nickel and titanium. There are many classifications of stents within the past 25 years and they are summarized in Figure 4.

The efficacy, long term safety, and clinical outcomes are important aspects considered in medical studies (Cutlip, 2007). Despite research proposed various types of stents with respect to design and manufacturing, many clinical studies report stent thrombosis, restenosis, hyperplasia, and myocardial infarction in patients. Numerous studies are continued on bare metal versus drug eluting stents, as bare metal stents show high restenosis rates while drug eluting stents show high thrombosis rates (Luscher, 2007). In addition to these stent varieties, researchers have proposed stents with biodegradable materials. These stents are designated as the present generation stents (Dauerman, 2011).

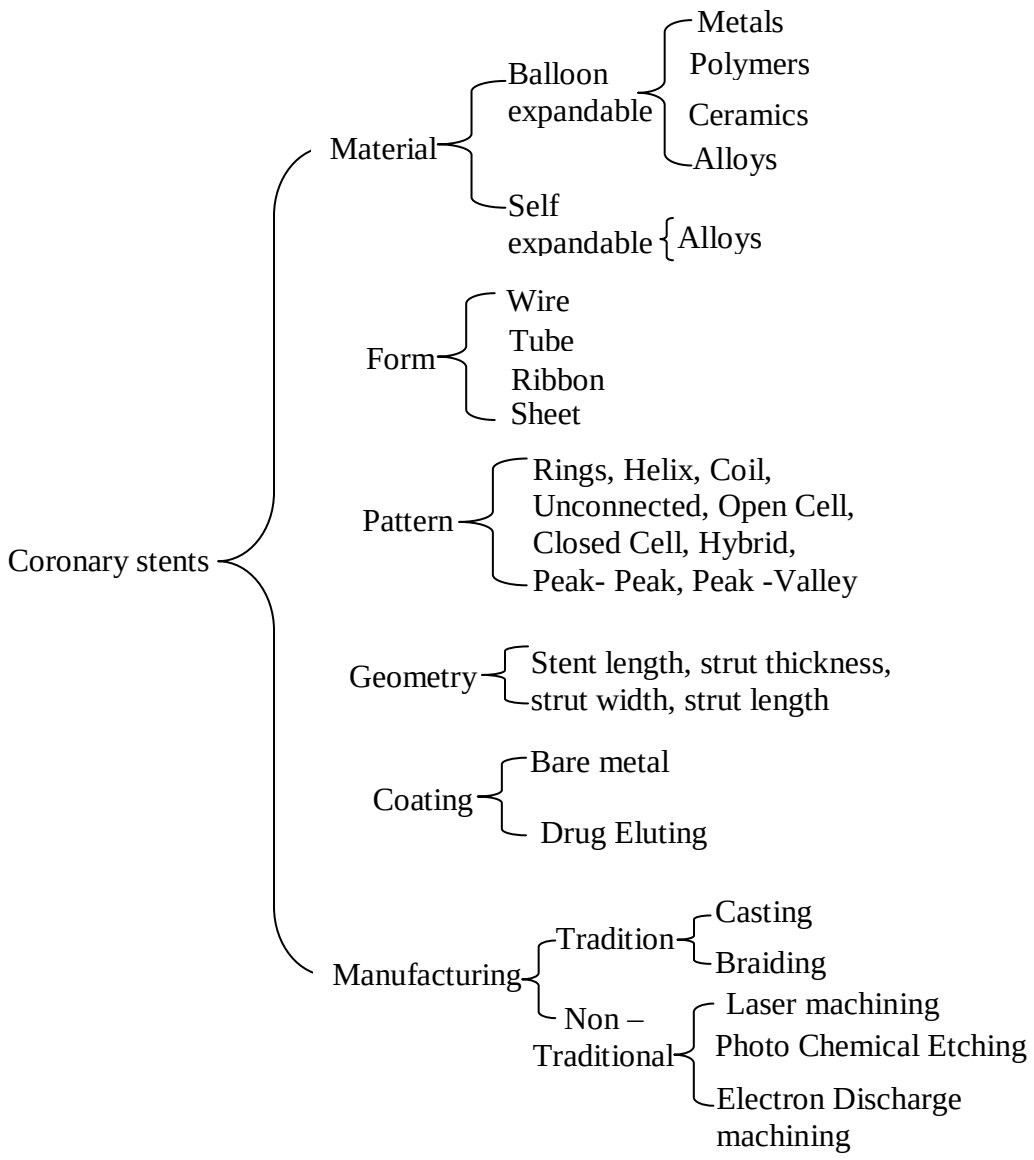


Figure 4. Stents classification (source: Stockel, 2002 and Lally, 2006).

Many stent designs with the above mentioned materials have been introduced in the market to prove their preeminence against each other. The designs vary with strut shapes, sizes and diameters. Nowadays, stents have very small diameters which range from 2.5 mm- 5.5 mm (Butany et al., 2005) with thin struts. Thick strut stents have been used for decades. Stents with thick struts need higher pressure to deploy in the arteries which can lead to vascular injury.

Hence, thin strut stents are introduced in the market. High contact area between stent and plaque (i.e., metal to artery ratio) cause thrombosis and restenosis (Lau, 2004b); therefore, thin strut stents have been proven better performances because of less vascular injury (Lau et al., 2004b) and low metal to artery ratio.

Apart from the design aspects, manufacturing methods also play vital role as they face stent efficacy challenges. Stent surface characteristics such as burrs, oxide layer formations caused during manufacturing lead to thrombosis and hyperplasia (Mani, 2007 & Zhao, 2003). Therefore, precision manufacturing techniques such as laser machining, photochemical etching, electro-discharge machining, water jet, braiding, vapor deposition, etc., are considered necessary to manufacture the stents (Stockel, 2002) and to overcome such drawbacks. Proper surface treatment techniques must be carried out to remove burrs and oxidation layers.

1.3 Research Scope

The interaction between stent, balloon, and artery play a significant role during deployment. Deployment of the stents in the arteries leads to pressure exertion on the artery walls. High pressure exertion at the plaque site precedes vascular injury. So, design of the stent struts plays a major role in successful deployment and functioning of stent.

Simulation of stent, balloon, artery, and plaque helps to imitate the stress study on the stent and arterial wall. Computer aided design and finite element analysis software provide inexpensive simulation results for stent behavior. Recently, simulation studies have concentrated on the deployment behavior of stent, balloon and their effects on plaque and artery. The aspects of stent behavior that are studied in research involve elastic recoil, foreshortening, longitudinal recoil, dogboning, radial stiffness, coverage area, fracture mechanics, bending and flexibility (Migliavacca, 2002; Lau, 2004b; Takahata, 2004; Wang, 2006 & Pant, 2011).

Materials of the stents also have a great effect on the stent performance. The materials are selected on the basis of mechanical properties, biocompatibility and biofunctionality (Lally et al, 2006). Significantly, every material has its own importance as per the biocompatibility and flexibility parameters are concerned. The material selection varies from metals, composites, polymers, and ceramics. Sometimes, stents are made from combination of materials such as stainless steel and nitinol for flexibility, gold or platinum for rigidity and radiopaqueness (Kuehling, 2010). Another important material aspect considered in current studies is the biodegradability of stents. Stents are expected to stay in the body for a period of 12-24 months and biodegrades after the artery is back to its normal position (Hermawan, 2010). The proper biodegradable material also prevents early recoiling of stents (Kandzari, 2002). Hence, the research on biodegradable materials is on pace.

The method of manufacturing matters in proper functioning of stents. Surface finishing is a machining operation which is an important process after manufacturing stents. Burrs, roughness and oxide layer formation on the material affects the proper functioning of stent and surface finishing treatments are in use to eliminate them (Koós, 2007 & Mani, 2007).

Material, design, manufacturing, clinical outcomes are some characteristics, the researchers investigate in the field of coronary stents. Thus, this study provides a new product development methodology for coronary stents with emphasis on design, simulation and manufacturing.

1.4 Product Development Strategy

Product developments are phases of the product from concept to product life in the market. In detail, the phases include idea generation, feasibility study, product design, simulation testing, prototype testing, manufacturing, product release in the market, and life of the product in

market. This research concentrates on the product development methodology of coronary stents and elaborates the conceptual phase, design phase and manufacturing methods. The methodology is implemented by modeling and testing novel stent designs from the objectives of conceptual and design phases.

1.5 Research Motivation

Plaque formation differs from one artery to another (Kandzari, 2002), so, many kinds of stents are introduced in the market to deploy in the complex passages. Drug carrying stents are required to prevent restenosis, hyperplasia and thrombosis. In 2002, there were 43 coronary stents and stent families available in the market (Gay, 2006). Even though there are many stent designs available, the clinicians and medical device manufacturers are looking for new stent designs to deploy in complex plaque strictures and to achieve exceptional clinical outcomes. Hence, there is great requirement for new stent designs in the current health care environment.

Computer aided design and finite element analysis software which provides design and simulation results, helps to study many engineering aspects and act as better cost and time effective solutions. The designs can be further remodeled according to the simulation results and obtain effective outcomes. Magnesium is a biodegradable material and has low thrombosis rates (Erne et al., 2006). Therefore, the stent designs in this research are studied by design and simulation software by comparing the designs with magnesium alloys and other biocompatible materials.

1.6 Outline

Chapter 1 introduces deployment procedure of stents, classification of stents, product development strategy and need for new stent designs.

Chapter 2 reviews the literature on stent materials, design requirements and manufacturing methods that were developed in the past years.

Chapter 3 explains the product development of coronary stents from concept stage, design, simulation, manufacturing to clinical outcomes. This chapter proposes product development methodology of coronary stents with emphasis on design, simulation and manufacturing.

The product development methodology introduced in chapter 3 supports to design three novel stents. Chapter 4 discusses the geometry and dimensions of the novel stents.

Chapter 5 demonstrates the simulation of the novel stents with biomaterials such as stainless steel, cobalt-chromium and magnesium. In addition, the novel stents are simulated with various magnesium alloys and compared the outcome with one of the stents available on the market. The chapter interprets simulation results and the performances of the stents.

Chapter 6 reviews the significance of this research work and further recommends future work on coronary stents.

CHAPTER 2

Literature Review

Stents are medical devices inserted in the human body through minimal invasive treatments. Minimal invasive treatments have increased since 1980 because of the small incisions and less recovery time (Song, 2010). Stents are inserted at the afflicted site to ease the flow of fluids and to prevent blockages. Stents are deployed in various parts of the human body such as brain, cerebral arteries and veins, neck, trachea, esophagus, bronchial tubes, coronary, peripheral, biliary ducts, iliac arteries, renal, and urethras (Kuehling, 2010; Shedlov, 2005 & Weber, 2003).

Coronary stents are implanted in cardiovascular treatments to prevent myocardial infarctions. These are deployed in complex plaque strictures of coronary arteries. The performances of stents are studied after deployment which incorporates the factors that affect vascular compatibility, mechanical support offered, and design effectiveness (Pant et al., 2011). These are the factors that lead to restenosis, thrombosis, and neointimal formation (Pant et al., 2011). Thus; material, design, and manufacturing method play an important role in proper functioning of the stent (Stockel et al, 2002). This chapter reviews materials in section 2.1; clinical performance in section 2.2; design requirements in section 2.3; shape, size, and structure in section 2.4; and manufacturing methods of stents in section 2.5.

2.1 Material Selection

Cardiovascular stent material engages in an important role in the clinical performance because of the mechanical support offered to the artery and compatibility of the material to the artery (Zhao, 2003). The materials of stents are selected on the basis of mechanical properties, biofunctionality, biocompatibility (i.e., corrosion resistant, less toxic, non-inflammatory and

thromboresistant), and biological inertness (Lally, 2006). These materials are classified into metals, metal alloys, polymers, and ceramics. These classifications are described with materials and their properties in the sections below. Figure 5 explains the properties of metals, polymers and ceramics.

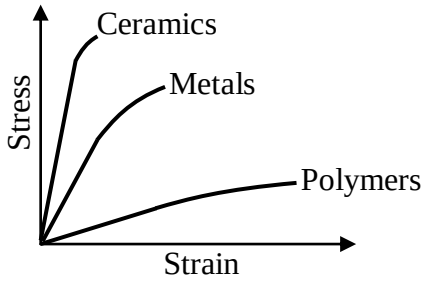


Figure 5. Properties of ceramics, metals, and polymers (adapted from Fischer, 2008).

Metals play significant roles in stent materials, because of their optimal mechanical characteristics offered to recover the artery (Zhao, 2003). They have a high elastic modulus due to high tensile strength, leading to low stresses in the material (Kranz, 1999). Thus, metals such as iron, titanium, tantalum, cobalt, chromium, magnesium, nickel, iron, zinc, etc.; are biocompatible and are considered as biomaterials (Kuehling, 2010).

Metal alloys are mixtures of two or more materials in certain amounts to obtain better performance properties. The amount of strength, ductility, and toughness of the material; matters during the selection of the material (Kuehling, 2010). The materials such as stainless steel, nitinol (Ni-Ti), cobalt-chromium (Co-Cr), etc.; are preferred (Lally, 2006) and these are corrosion resistant metal alloys. Merdan (2005) in his studies mentioned about biocompatible materials such as stainless steels 304 L, 304V, 316LV; mild steels, Ni-Cr-Fe alloys, platinum enriched stainless steels, and tungsten alloys. Iron and magnesium are considered as less toxic metals and little amounts of calcium, zinc, and manganese alloys show beneficial properties (Hermawan, 2010).

Polymers are used as stent materials as they have viscoelastic properties. Polytetrafluroethylene (PTFE), ethylenetetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM), polybutylene terephthalate (PBT), polyether block ester, polyurethane, polypropylene (PP) are some of the polymer stent materials biocompatible with human body (Merdan, 2005). Some problems faced by polymer materials are bulkiness (Erne et al, 2006), low radial strength, inflammatory responses (Moravej, 2010), and low young's modulus (Kranz, 1999). Hence, these are used as coatings on the surfaces of stents (Weber, 2003). Polymer coatings help in reducing the rates of thrombosis and neointimal hyperplasia (Bailey, 2009). The concern with polymer coatings is the loss of adhesion coating while crimping and unsheathing of stents (Roorda, 2007).

Ceramics such as silicon nitrides, silicon carbides, silicon oxides, carbon nitrides, and calcium phosphates are used as stent materials (Kuehling, 2010). Ceramics are inorganic, hard, and strong materials. However, ceramics have low tensile strength and lead to crack propagation (Kranz, 1999).

The stent materials are further classified according to the expandable states. There are two types of expandable mechanisms according to the stent materials. They are balloon expandable stents and self-expandable stents (Kanesaka, 1998). In balloon expandable stents, a balloon inflates and expands the crimped stent at the site and simultaneously expands the artery (Kanesaka, 1998). The concern with this type of stent is the balloon inflation pressure which expands the artery diameter. If the pressure applied to inflate the balloon exceeds nominal pressure, it causes vascular injury (Lau, 2004a). In self-expandable stents, the stent expands at temperature of about 37^0C (Venkatraman, 2006). Nitinol is a self-expandable material; hence, this material is utilized as a self-expandable stent material (Song et al., 2010). During

deployment, balloon expandable stents exhibits plasticity and self-expandable stents exhibits elasticity (Lally, 2006 and Stockel, 2002).

Stents are classified according to the coatings on the material. Stents with no drug coatings are called bare metal stents (BMS), and stents with drug coatings are called drug eluting stents (DES). Bare metals have higher restenosis rates; therefore research has introduced drug eluting stents (Luscher, 2007). Later, bare metal stents with thin struts had lower restenosis rates. (Vik-Mo, 2009). BMS are of two types, first generation (thick struts) and second generation (thin struts) (Dauerman, 2011). DES's are classified as first generation (thick stents, thick polymers), second generation (biocompatible polymers, thin struts), third generation (bioabsorbable polymers) and fourth generation (disappearing, bio-degradable) stents (Dauerman, 2011). To improve the functionality of stents, drugs are used as anti-thrombogenic, anti-proliferative, anti-inflammatory, anti-coagulants or cholesterol-lowering agents (Weber, 2003). A few drugs used on the DES's are heparin, paclitaxel, sirolimus, zotarolimus and everolimus (Roorda, 2007).

Iron works as a biodegradable material and also an important element in the human body (Moravej, 2010). Stents are expected to be biodegradable after the mechanical integrity is accomplished. These stents are required to support the artery for the duration of 6-12 months (Moravej, 2010) and in some cases the period from deployment to total degradation are 12-24 months (Hermawan, 2010). Poly (L- lactide) or PLLA is a polymer used as a biodegradable material (Venkatraman, 2006). Magnesium alloy is good biodegradable material but degrades in short time (Moravej, 2010). Many investigations are carried on magnesium alloys because of potential accomplishment achieved with biodegradable materials i.e., restenting (Yun, 2009).

The ability of mechanical support offered to the artery, depends upon material properties, which include considerations such as Young's modulus and tensile strength which are important

in material selection process (Kranz, 1999). Some of the mechanical properties of materials consist of ductility, good elongation, high tensile strength, etc., (Poncin, 2003 and Moller, 1998). Table 1 summarizes the stent materials and their properties.

Table 1

Stent Materials and their Properties

Metals	Properties	Alloys
Stainless steel	Passivative, corrosion resistant	316 L
Nitinol	Self expanding, super elastic, good MRI	NiTi
Titanium	Passivative, less ductile	
Tantalum	Passivative, highly ductile, corrosion resistance	
Nickel	Highly toxic, inflammatory	
Chromium	Highly toxic, inflammatory	Co-Cr
Magnesium	Biodegradable, less toxic, immediate degradation, less ductile	MgLi
Gold	Radiopaque	
Niobium	Passivative	
Zirconium	Passivative	

Source: Kranz, 1999; Lally, 2006; Hara, 2006; Koós, 2007; Bailey, 2009; Hermawan, 2010.

The characteristics ideal stent flexibility, trackability, low profile, radiopaqueness, biocompatibility, high radial resistance, low metal density, good scaffolding, and thromboresistance (Lau, 2004b). Table 2 summarizes the characteristics and properties required in a stent material.

Table 2

Characteristics and Property of Stent Material

Characteristic	Property
Corrosion Resistance	High
Biodegradable	High, time consistent
Biocompatible	High
Radiopacity	Medium
MRI	High
Yield stress	High
Elastic modulus	Low
Brittle	Low
Toxic	Low
Thrombosis	Low
Restenosis rate	Low
Metal density	Low
Radial strength	High

Source: Stockel, 2002; Lau, 2004b; Lally, 2006.

2.2 Clinical Performances

In clinical performances, the safety and effectiveness of stents are observed after deployment. The observation period varies from 30 days to 5 years and depends on the factors affecting the stent performance (Groove, 2007 & Luscher, 2007). The performances of stents are affected by thrombosis, restenosis and neointimal hyperplasia.

2.2.1 Thrombosis. The formation of blood clots at the stent deployed site is measured as stent thrombosis and this could lead to failure of the stent efficacy and increase the rate of mortality (Luscher, 2007). Stent thrombosis is a common syndrome with the bare metal and drug eluting stents because of the platelet adhesion to the stent material (Cook, 2009 & Groove, 2007). Hence, anti-platelet medications are prescribed to prevent the formation of blood clots (Cook, 2009 & Weber, 2003).

2.2.2 Restenosis. The occurrence of re-blockage, because of the tissue growth or improper mechanical support offered by the stent at the afflicted site, is known as restenosis (Capelli, 2009 & Bedoya, 2006). Restenosis depends on the factors such as length of lesion, diameter of artery (Shedden, 2009), design of stent (Pant, 2011 & Lally, 2006), flexibility of stent and ratio of metal-to-artery (Capelli, 2009). Drug eluting stents with anti-proliferative agents help to lower the restenosis rates (Hara, 2006 & Weber, 2003). Neointimal hyperplasia is followed by restenosis (Pant et al., 2011 & Bedoya, 2006).

2.2.3 Neointimal hyperplasia. Neointimal hyperplasia is the formation (growth) of tissue on the stent and re-blocks the passage. The high pressure applied on the artery during inflation lead to vascular injury (Hara, 2006 & Palmaz et al., 2002). This is one of the reasons which cause neointimal hyperplasia (Lally, 2006). Design (Butany et al., 2005), surface characteristics (Mani, 2007), radial force, and material selection (Taylor, 2001) are few aspects that lead to neointimal formation.

2.3 Design Requirements of Coronary Stents

Design plays a major role in stent performance. The design considerations for stents are high radial strength, low elastic radial recoil, good flexibility, low stent profile, good trackability,

minimal foreshortening, minimal elastic longitudinal recoil and optimal scaffolding (Lally, 2006 & Gay, 2006).

Stents are manufactured with a nominal diameter and then compressed to smaller diameter (crimped) to actuate through the passage to the lesion site and expanded to the size of nominal diameter (deployment) (Kuehling, 2010 & Gale, 2007).

The expansion of the stent at the deployment site plays an important role as the diameter of the stent and the artery has to be equal after expansion (Etave, 2001 and Holzapfel, 2005). The outer diameter in an expansion state is 0.1 inch (2.5 mm), in a crimped state is 0.006 inch (0.15 mm) and thickness between the walls is of 0.003 inch (0.08 mm) (Saunders, 2007). During the stent deployment procedure, internal diameter of the artery increases by 0.5 mm (i.e., from 2.5 mm to 3 mm) (Capelli, 2009).

The pressure applied to inflate the balloon inside the artery is 10-20 atm (Maguire, 2005). If the diameter of the stent is less than the diameter of the artery then the prevention of stenosis is halted. If the diameter of the stent exceeds the diameter of the artery then this leads to damage of the artery wall which is not expected during or after deployment of stent. The amount of pressure required for the expansion depends on the lesion type (Pericevic, 2009), stent material, and strut thickness (Etave, 2001). The pressure required to expand the stent is higher if the struts are thicker (Etave, 2001). The stiffness of the stent depends on the strut thickness (Holzapfel, 2005). A strut thickness of less than 100 μm shows better performance (Bailey, 2009). After deployment, a stent undergoes compressive pressure exhibited by the artery as the artery is elastic by nature (Etave, 2001 and Chua, 2004b). Hoop strength is another characteristic considered in the stent expansion. During expansion the stent is expected to have a high range of hoop strength (Moller, 1998).

Hemodynamics is another important aspect acknowledged in studies. In this, the flow of blood through the stent passage is studied as the blood pressure in human body ranges between 10 kPa and 16 kPa (Gideon, 2009). Stent performance can fail because of fatigue, as stent is designed to undergo 380 million cycles (10 years) before it leads to fracture (Lally, 2006).

Testing the performance of the stents after deployment is not economical or an appropriate method, hence computational methods such as finite element analysis (FEA) studies have been executed to review the performance of the designs/products. Ansys is one of the finite element analysis software used for designing and simulation of the products. Some characteristics of stents that have to be considered while designing and simulation include outer diameter, inner diameter, strut thickness, strut width, strut length, number of struts, length, metal to artery ratio, foreshortening, recoiling and dogboning (Park, 2008 and Chua, 2004 b). The stress and strain characteristics are different for each material; hence the design has to be tested for each material (Kranz, 1999).

The above mentioned characteristics of stents are evaluated by using simulation software. Park and Migliavacca (2008 & 2002) in their studies mentioned some formulae to calculate the following:

2.3.1 Flexibility. The ability of the stent to pass inside the artery through the lesion area and this characteristic is calculated by

$$EI = \frac{PL^3}{3\delta} \qquad (1.1)$$

EI - Bending stiffness, P –Pressure, L – Length of stent, δ – Deflection

2.3.2 Radial stiffness. The support provided by the stent to the artery wall after the deployment of stent and this is given by

$$\text{Radial Stiffness} = P_{initial} * \text{ Eigen Value} \qquad (1.2)$$

$P_{initial}$ = Initial pressure, E.V. – Eigen value

2.3.3 Longitudinal recoil. The ability of the stent to shorten after deployment and removal of balloon catheter is calculated by

$$\text{Longitudinal Recoil} = \frac{L_{load} - L_{unload}}{L_{load}} \quad (1.3)$$

L_{load}- is the length of stent before removing the balloon catheter. L_{unload} – a length of stent after removing the balloon catheter.

2.3.4 Foreshortening. The ability of the stent to deform longitudinally after deployment.

$$\text{Foreshortening} = \frac{L - L_{unload}}{L} \quad (1.4)$$

L – Original length of stent, L_{unload} – Length of stent after removing the balloon catheter

2.3.5 Radial recoil. The ability of stent to contract after the balloon catheter is removed.

$$\text{Radial Recoil} = \frac{R_{load} - R_{unload}}{R_{load}} \quad (1.5)$$

R_{load}- Radius of stent before removing the balloon catheter, R_{unload} – Radius of stent after removing the balloon catheter

2.3.6 Dogboning. The design characteristic to prevent restenosis caused my mechanical stress.

$$\text{Dogboning} = \frac{R^{load}_{distal} - R^{load}_{central}}{R^{load}_{distal}} \quad (1.6)$$

$R_{load\ distal}$ – Distal radius of the stent, $R_{\ load\ central}$ – Central radius of the stent

2.3.7 Coverage area. The area between the arterial wall and stent

$$\text{Coverage Area} = \frac{\text{Surface of sent}}{\text{Area of artery}} \quad (1.7)$$

2.3.8 Target life. The fatigue durability to undergo cycling loads.

$$\text{Target Life} = \text{Pulse per min} * 1\ \text{day} * 10\ \text{years} \quad (1.8)$$

The product life is considered to be 10 years i.e., 420,500,000 cycles of load.

Stresses are formed when the stent is crimped, expanded during deployment, and compression exerted by the artery (Tan, 2001). The following formulae are given by Tan (2001) to calculate the circumferential stress in the stent.

The circumferential stress in the wall of the stent is given by

$$\sigma_\theta = \frac{PD}{2t} \tag{1.9}$$

The above equation is given as

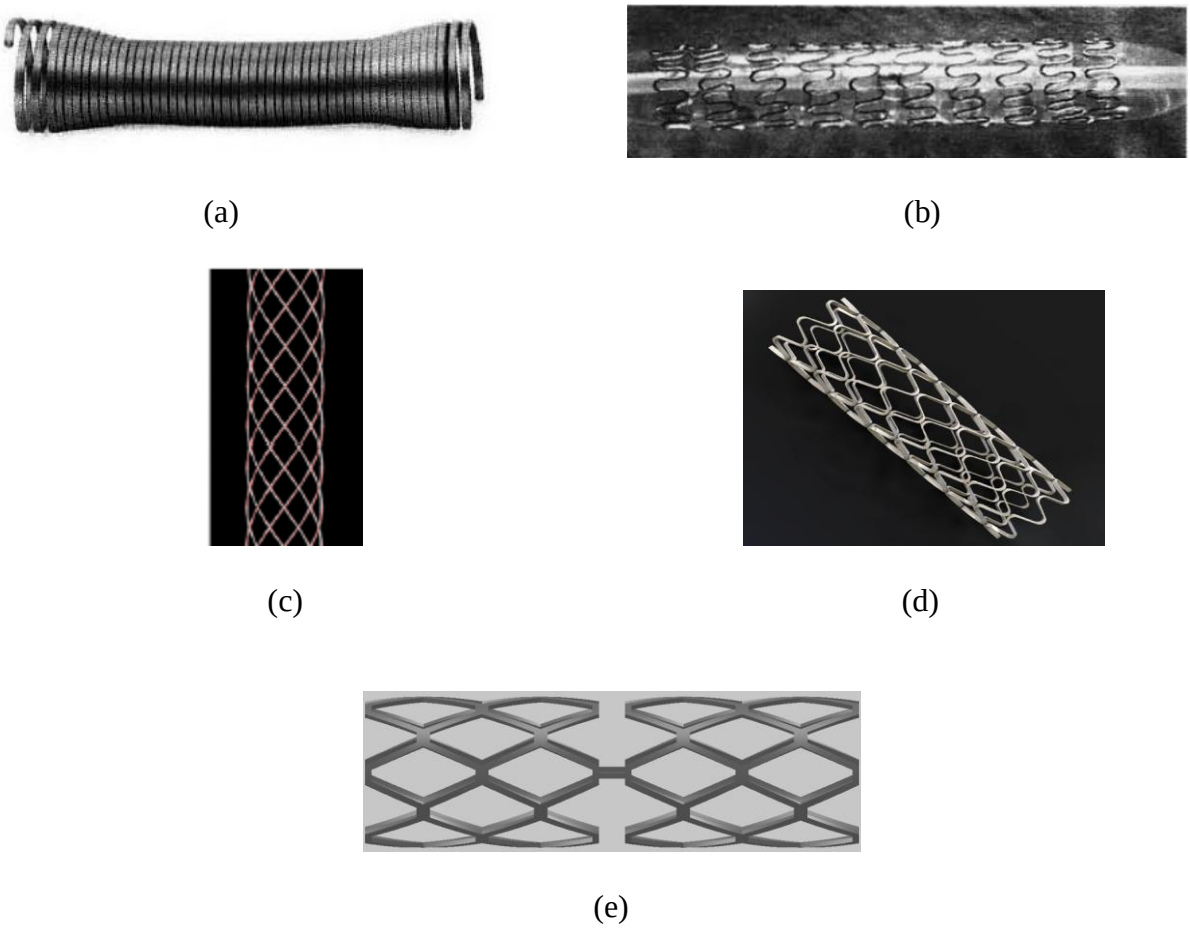
$$\sigma_\theta = 2P\left(\frac{D}{d}\right)^2\left(\frac{h}{L}\right) \tag{2.10}$$

where D = stent diameter, t = thickness, h = length of stent material, L = length of wire, d/2 = wire radius.

The number of slots increase the expansion rate of the struts as large width have high elastic recoil and wide slots with narrow struts have less foreshortening (Chua, 2004 b). The stress concentration is high at the corners of slots during expansion and low at the middle of the struts and bridging struts (Chua, 2004 b). Considering all the above characteristics, the design plays a significant role in stent's performance.

2.4 Shape, Size and Structure

Stents have various patterns and are classified according to diameter of stents, shape of struts, width, length and thickness of struts. Coronary stents usually have a length of 8-60 mm, diameter of 2.25-5 mm, strut width of 0.08-0.1 mm and thickness of 0.07-0.14 mm (Butany, 2005). Stockel (2002) described the stents according to the shape of the struts as coiled, helical spiral, woven, individual rings and sequential rings.



(a) (b)

(c) (d)

(e)

Figure 6. Stent strut patterns (a) coil (b) helical spiral (c) woven (d) individual rings (e) sequential rings (source: Stockel, 2002).

2.4.1 Coil. These stents are in coil form being that a flat wire turned into coil has high flexibility. However, the draw backs of these stents are low radial strength (Stockel, 2002) and high restenosis rates (Lally, 2006). A coiled stent is shown in the Figure 6 (a).

2.4.2 Helical spiral. These stent struts are minimally connected to each other and they are highly flexible stents as shown in Figure 6 (b). The drawback of these stents is absence of longitudinal support.

2.4.3 Woven. These stents are woven from wires and widely used as self-expanding stents as shown in Figure 6 (c). The advantage of these kinds of stents is the excellent mechanical support offered to the artery by covering the surface area by its braided wires.

2.4.4 Individual rings. Individual rings with "V" shape struts are joined during manufacturing. Figure 6 (d) depicts the individual rings stent.

2.4.5 Sequential rings. These rings are similar to individual rings but connected to rings with various shaped struts. This kind of stent is shown in Figure 6 (e).

A brief description of stents available in the market with different materials, expansion types and physical characteristics are given in Table 3.

Table 3

Stents Available in the Market- Materials, Types and Physical Characteristics (Source: Butany, 2005)

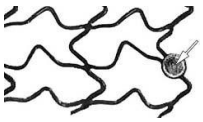
Stent Name	Stent material	Type	Physical characteristics	Design
be Stent 2	316 L Stainless steel	Balloon expandable, slotted tube	Flexible radial "S" crowns and longitudinal "V" crowns crossing at a junction	
Biodiv Ysio	316 L Stainless steel, coated with polymers	Balloon expandable, slotted tube	Sinusoidal rings with round edges and rectangular edges are connected alternatively. These rings are connected with 'S shaped articulation.	

Table 3

Cont.

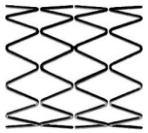
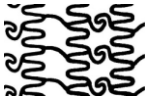
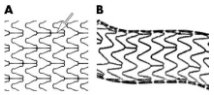
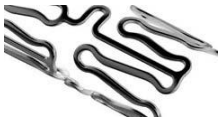
Bx Velocity	316 L Stainless steel	Balloon expandable, slotted tube	Sinusoidal rings connected with ‘n’ shaped segments.	
Driver	Cobalt alloy surface treated with chrome oxide	Balloon expandable, tubular	Sinusoidal rings, minimally connected for flexibility	
Express	316 L Stainless steel	Balloon expandable, slotted tube	Narrow sinusoidal rings connected to wide sinusoidal rings alternatively	
Gianturco-Roubin II	316 L Stainless steel	Balloon expandable, coil	Coil attached to a single longitudinal strut	
JOSTENT Flex	316 L Stainless steel	Balloon expandable, slotted tube	Sinusoidal rings are alternatively connected with spiral and diagonally curved links	
Multi-Link PENTA	316 L Stainless steel	Balloon expandable, slotted tube	Rounded sinusoidal rings	

Table 3

Cont.

Multi-Link RX PIXEL AND ULTRA	316 L Stainless steel	Balloon expandable, slotted tube	Zigzag rings with rounded corners connected with straight links	
Multi-Link Vision	Cobalt chromium alloy	Balloon expandable, slotted tube	Zigzag rings with rectangular edges connected with 'U' link extended with straight link	
NIR ™	316 L Stainless steel	Balloon expandable, slotted tube	Sinusoidal rings connected with wide 'v' shaped links	
NIRFLEX	316 L Stainless steel	Balloon expandable, slotted tube	Sinusoidal rings connected alternatively to long and shorts crowns. The crowns are connected to 'Z' shaped links	
Palmaz-Schatz 153/ 154	316 L Stainless steel	Balloon expandable, slotted tube	Diamond shaped mesh	
Wall stent	Platinum covered with cobalt alloy	Self expandable, tubular mesh	Cylindrically braided mesh	

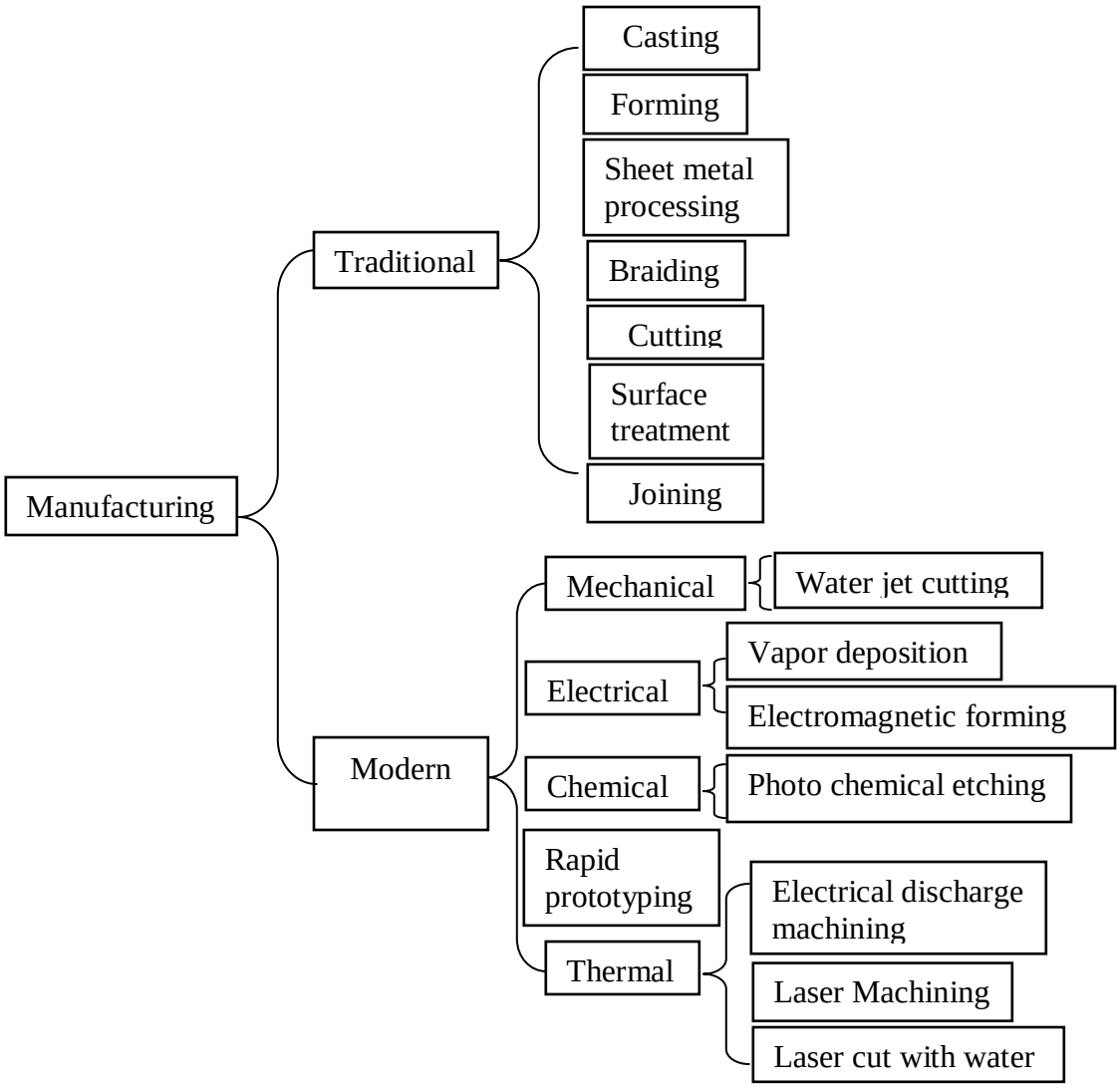


Figure 7. Classification of stent manufacturing methods.

2.5 Manufacturing Methods

Stents are manufactured from several forms of materials such as machining from tubular forms, machining on the sheet, and later, the ends are attached by welding, rolling, etc., to form into a tubular form (Stockel, 2002). There are five forms of material recommended to manufacture stents by Stockel (2002) and Kuehling (2010).

a) Forming from a wire

b) Machining on a hollow tube

c) Rolling a design cut sheet

d) Casting is pouring the stent material in indentations

e) Vapor deposition

Stents are manufactured in several methods and they are classified according to traditional and modern manufacturing methods. Some of them are laser cutting, electrical discharge machining, photochemical etching, rapid prototyping, casting as shown in Figure 7. Some of these manufacturing methods are described in this review.

2.5.1 Laser machining. Laser cutting is most widely used manufacturing method in medical device industry because of its precision machining process (Caves, 2006). A high intensity beam of light operates according to the stent pattern to remove the material on a tubular blank. The material removal rate with the laser beam is about 0.1 to 0.5 µm of material for each pulse (Caves, 2006). The high intensity laser beam generates heat, forming oxide layers and burrs so the machining follows annealing, pickling, etching, de-scaling, polishing, cleaning and rinsing (Koós, 2007). There are various types of laser machining methods introduced in studies to manufacture stents. The methods are discussed in the following sections.

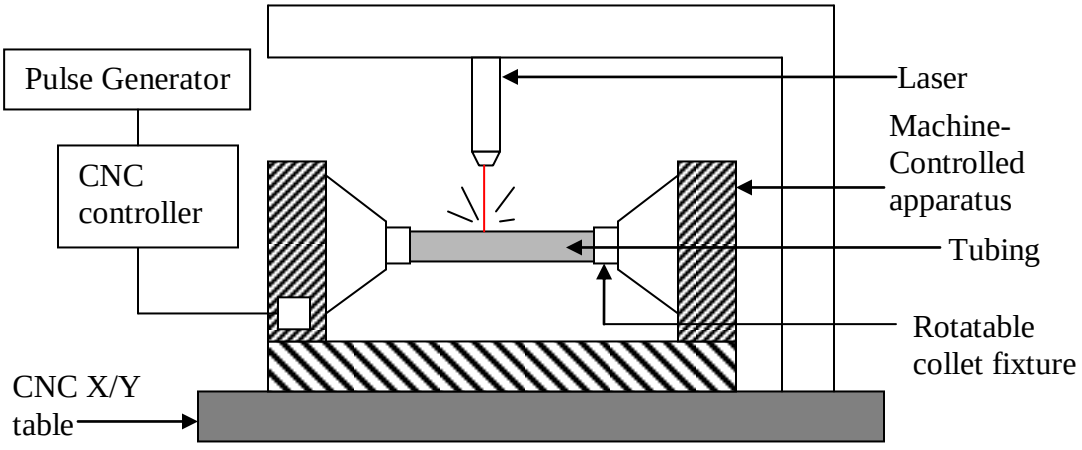


Figure 8. Laser beam cutting machine (adapted from Shedlov 2005 & Saunders 2007).

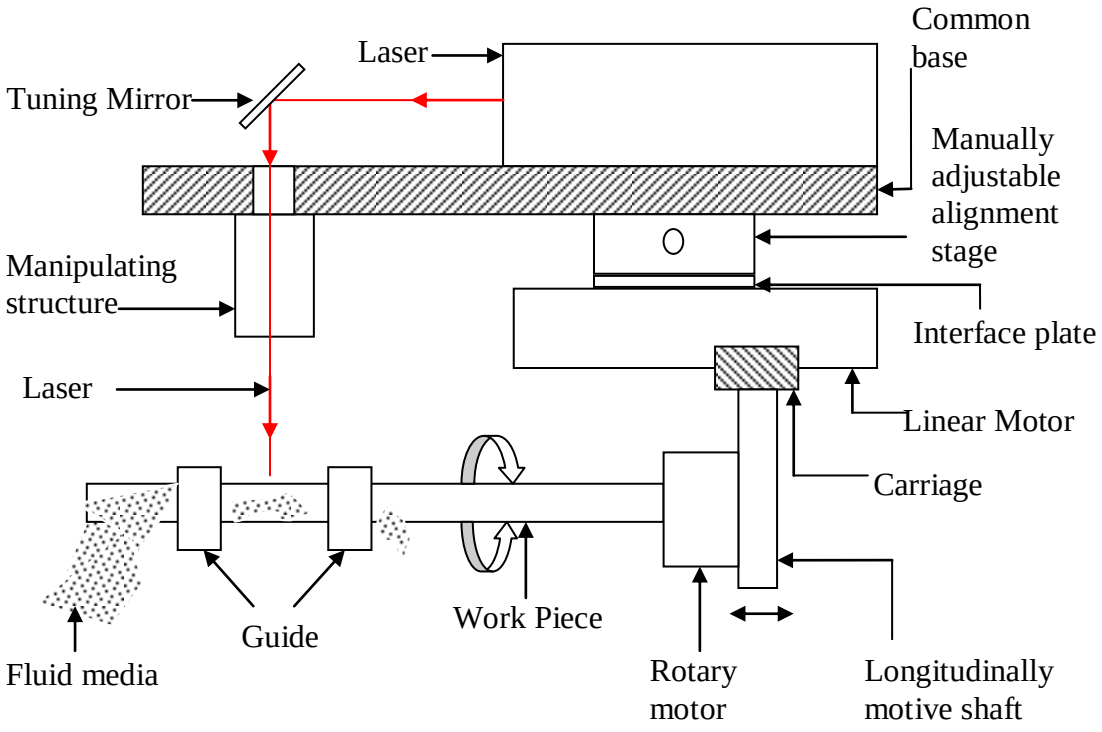


Figure 9. Laser cutting with linear and rotary motors (adapted from Merdan, 2005).

2.5.1.1 Laser cutting with computer numerical control (CNC) machine and pulse generator. In this manufacturing method, a rotatable collet fixture holds a mandrel positioned inside the work piece. For linear motion in x and y directions the machine controlled apparatus aligns on a CNC X/Y table and this table further acts as a base to support the equipment. A pulse generator connects the CNC controller and laser simultaneously (Shedlov 2005 & Saunders 2007) as shown in Figure 8. The controller passes coded instructions and the work piece rotates accordingly under the laser beam to cut the material with precision. Laser beam with no pulse generators causes high heat and melts the work piece material. Therefore, ultrashort pulse lasers that produces short pulses i.e., less than 10^{-11} seconds are introduced (Weber, 2003). This makes a good surface finish and after machining surface treatments are insignificant (Weber, 2003).

2.5.1.2 Laser cutting with linear and rotary motors. Merdan (2005) and Shedlov (2005) explained this method as stent cutting device with linear and rotary motions to manufacture the

stent. A common base on the bottom surface attaches the linear motor. On the top surface of this common base aligns the laser machine that remains stationary. This means, the components fixed on the top of the linear motor are stationary. The linear motor fastened above the carriage moves a longitudinally movable shaft with rotary motor in linear motion that is fastened below the carriage. The rotary motor holds the work piece and rotates it underneath the laser beam as shown in Figure 9. As the work piece rotates, it moves longitudinally and the laser beam cuts the tubular work piece in the desired pattern and the fluid aids to cool the work piece. The direction of the laser beam on the work piece changes with a preset tuning mirror. The fluid media removes debris on the work piece and acts as coolant, lubricant, and polishing agent.

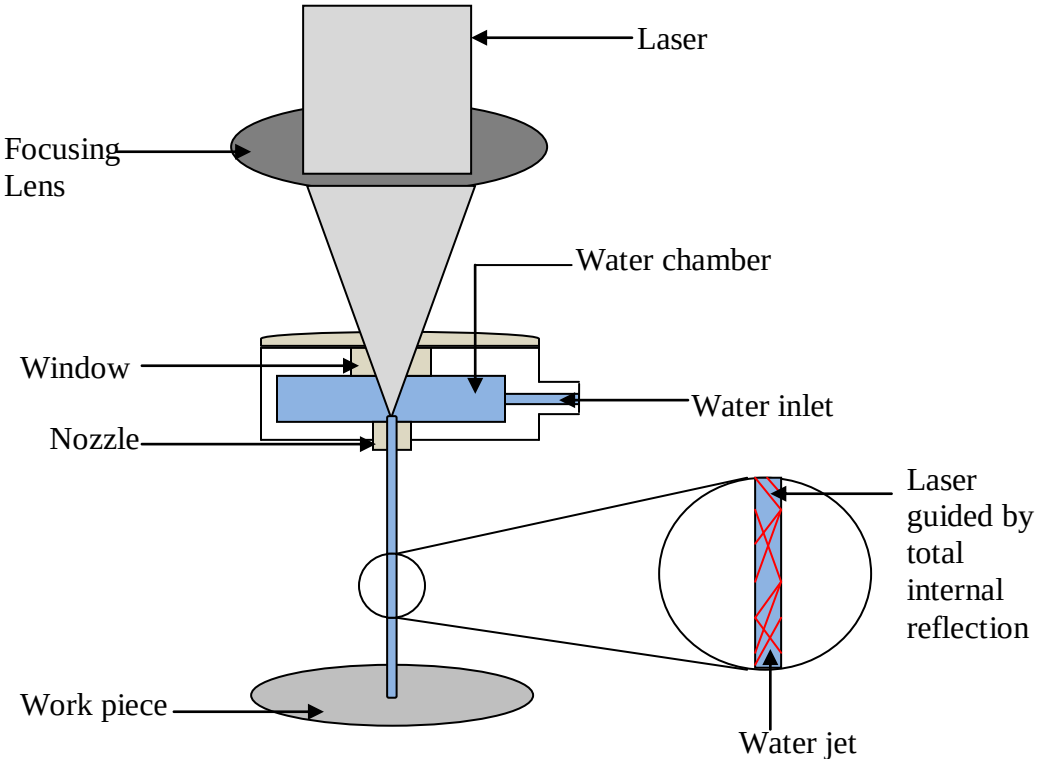


Figure 10. Water jet guided laser machining (adapted from Sokolowski, 2007).

2.5.1.3 Laser cutting with water jet. Richerzhagen (2004) explained this method as water with high intensity of force and pressure is rendered for cooling as well as for internal reflection.

In this method, the principle of total internal reflection utilizes water jet guided laser beam machining as shown in Figure 10. The water from inlet passes through the laser beam. The laser beam reflects internally in the stream of water and the water flows on to the work piece and the laser cuts the material in the preferred shape. The main advantage of this method is that the work piece is free from heat, chemicals, flame charring, burrs and contamination (Sokolowski, 2007).

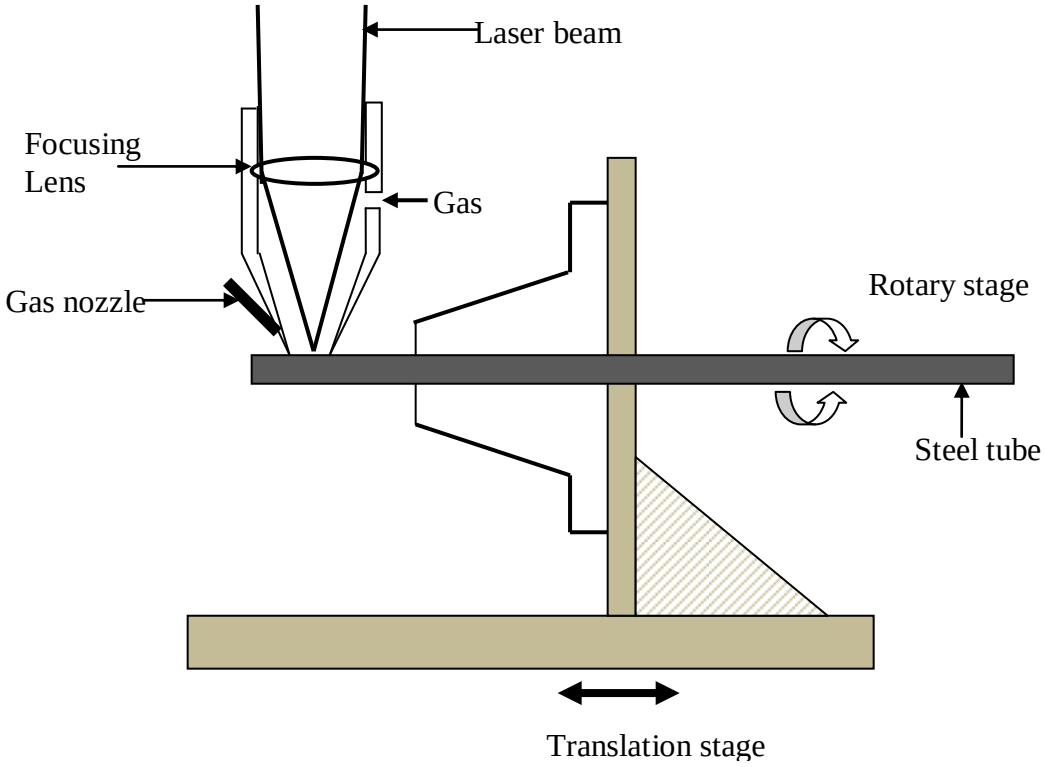


Figure 11. Laser beam machining with gas (adapted from Momma, 1999).

2.5.1.4 Laser cutting with gas jet. Momma (1999) explained this manufacturing method with a tubular metal work piece placed on a translation motion system. A metal tube affixes a stationary laser beam machine as shown in Figure 11. A gas nozzle between the beam and the work piece introduces oxygen gas. This oxygen gas from nozzle helps to melt the metal rapidly while cutting the metal in short time as well as helps to prevent heat-affected zones. The

disadvantage of this method is the formation of oxidation layers on the surface of the stent as a result of the practice of oxygen gas.

2.5.2 Electrical discharge machining (EDM). In EDM, heat produces by the discharge of electrons. In this process, a dielectric fluid aids in electrical discharge to remove the material from work piece with the tool i.e., electrode (Theisen, 2004). The tool and conductive work piece immerses in the dielectric fluid (water or oil) and the power supply in the dielectric fluid produces sparks between the tool and the work piece. The dielectric fluid as well acts as a coolant and removes the debris formed throughout the material removal process (Roorda, 2007). Thus, material removal takes place by melting and evaporation processes.

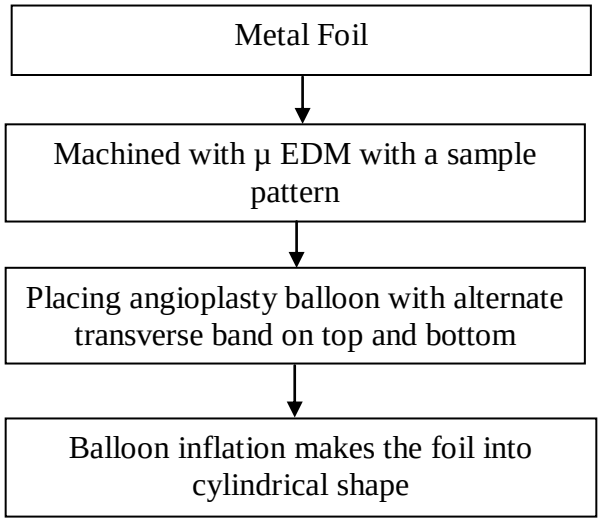


Figure 12. Process flow of the µEDM on metal foil to make a stent (Takahata et al, 2004).

***2.5.2.1 Microelectrodischarge machining* (µEDM).** Takahata (2004) explained µEDM stent manufacturing method with a metal foil as represented in Figure 12. This manufacturing method consists of 50 µm thick stainless steel 304 foil, µEDM, design pattern, and angioplasty balloon. The design pattern in this method has beams on two sides with a longitudinal axis. The two side beams connects three involute loops as shown in Figure 13. The µEDM process

machines the metal foil in involutes pattern. An angioplasty balloon inserts into alternate transverse bands of the foil and the inflation of the balloon expands the foil into cylindrical shape or tubular stent.

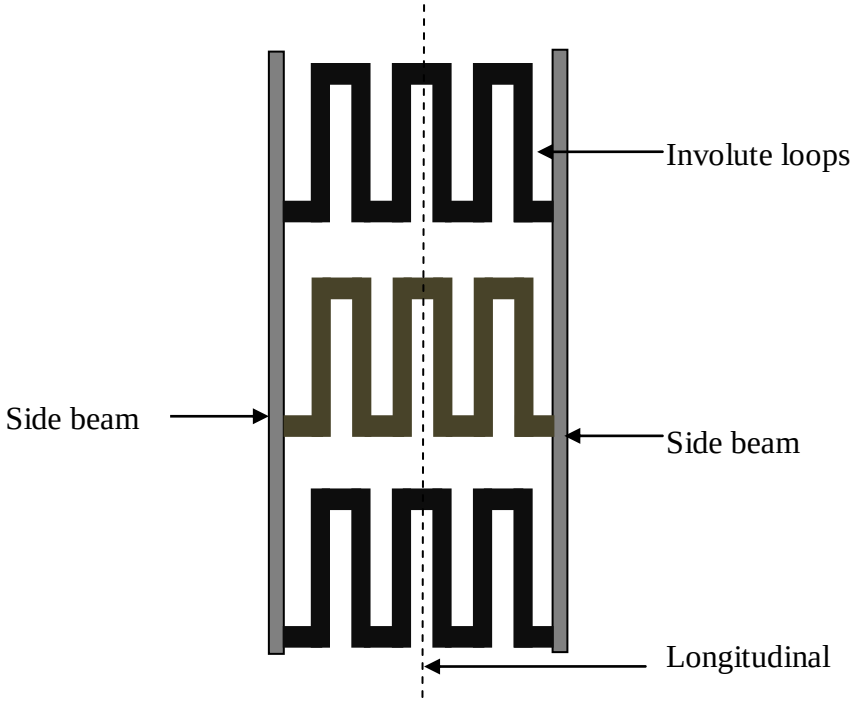


Figure 13. Involute loops formed on the foil by μEDM (adapted from Takahata, 2004).

***2.5.2.2 Electrostatic discharge machining*.** Donadio (2000) explained this method as electrostatic discharge machine (EDM) with two charged electrodes to make the slots on the work piece. A holding device with a fixture clasps the work piece to rotate and shift towards charged electrodes. The two electrodes have different design profiles with definite geometrical angular notches as shown in Figure 14 (a) and (b). The first electrode has a rectangular extension notch with an angle of 82^0 and width of 0.01 inches for the rectangular extension. The depth of the notch is greater than the radius of the tubular work piece because the charged electrode comes in contact with the work piece and cuts the slots. The second electrode has triangular notch with an angle more than 90^0 and the depth of the notch is smaller than the radius of the tubular work piece. This angular notch design helps to extend the electrode to uncut the work

piece on the other side. Simultaneously, another pair of similar electrodes positioned on the other side of the work piece cuts and generates the slots along with the first pair. The processed stent is shown in the Figure 14 (c).

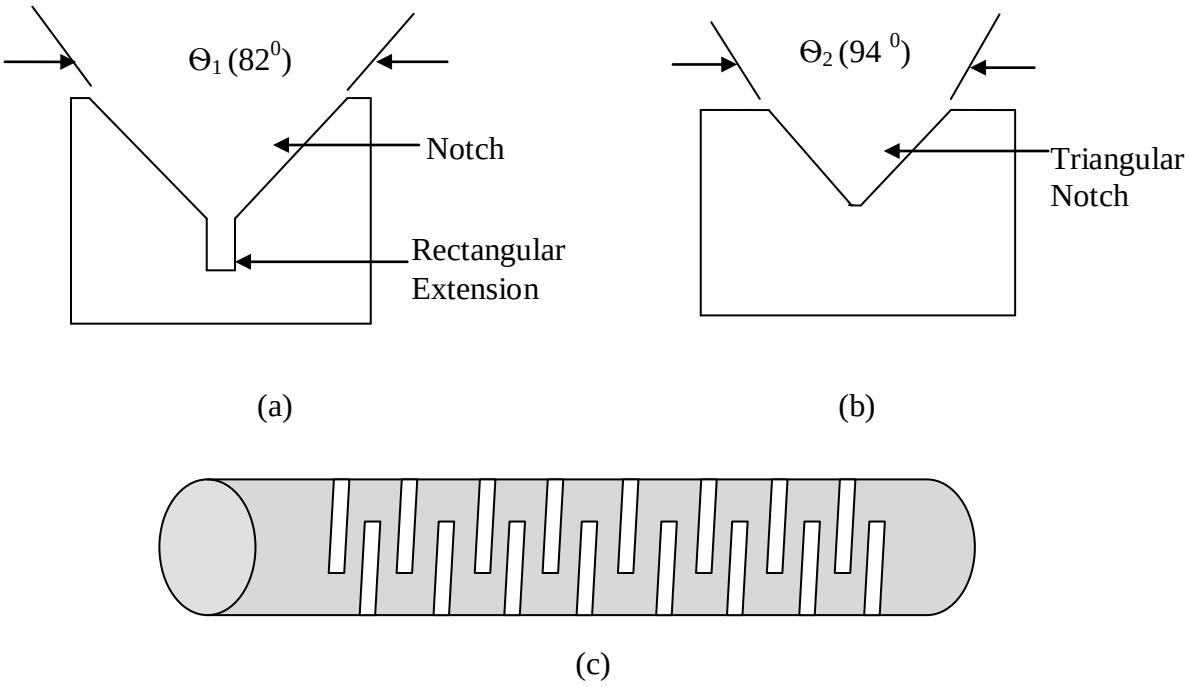


Figure 14. Electrodes and machined work piece by electrostatic discharge forming method (adapted from Donadio, 2000).

2.5.3 Hydro cutting. Roorda (2007) has stated several methods of manufacturing stents; one of them is the hydro cutting machining. This method introduces a jet stream with high intensity of water on the surface of the material to cut the material into slots. In hydro cutting, the material exposes to jet stream with abrasives such as garnet to form the slots. Apart from abrasives, hot water with chemical applications also promotes the cutting process. Sand blasting is a technique similar to water jet cutting except that sand is imposed instead of water.

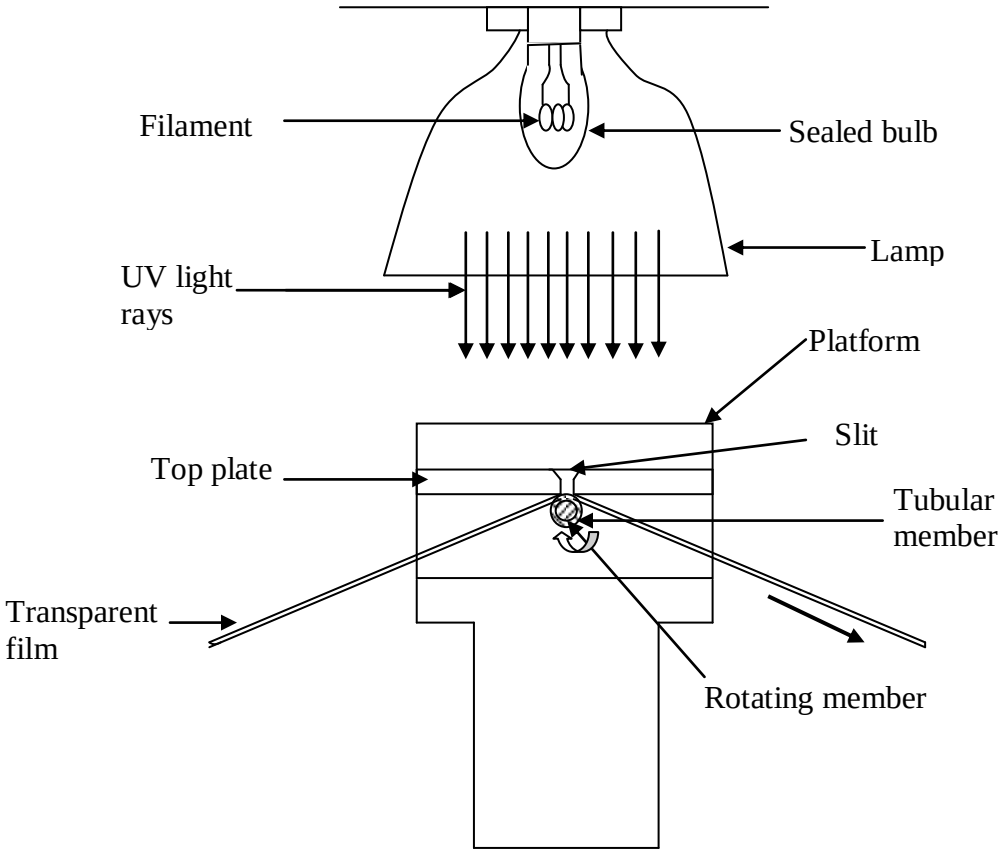


Figure 15. Photosensitive chemical etching process (adapted from Trozera, 2003).

2.5.4 Photosensitive chemical etching. Dustrude (1999) and Trozera (2003) explained this manufacturing method with tubular work piece, ultraviolet (UV) light, and transparent film. The procedure undergoes preliminary treatments such as electro-cleaning process to clean the work piece in a solution and application of a photosensitive resistance coat on the work piece.

The apparatus consists of lamp with a UV wavelength, a sealed bulb with a filament, a platform with top plate and a slit to narrow the UV light. The setup is shown in Figures 15 and 16. The tubular work piece installs a transparent film with specific design pattern on the top and aligns with a rotating member inside the hollow zone. The UV rays from the light source exposes the work piece and this endows photo sensitive resistance coat on the material to react and change the properties of exposed areas on the work piece. The work piece withstands

electrochemical etching treatment to form the stent structure. The transparent film connects to a weight to provide tension and consecutively to uphold proper contact with the work piece.

The UV light ranges between 360 and 440 nanometers with a wavelength of 390 nanometers. The chemical etchants essentially use Ferric chloride at a grade of 36- 42 degrees, Baume at 125^0 F, and 5 volumes of HCL solution i.e., 1 volume of HCL, 1 volume of nitric acid, 3 volumes of water (Donadio, 2000).

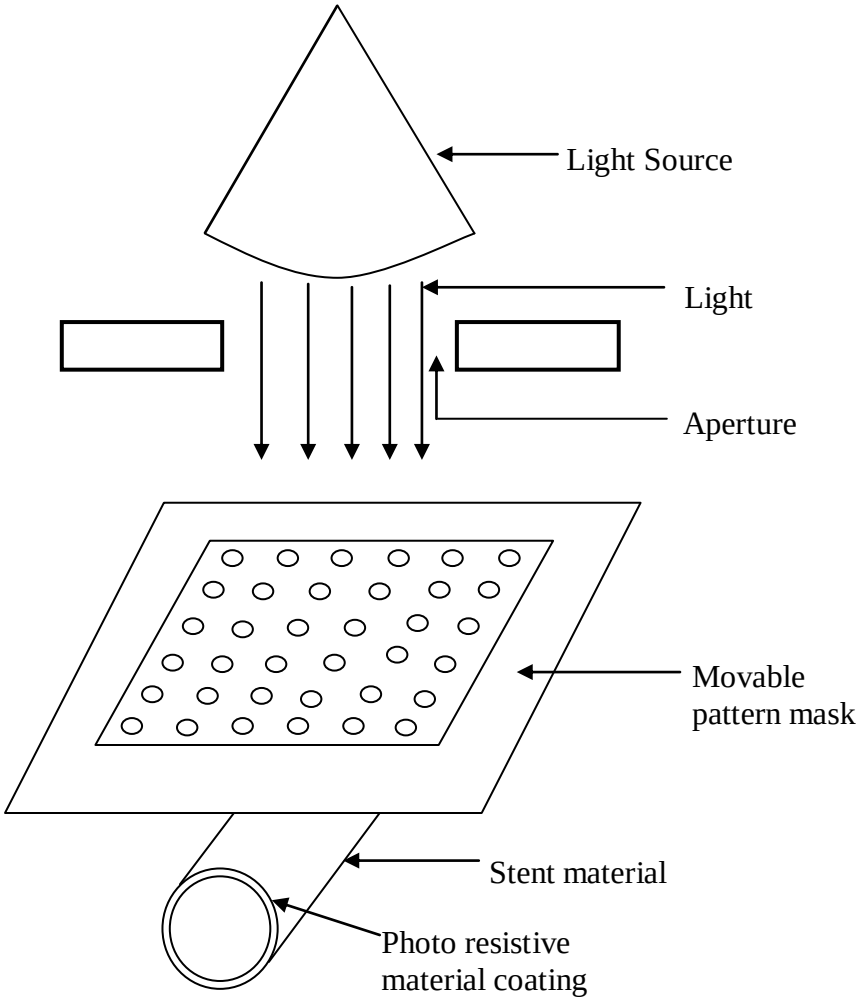


Figure 16. Photosensitive chemical etching process (adapted from Donadio, 2002 and Dustrude, 1999).

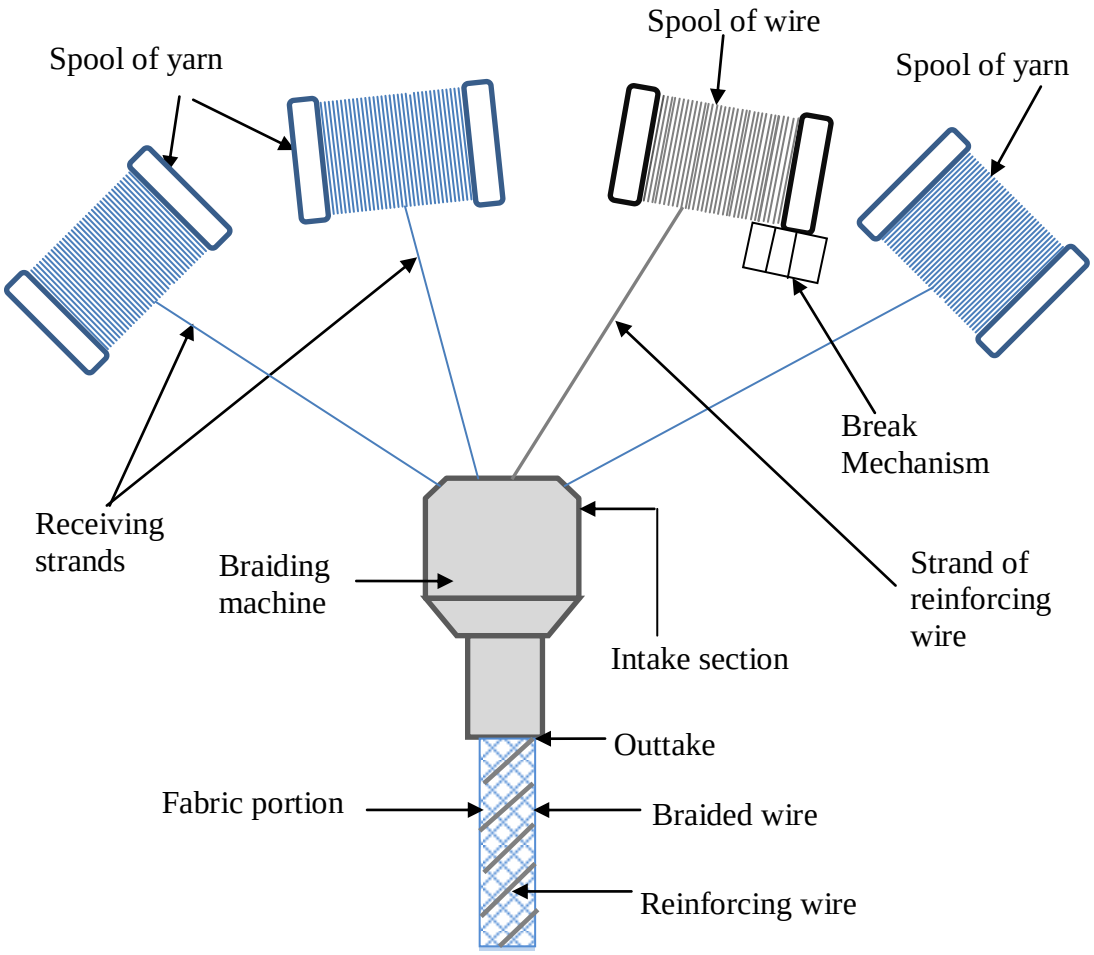


Figure 17. Braiding machine with yarn and wire to form tubular stent (adapted from Jayaraman, 2002).

2.5.5 Wire braiding. Jayaraman (2000) illustrated this arrangement as the braiding machine with spools of yarn and a spool of reinforced wire. The spools provide yarn and reinforced wire to the knitting machine as shown in the Figure 17. The machine has an intake section and weaves all the strands accordingly. The number of spools of yarn has to be more compared to spools of wire i.e., 2:1 ratio has to be maintained all the time in this process.

The break mechanism connects the spool of wire and inactivates whenever the wire is inessential. The supply speed of the yarn and wire to weave is in the ratio of 4:1. The materials

employed for yarns are natural fabric, polyester, polypropylene, polyethylene and for wire are metal alloys.

2.5.6 Electromagnetic forming. The apparatus consists of forming coil (electromagnetic generators), energy storage capacitors, power supply, conductive metal object (work piece) and field shape mandrel. The energy storage capacitor connects power supply and forming coils. The work piece and field shape mandrel are positioned between forming coils as described by Baum (2007) and the apparatus is shown in Figure 18. The forming coil generates electromagnetic pulses from the capacitors and the work piece (conductive material) thus induces eddy currents. The magnetic field from the forming coil and eddy currents from work piece interacts with each other and leads to formation of repulsions between them. These repulsions simultaneously lead to stress formation and deform the metal permanently. The field shape mandrel helps to cut the metal with the magnetic field at precise points, thus forming the desired shape.

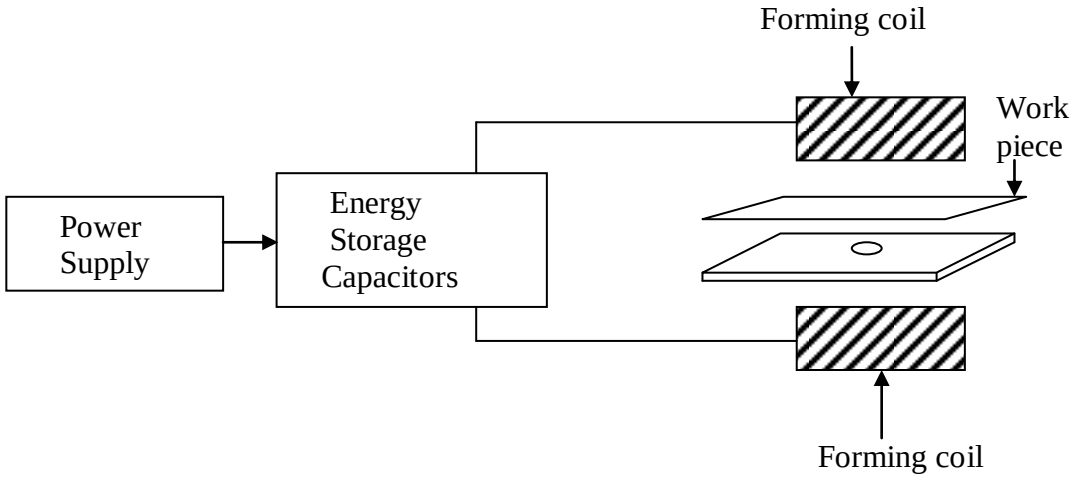


*Figure 18***.** Electromagnetic forming: apparatus manufacturing medical stents (adapted from Baum, 2007).

Figure 19 shows a hollow work piece with plurality of holes placed inside the tubular work piece and the whole set up is placed between coils. As the coil produces electromagnetic

field, the work-piece forms eddy currents and this leads to repulsions. These two form a mechanical force towards the center of mandrel. This force leads to formation of holes on the work piece.

Additionally, the EMF method fabricates sheet metal pieces in similar manner and joins the sheet by one of the methods such as gas welding, electron beam welding, soldering, brazing, adhesive bending, explosive welding, or arc welding.

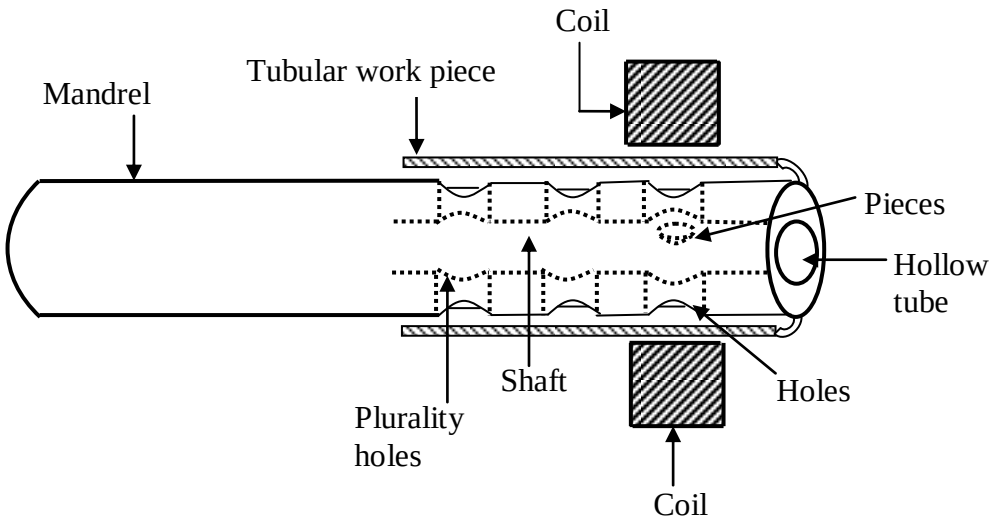


Figure 19. Tubular work piece with EMF procedure (after Baum, 2007).

2.5.7 Casting. Casting is an ancient method of fabrication, associated with molds and molten material. The molten material fills the mold and solidifies to form a pattern/structure. The method is set forth to fabricate stents. There are several methods of casting and few of them are described in the following sections.

***2.5.7.1 Centrifugal casting*.** The equipment includes casting flask and female mold as shown in Figure 20. Mirizzi (2003) illustrated the method with a female mold assigned in the casting flask. The screws fasten the mold and flask tightly and molten material fills the mold. The molten materials such as steel, tantalum, Ni-Ti, polymers are introduced into the female

mold cavity. A female mold consists of grooves which lead to formation of the stent structure. The mold rotates to spread the casting material equally into the grooves. The rotational force accelerates high velocity and institutes centrifugal force. This centrifugal force allows the casting/molten material to move radially outwards i.e., into the grooves of the mold. This also helps to solidify the material to form the stent structure.

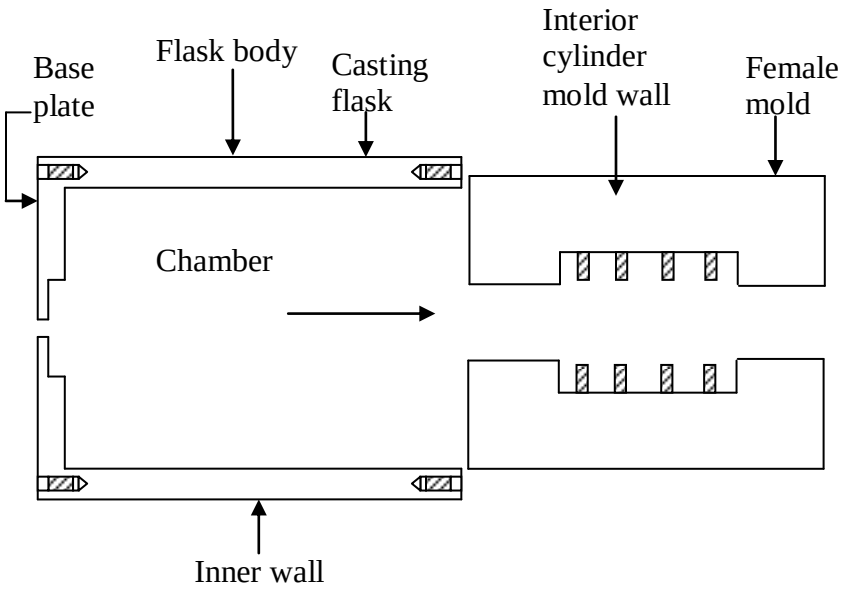


Figure 20. Centrifugal casting method (adapted from Mirizzi, 2003).

***2.5.7.2 Pouring the stent material in the indentations/ grooves*.** One of the procedures to manufacture stents is deposition of the stent material on a sacrificial structure (SS). Fabrication materials of SS are sugar, starch, ice, wax, polyvinyl alcohol and polyvinyl acetate materials that dissolve in water (Roorda 2007 & Weber 2004). The composition of SS is accomplished from injection molding, extrusion, laser ablation or by prototyping techniques.

The negative stent/ SS have indentations or grooves. The molten material either introduced by spraying or coating fills these indentations or grooves. The other method is to dip the SS in the molten material solution. SS is discarded after formation of the stent. This

manufacturing method is explained by Weber (2004) and Figure 21 (a) and (b) depicts the materials poured in indentations/grooves. This method integrates desired mechanical characteristics as the indentations fill the layers with different kinds of materials. Different layers of materials include thermoplastic/thermosetting polymers, biodegradable polymeric materials, fibers and metals.

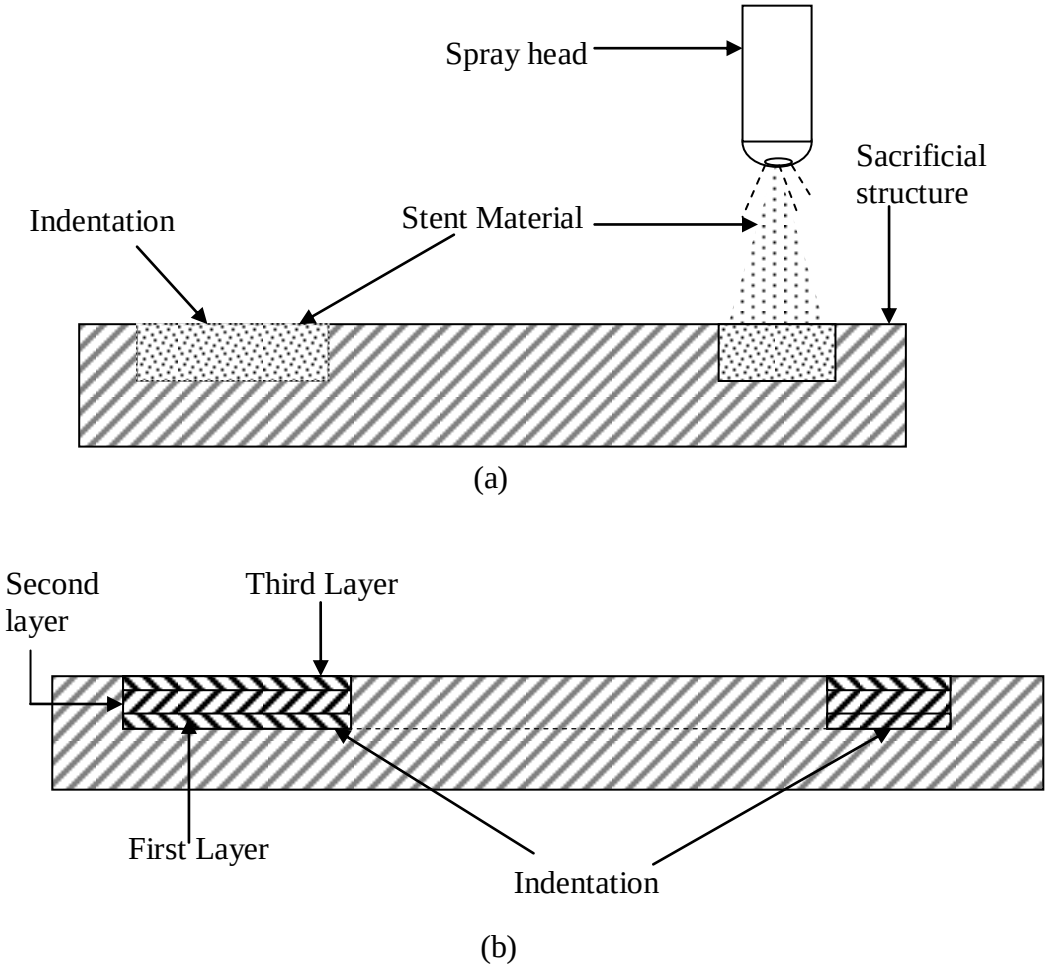


Figure 21. Pouring stent material in the indentations or grooves (adapted from Weber, 2004).

Likewise, electrochemical deposition method engages SS made of copper to form stent material. After formation of stent, the copper material dissolves in solvent (Moller 1998). The stents manufactured by casting have normal flow passage and expansion state as other stents manufactured by various methods.

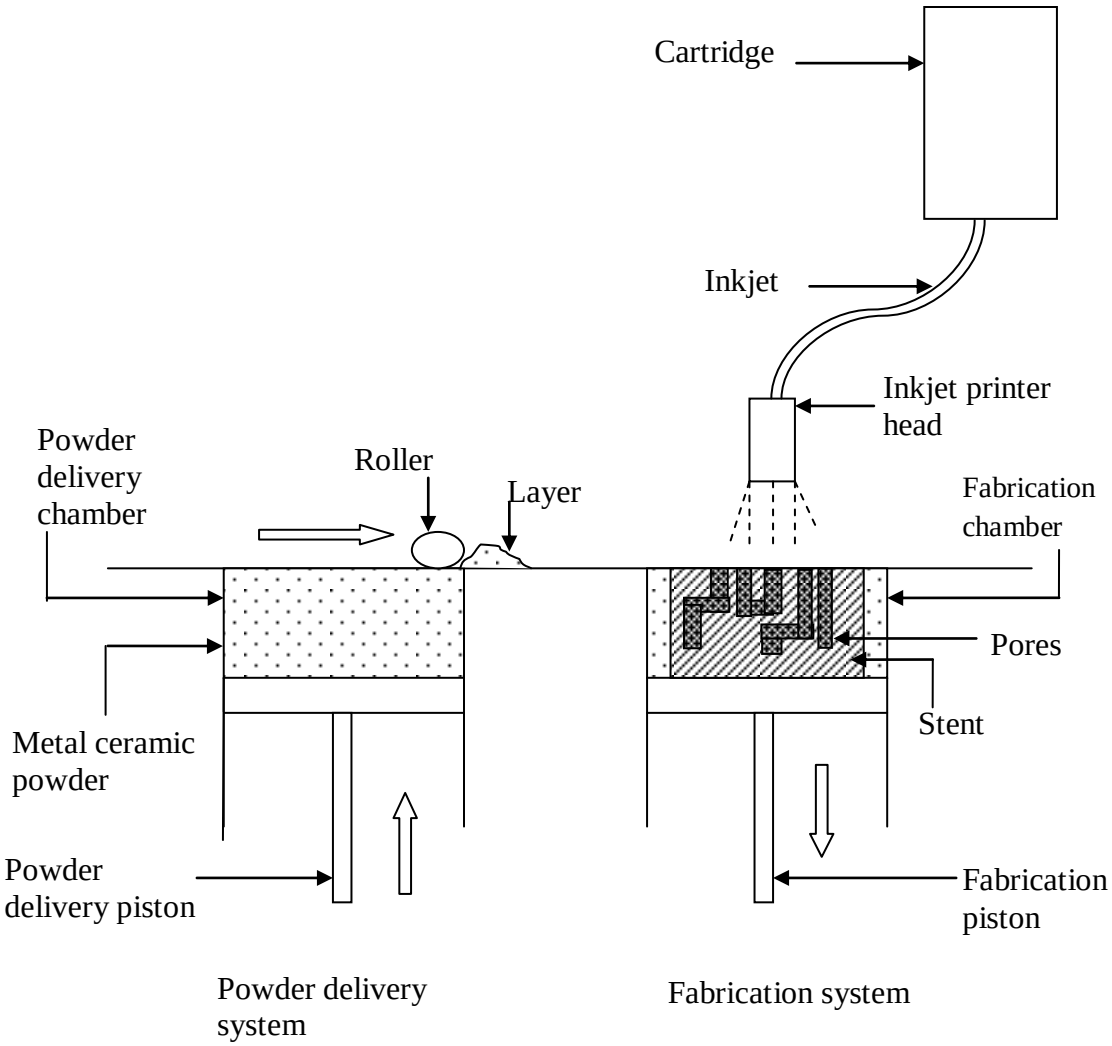


Figure 22. Rapid prototyping method (adapted from Roorda, 2007).

2.5.8 Rapid prototyping. The setup consists of inkjet printer, cartridge, powder delivery system and fabrication system. Figure 22 depicts the prototyping process. Roorda (2007) illustrated the process with inkjet line from cartridge that carries ink to the inkjet printer head. The powder delivery system has a powder delivery chamber with a piston and the chamber is filled with ceramic powder/metal. The piston moves upward to deliver the powder layer by layer to the fabrication system. The fabrication system has a fabrication chamber with a piston. The roller helps to roll the powder from powder delivery system to the fabrication system. The inkjet cartridge binds the powder and deposits on the stent in the fabrication system. After formation of

each layer the fabrication system piston moves downward and the powder is bound by the fluid from the inkjet. The layers of the powder bind and harden to form the stent.

The pores present on the stent separate the unbound ceramic powder and the cleaning process clears the unbound powder on the stent.

2.5.9 Vapor deposition. Vapor deposition consists of evaporation, sputtering, ion beam assisted deposition and chemical vapor deposition methods. The source material deposits layer by layer on the mandrel to form a stent. The following sections illustrate the evaporation and ion beam processes.

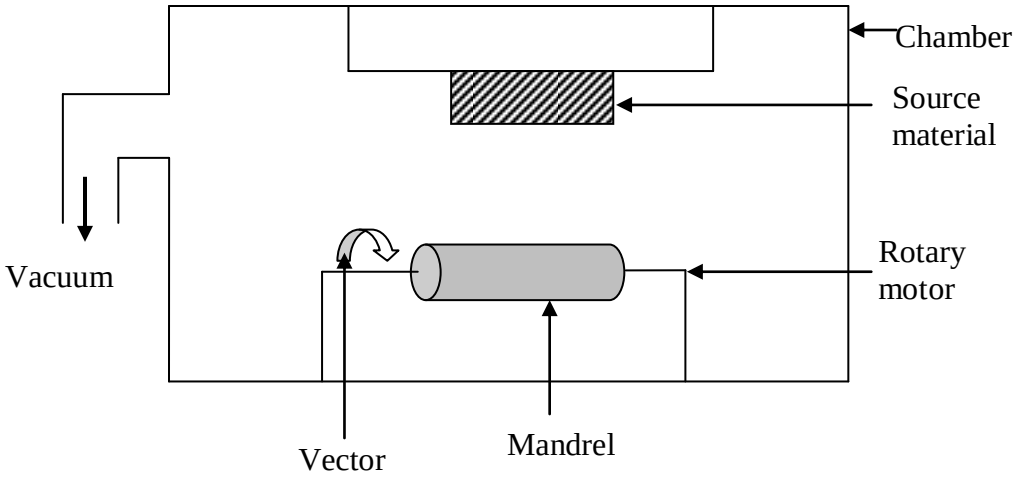


Figure 23. Vacuum deposition by evaporation (adapted from Whitcher, 2005).

***2.5.9.1 Evaporation process*.** Whitcher (2005) demonstrated the evaporation process as a chamber with rotary motor, mandrel, source material and vacuum. Figure 23 represents the evaporation process equipment. The set up allocates the mandrel on the rotary motor and it rotates in the direction of vector with a speed of 1-60 rev/min. Vacuum fills the chamber and develops appropriate vacuum pressure. The source material flows from top of the chamber towards the mandrel. The termination of the process takes place when a desired thickness of

material deposits on the mandrel. Drilling, cutting or other machining processes separates the material from mandrel.

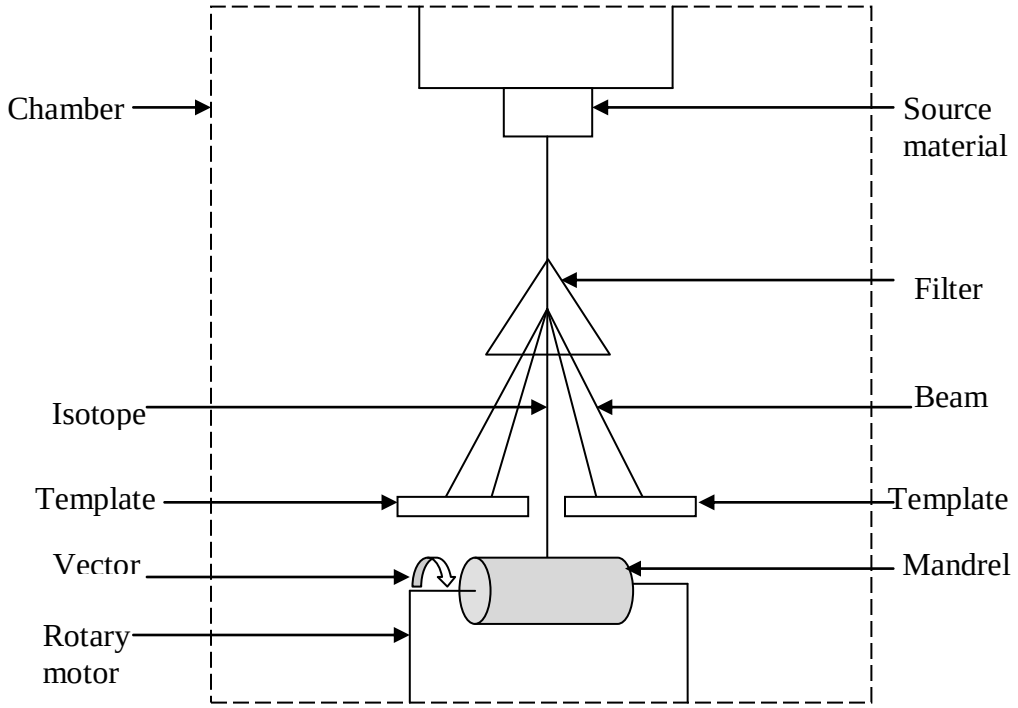


Figure 24. Vacuum deposition by ion beam (adapted from Whitcher, 2005).

***2.5.9.2 Ion beam process*.** The set up consists of filter and templates organized in a chamber. In this method, the filter prevents the contaminants from the source material or separates the isotopes of an element. The templates help to narrow the path of isotopes and allow a single isotope to pass towards the mandrel and form a layer on it. Whitcher (2005) elucidated the ion beam process as shown in Figure 24. The separation of the mandrel and material take place after sufficient amount of material deposits on the mandrel. Cutting, milling, grinding, drilling or laser cut procedures executes the separation process.

Pattern mask/reverse image on the mandrel serve in the formation of struts. The pattern mask on the mandrel allows the material to deposit in the slots. After formation of thick layers of the material the separation process takes place to separate mandrel and pattern mask from the

material. Vapor deposition method provides the solution to obtain multiple layers of the material with mechanical and biocompatible properties. In this manufacturing method, cleaning process is inessential but follows the chemical etching or polishing procedures to remove imperfections on the material.

Table 4 illustrates the advantages and disadvantages of the manufacturing methods of stents.

Table 4

Advantages and Disadvantages of Manufacturing Methods

Manufacturing	Advantages	Disadvantages
Laser machining	Precision cut	Expensive, compulsion of surface treatment technique
Electro discharge Machining	Smooth surfaces	
Hydro- Cutting	Cold shaping, no chemical reactions and flame	
Braiding	Highly flexible, cold working	Complications in forming complex patterns
Vapor deposition	Desired compositions, mechanical properties, geometries and surface smoothness are obtainable.	

Source: Moller 1998; Trozera 2003; Witcher 2005; Roorda 2007.

2.6 Conclusion

This chapter reviewed the material characteristics, design patterns, design functionality and some of the manufacturing techniques that are practiced in developing stents. The review assists to promote product development methodology of coronary stents on material, design and manufacturing techniques.

The formation of plaques inside the arteries varies from person to person and clinicians have to select the appropriate stent to be deployed in the artery (Tan, 2001). Although there are many stents available, because of the complex lesions, there is a need for new designs. So, manufacturers and clinicians focus on explorations of new stent designs. Thus, this research concentrates on product development methodology of stents to develop and test new designs. Chapter 3 incorporates all the information necessary for product development of coronary stents and focuses on design phases of the stents.

CHAPTER 3

Methodology for Product Development of Coronary Stents

3.1 Problem Statement

Over the past 25 years, many stent designs have been developed and these are available for use in the market. Even though there is ample selection of stents, the medical device industries still explore for new designs to operate the complex lesion structures. Clinicians and medical device manufactures look for new stent designs or to improve the existing designs to deploy the stents successfully in the torturous lesion arteries. To develop new designs or to improve the existing stent designs in functionality aspects, product development methodology with phases is essential. The functionality aspects include materials, pattern, geometry, simulation tests and manufacturing methods. The research in the past has concentrated in all the functionality aspects, but until now no research has initiated product development methodology for coronary stents.

The methodology is essential to consider all the phases of product development at conceptual stage. This consideration directs the decision making process that lead to cost-effective and time conservation practices. Thus, this research develops a new product development methodology of coronary stents for complex medical needs and analyses the methodology by modeling novel stents and compares the results with Cypher stent (J & J Co.).

3.2 Research Objective

The stages of product development of coronary stent from concept to deployment in the in the patient are critical. These stages with development methods influence decision making and optimization principles to improve quality, time and cost effectiveness. Thus, a comprehensive

evaluation of the concepts is extremely significant. The research identifies this significance and develops a methodology for coronary stents.

The objective of this study is to develop a new methodology for coronary stent product development with emphasis on design, simulation and manufacturing. The new methodology compels multiple schemes of engineering design disciplines upon coronary stent product development to endeavor adaptable and cost-efficient techniques. This product development approach for coronary stents is presented with design, simulation and optimization strategies and these are described in detail.

3.3 Development Strategy

Product development generally includes introduction of a new product in the market or accompanies some new features to existing products (Santos, 2011). Product development includes market research to accumulate customer's needs, research and development to make product design with simulation and to manufacture the prototypes for bench testing, product manufacturing and deployment in the market. The product development prototypes and tests utilize CAD and FEA software to design and simulate the functionality. These help to rebuild and optimize the product in terms of quality and reliability.

Product development usually takes approximately 6 months to 10 years to build a product from idea to deployment in the market. The enormous time frame of product development life cycles requires the need for concurrent engineering. In concurrent engineering (CE), all the phases of product development are considered at the concept stage to economize time and resources. This necessitates the involvement of all departments to generate ideas to satisfy customer's quality requirements, availability of resources and economical resources. The assumptions are compiled to make decisions to build a product with high quality within

appropriate costs and time frames. The general view of product development is shown in Figure 25 and the arrow around depicts the decisions flow throughput of all departments during concept stage in concurrent engineering.

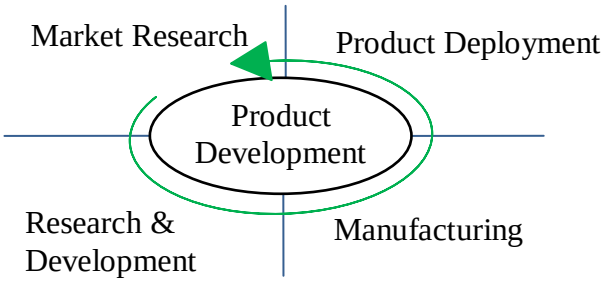


Figure 25. General view of product development.

Product development of coronary stents include concept generation, voice of the customer (Santos, 2011), product design in computer aided software, product performance test in finite element software, prototype tests, selection of manufacturing method (Kamrani, 2006), Food & Drug Administration (FDA) approval to conduct in-vivo experiments, performance results of in-vivo tests, FDA approval and insertion of the medical devices in patients (Kaplan, 2004). The time frame of product from its concept stage to prototype testing stage approximately classifies 2-3years (Kaplan, 2004). Medical device placements in patients follow clinical studies for 24 months' time frame (Kaplan, 2004).

3.4 Methodology Structure

The product development process flow of coronary stents is shown in Figure 26. First, the process develops stent concepts to prevent the blockages in the arteries. These concepts with sketches are designed in designing software and tested in simulation software. The data is analyzed from the simulation results and then manufacturing techniques are scrutinized to select an optimized manufacturing technique for the stent design. A prototype of the stent is manufactured and bench tests are conducted to evaluate the functionality of the stent. The

functionality of stents is tested by conducting the in vivo experiments. Finally, FDA clearance is obtained to deploy the stents in patients and clinical outcomes are studied. From Figure 26, the product development process flow evidently corresponds to the information and decision flow. The design changes whenever there is performance problem and the information of these changes and further study are carried to design stage. The prototype testing problems are carried to manufacturing feasibility stage to address the surface treatments necessary to enhance the performance of the stent performance.

In this research, the product development methodology of coronary stents with prominence on design, simulation and manufacturing is proposed. Refer to Appendix A for paradigmatic model of product development methodology of coronary stents.

Design and simulation are further classified as conceptual design and detailed design phases. The conceptual design phase comprehends the concepts to build the stent platform. This phase includes the material, form, pattern, geometry, coating and designing software.

Detailed design phases include performance of the stent inside the artery, stress and strain during crimped and deployment stages, and software for simulation. The detailed design phase is not limited to the above simulation aspects, but includes a wide range of tests such as dogboning, recoiling, foreshortening, longitudinal recoil, flexibility, coverage area, fatigue analysis, etc.

The study further reviewed manufacturing techniques; these are classified as traditional and modern techniques. The stent designs are assessed for manufacturing feasibility by reviewing manufacturing techniques, such as: laser machining, electromagnetic forming, rapid prototyping, casting, etc. The traditional manufacturing techniques constitutes of casting, forming, sheet metal processing, braiding, surface treatment and joining. Modern manufacturing involves mechanical, electrical, chemical, rapid prototyping and thermal techniques. These

comprise of water jet cutting, vapor deposition and electrical magnetic forming, photo chemical etching, electrical discharge machining and laser machining.

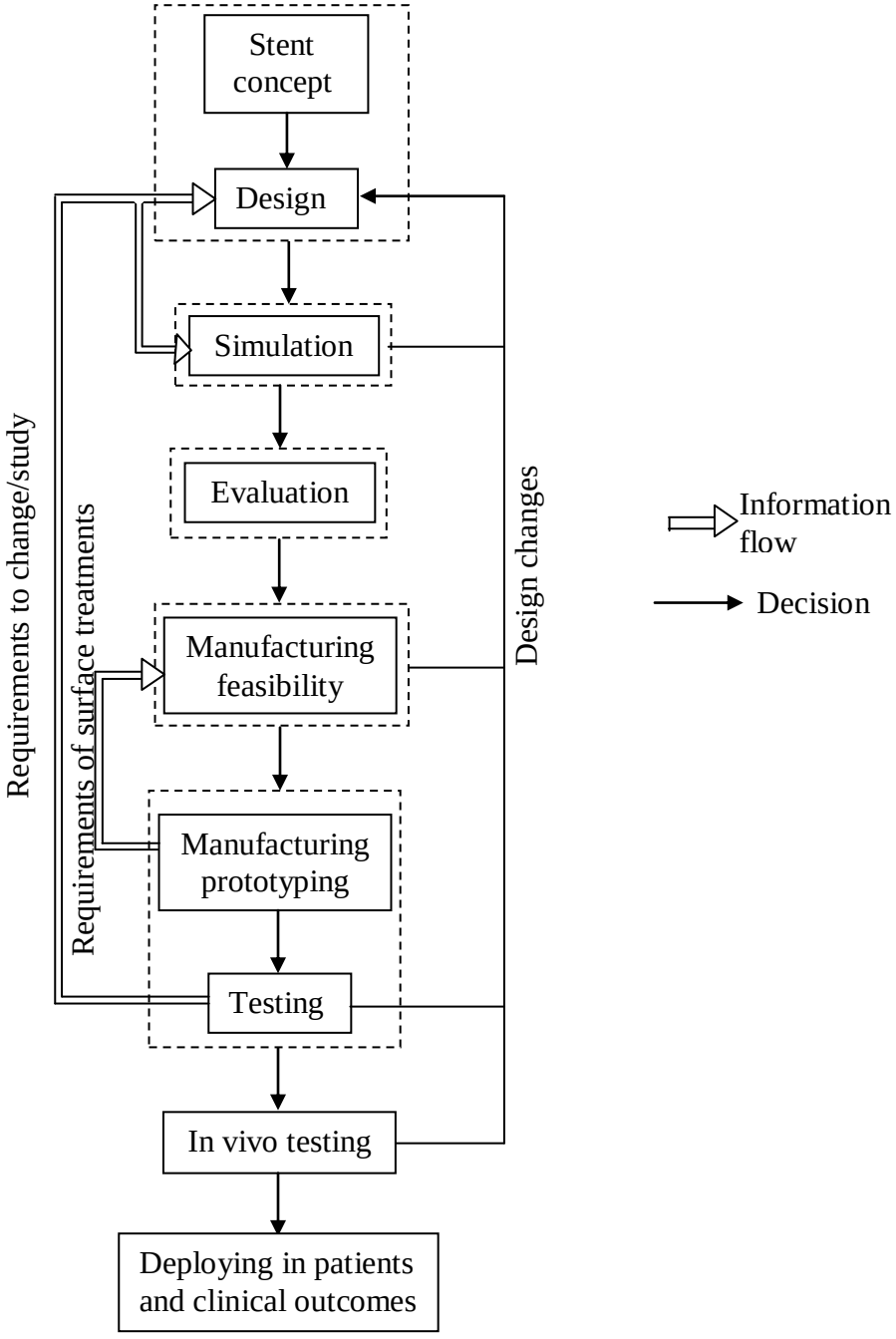


Figure 26. Process flow of design, simulation, manufacturing and clinical outcomes of coronary stents.

The deployment/delivery system consists of guide wire, catheter, stent mounted on balloon, balloon inflation system and pressure gauge. These are possible considerations in the methodology but the study is restricted to stents and deals with the characteristics stated in the above sections.

3.5 Application of Product Development Methodology

The methodology introduced in this chapter takes advantage of the conceptual design phase and detailed design phase to develop novel stent designs. The methodology is reviewed by constituting novel coronary stent designs and performing simulations with various materials such as stainless steel alloy, cobalt-chromium alloy, magnesium alloys; and comparing the results with Cypher stent (Johnson and Johnson Co.). The simulations with different materials carried out on the novel stent designs help to understand the design and its functionality. Figure 27 represents the multiple schemes of design, simulation and testing of the novel designs. The bi-directional arrows represent design, simulation and testing decisions and repetition of the processes.

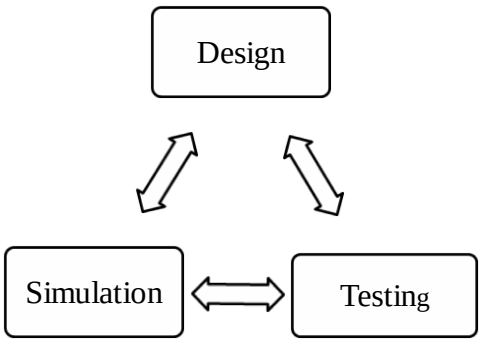


Figure 27. Design, simulation & testing-product development scheme (Vaizasatya, 2013).

The stent designs are modeled in Solidworks 2013 (Dassault Systèmes SolidWorks Corp, Massachusetts, USA) and transferred to Ansys Workbench 14.0 (ANSYS, Inc., Pennsylvania, USA) via IGES file format to test the performances by simulation.

The stent designs assume crimped state diameters with no balloon, artery and plaque environments for the analysis. In this study, the considerations such as material, surface contacts and friction information for balloon, plaque and artery are neglected because of sole concentration on stents.

Recently, the studies on stent materials have been inclined towards biodegradable stents because of the possibilities of impermanent stents in the arteries. Magnesium is considered as highly biodegradable material. Hence, this study concentrates on magnesium alloys for novel coronary stent designs. These stent designs are introduced and explained in chapter 4, and simulation results of the stent designs are discussed in chapter 5.

CHAPTER 4

Innovative Coronary Stents Design

4.1 Overview

Stent design plays a major role in success of stent performance. Poor performance leads to restenosis, neointimal hyperplasia, thrombosis and restenting. Conceptual design phase includes material, form, pattern, geometry and coating. In this study, the concepts are adopted to design three novel stents and these designs are modeled in CAD software i.e., Solidworks. Pattern and geometry of the novel designs are emphasized in this chapter.

4.2 Design Thoughts and Methods

Design of the stent plays an important role in flexibility, functionality, metal to artery ratio and radial force required to deploy the stent. The novel stent designs introduced in this research are a combination of closed and open cell slots connected to sinusoidal links or connectors. The three novel designs 1, 2 and 3 are designed in Solidworks 2013. Solidworks is computer aided design software supports to design 3-D models with geometric dimensions. The designs are modeled in crimped state with 1.5 mm diameter. The description of patterns, dimensions and 3- D designs of stents 1, 2 and 3 are described in the following sections.

4.2.1 Design 1. This design with diamond shape strut connects two marquise (elliptical with sharp edges) shape struts as depicted in Figure 28 and each diamond shape strut connects a sinusoidal link. This design in expanded circumferential form shows the number of crowns in a stent design as shown in Figure 28. For detailed geometrical dimensions refer to Appendix B, Figure B.1 and Table B.1. Figure 29-(a) and (b) displays design 1 in 3-D form.

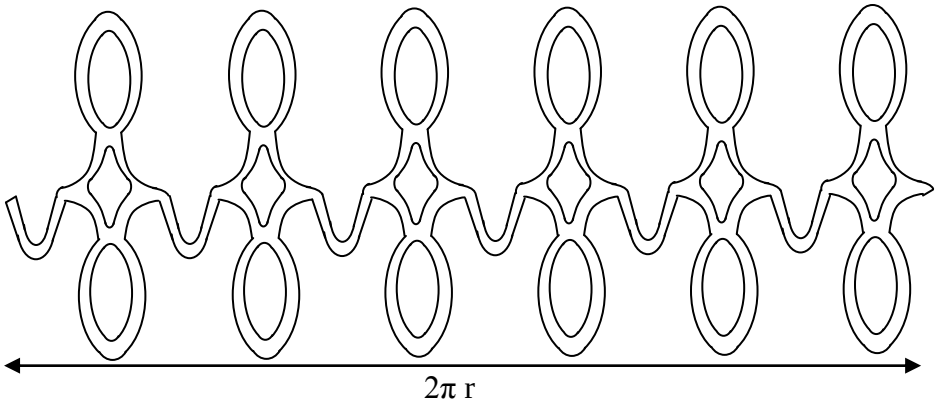
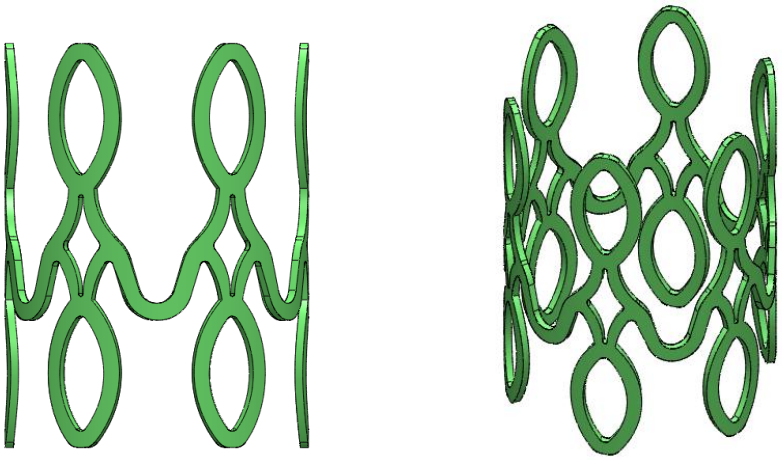


Figure 28. Design 1.



(a) (b)

Figure 29. 3-Dimensional design 1.

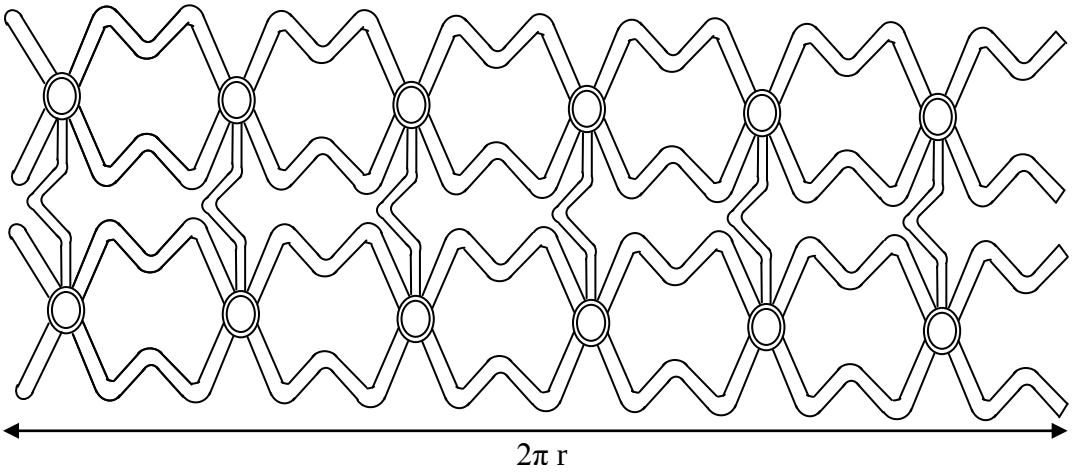
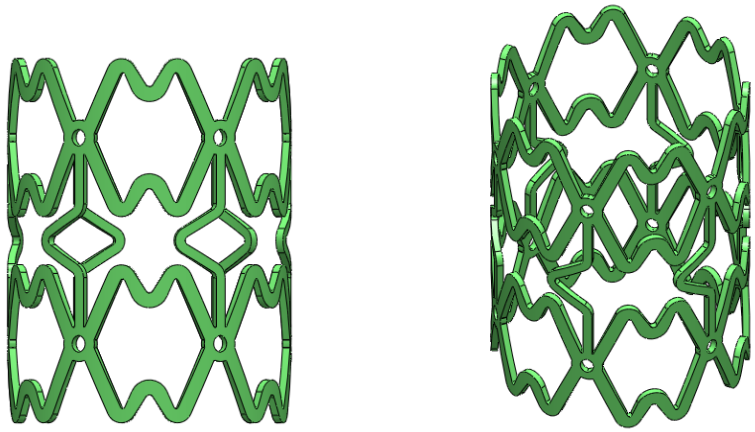


Figure 30. Design 2.

4.2.2 Design 2. The struts with solid ‘X’ connect sinusoidal links and ‘v’ extension struts connects the preceding rings of the stent. The ‘X’ pattern struts have a circular hole at the center. This stent design in expanded circumferential form is shown in Figure 30. Figure 31-(a) & (b) shows design 2 in 3-D form. Refer to Appendix B, Figure B.2 and Table B.2 for geometrical dimensions of design 2.



(a) (b)

Figure 31. 3-Dimensional design 2.

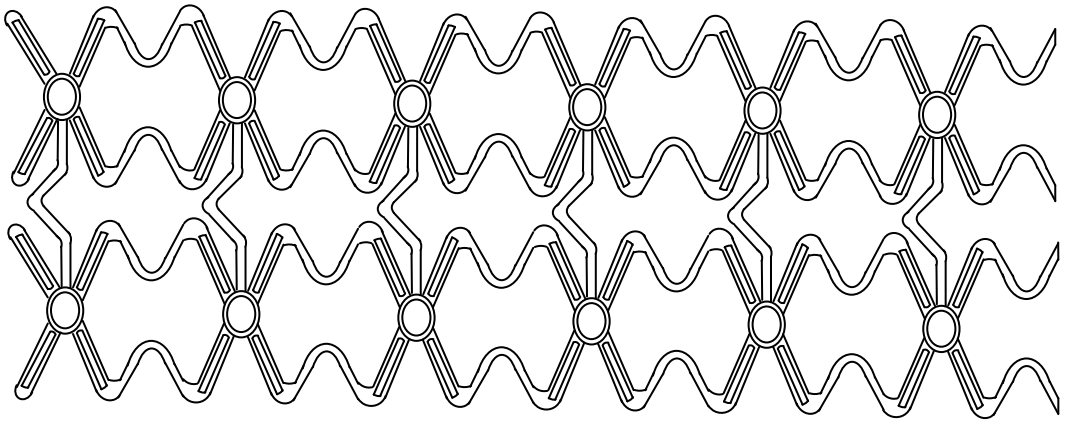
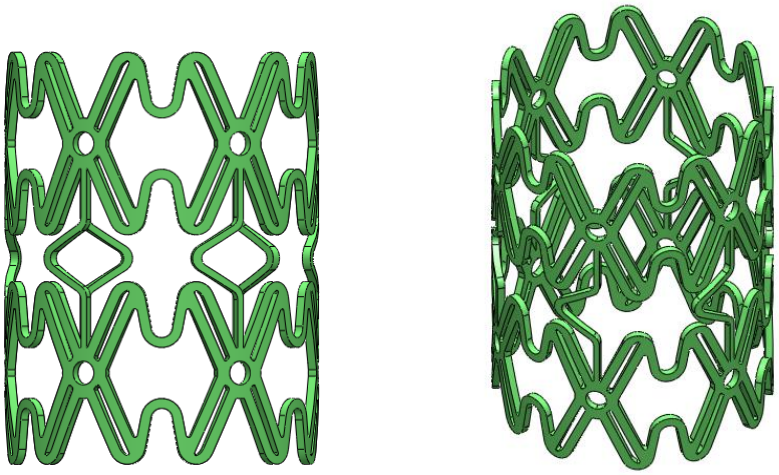


Figure 32. Design 3.

4.2.3 Design 3. The struts with ‘X’ connect sinusoidal links and ‘v’ extension struts connects the preceding rings of the stent. The ‘X’ pattern struts have a circular hole at the center

and rectangular slots on the extensions. This stent design in circumferential expansion form is shown in Figure 32. Figure 33-(a) & (b) shows design 3 in 3-D form. For geometrical dimensions illustration of design 3, refer to Appendix B, Figure B.3 and Table B.3.



(a) (b)

Figure 33. 3-Dimensional design 3

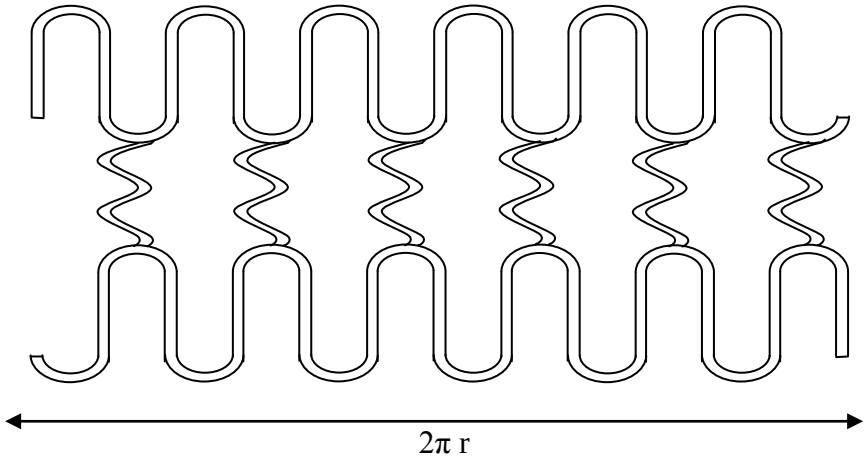
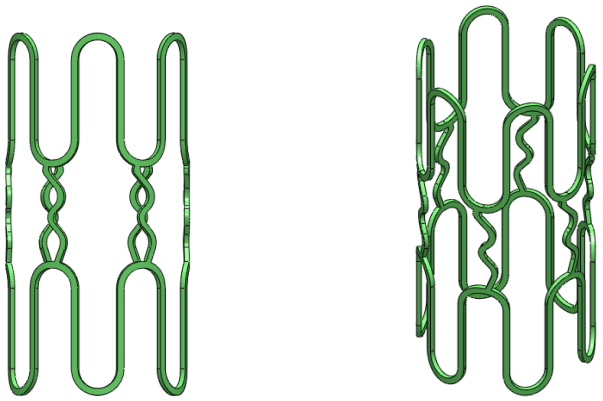


Figure 34. Cypher design.

4.2.4 Cypher stent. Cypher stent is a coronary stent with optimal design characteristics on the market, manufactured by Johnson & Johnson Co. In this research, Cypher stent represents a benchmark design and results in significant functionality comparison with the novel designs.

Cypher stent has inverted ‘U’ shape struts connect alternatively with sinusoidal connectors to link the preceding rings. The stent design in expanded circumferential form is shown in Figure 34. Figure 35-(a) & (b) shows the design in 3-D form. For detailed geometrical dimensions of Cypher stent, refer to Appendix B, Figure B.4 and Table B.4.



(a) (b)

Figure 35. 3-Dimensional Cypher stent.

4.3 Conclusion

This chapter introduced three novel stent designs built from conceptual design phase of product development methodology. The designs are modeled in Solidworks software with more detailed geometrical dimensions. The structures of the stent designs are elaborated and in chapter 5. These designs are simulated using Ansys Workbench, finite element analysis (FEA) software to study the behavior of the stents and to compare the results with Cypher stent.

CHAPTER 5

Design Simulation Results and Discussion

5.1 Overview

Stent designs introduced in the previous chapter are imported to Ansys Workbench software to perform simulation of designs for stress, strain and total deformation analysis. Ansys Workbench software provides FEA modeling, meshing and design analysis i.e., simulation of complex structures/designs. In this study, two types of simulations are performed on the stents. One is testing the novel designs to compare with a stent available in the market i.e., Cypher stent (J & J Co.). Second is testing the novel designs with magnesium alloys. The procedure and results of these simulation tests are discussed in the following sub-sections.

5.2 Simulation Process

Simulation is creating the real world environment to test the functioning of structures/ designs. Simulations are carried by importing and generating the designs to Ansys Workbench 14. The designs of stents are modeled in Solidworks 2013 and the files are converted to IGES file extensions, which makes easier to import and read in FEA software. Simulation consists of material properties, fine mesh generation, application of boundary conditions, and post processing analysis. The simulation processes of the novel stent designs are further explained in detail.

5.2.1 Material properties. The designs are tested with various materials such as, stainless steel, cobalt-chromium and magnesium alloys. The properties that are considered for materials are Young's modulus, Poisson's ratio and yield strength. Each material property is mentioned in Table 5 and the values of the materials are utilized to test the stent designs. The characteristic of materials are assumed as non-linear isotropic hardening.

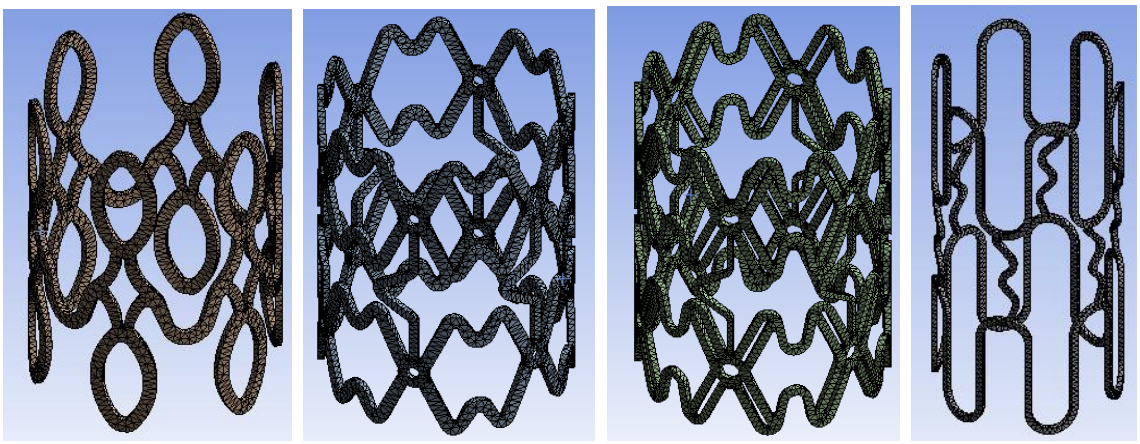
Table 5

Material Properties

Material	Young's Modulus (MPa)	Poisson's Ratio	Yield strength (MPa)	Tensile strength (MPa)	Density (Kg/m^3)
Stainless steel – 316L	193000	0.3	350	654	8000
Cobalt-Chromium – L605	243000	0.3	671	1150	9100
Magnesium – WE43	44000	0.3	160	270	1830
Magnesium– AZ31	45099	0.3	138	276	1830
Magnesium – AZ80	45157	0.3	234	354	1830
Magnesium – ZK60	45383	0.3	228	304	1830

Source: Poncin, 2003; Mani, 2007; Hermawan, 2010; Gastaldi, 2011.

5.2.2 Mesh design. Mesh is generated for the designs with triangular elements and each triangular element has 3 nodes. The number of nodes and elements formed during mesh generation for stent designs 1, 2, 3 and Cypher are presented in Table 6. The designs are finely meshed to simulate as shown in Figure 36-a, b, c, and d for designs 1, 2, 3 and Cypher respectively.



(a) (b) (c) (d)

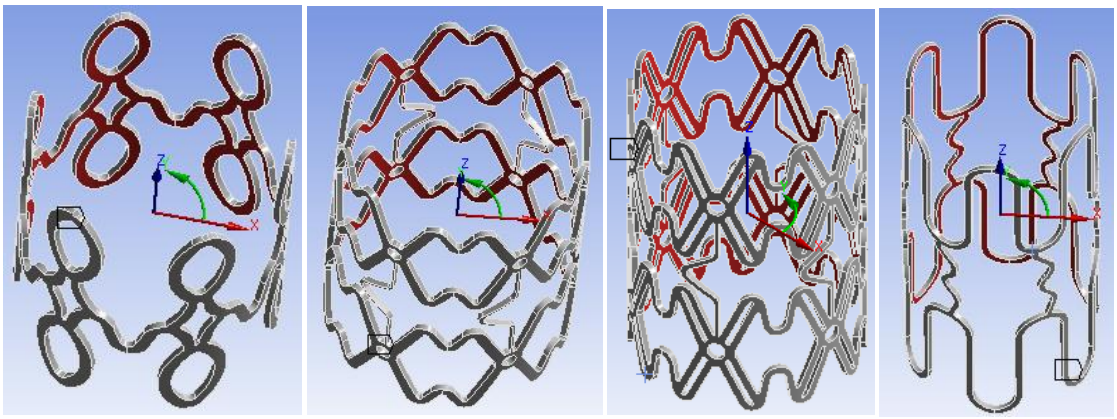
Figure 36. Mesh generation.

Table 6

Number of Nodes and Elements of Stent Designs

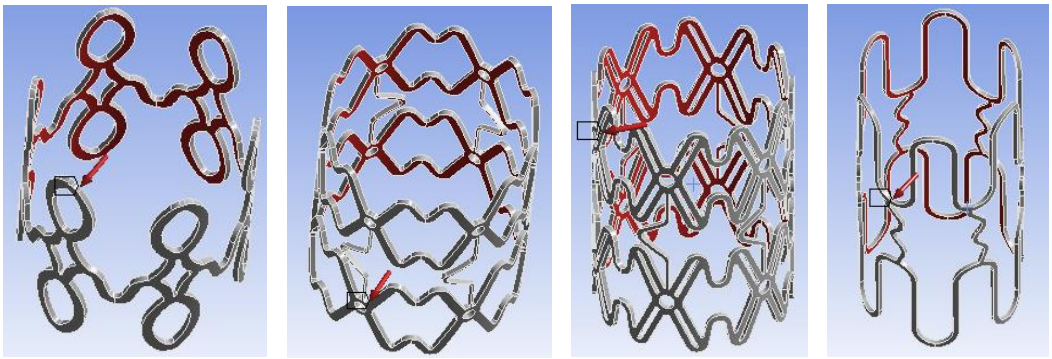
Design	No. of Nodes	No. of Elements
1	9075	3681
2	26194	12247
3	37901	16999
Cypher	7611	2633

5.2.3 Boundary conditions. Simulation of design involves applying boundary conditions as inputs. In this study, displacement and pressure are applied as boundary conditions. Displacement of 1.5 mm is applied in X-direction in cylindrical coordinate system as shown in Figure 37- a, b, c and d. This ensures the stent to expand radially in X-direction. A pressure of 10-20 atm is applied gradually in radial manner on the stent to deploy the stent to 3 mm diameter as shown in Figure 38 – a, b, c and d.



(a) (b) (c) (d)

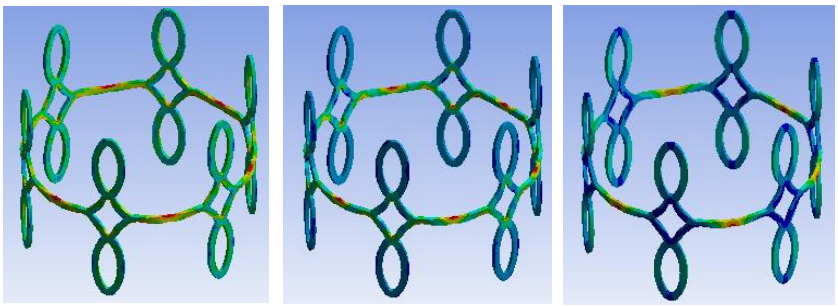
Figure 37. Boundary condition-displacement.



(a) (b) (c) (d)

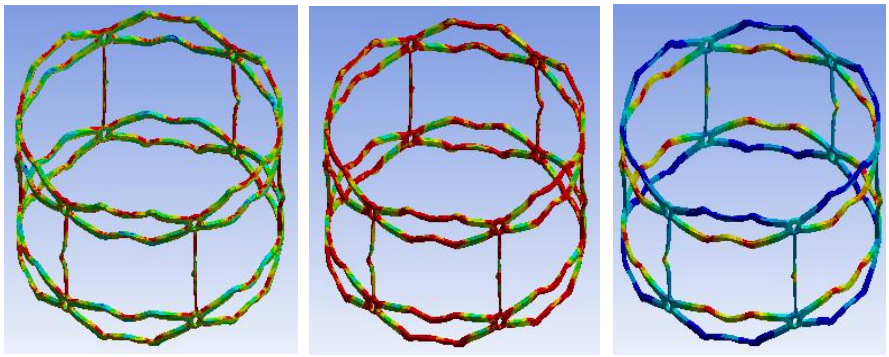
Figure 38. Boundary condition-pressure.

5.2.4 Post processing. The simulations of stent designs are carried after mesh generation, application of boundary conditions and material properties. The designs are tested for von Mises stress, strain and total deformation. Designs 1, 2, 3 and Cypher stent with stress, strain and total deformation analysis are shown in Figures 39, 40, 41 and 42 respectively. The simulation results of design 1, 2 and 3 are compared with Cypher stent and the performance of each stent design with magnesium alloys.



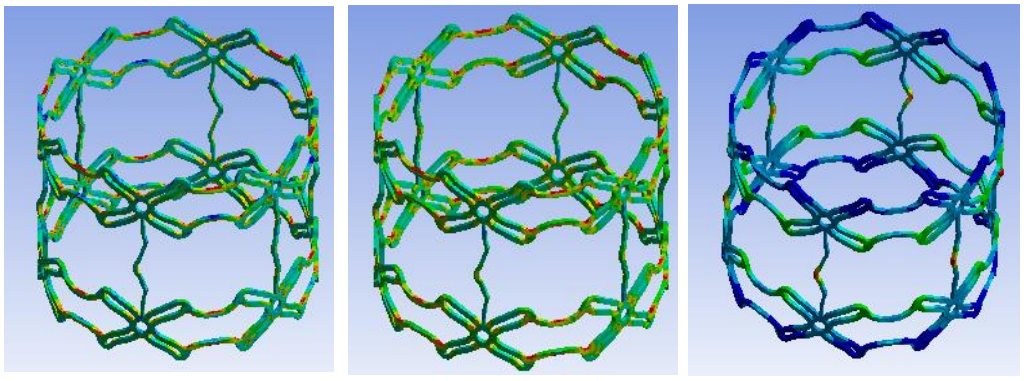
(a) (b) (c)

Figure 39. Equivalent (von Mises) stress, strain and total deformation.



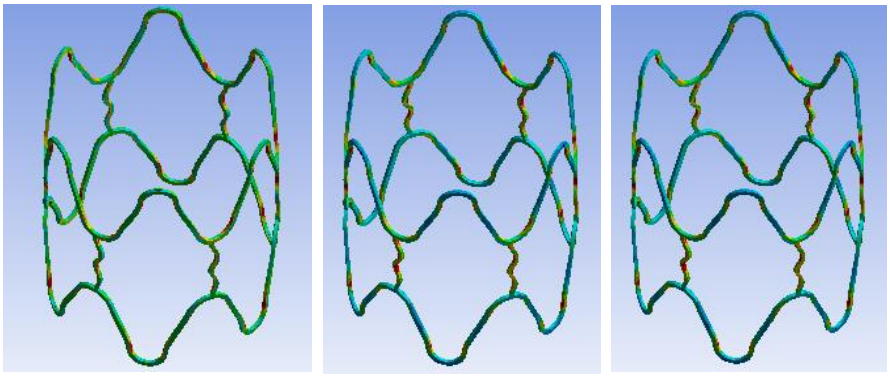
(a) (b) (c)

Figure 40. Equivalent (von Mises) stress, strain and total deformation.



(a) (b) (c)

Figure 41. Equivalent (von Mises) stress, strain and total deformation.



(a) (b) (c)

Figure 42. Equivalent (von Mises) stress, strain and total deformation.

5.3 Mass and Volume

The application of material properties on the stent designs in Ansys software provides mass and volume parameters of the stents. The mass and volume data of stent designs are provided in Appendix C, Table C.1 and Table C.2 respectively.

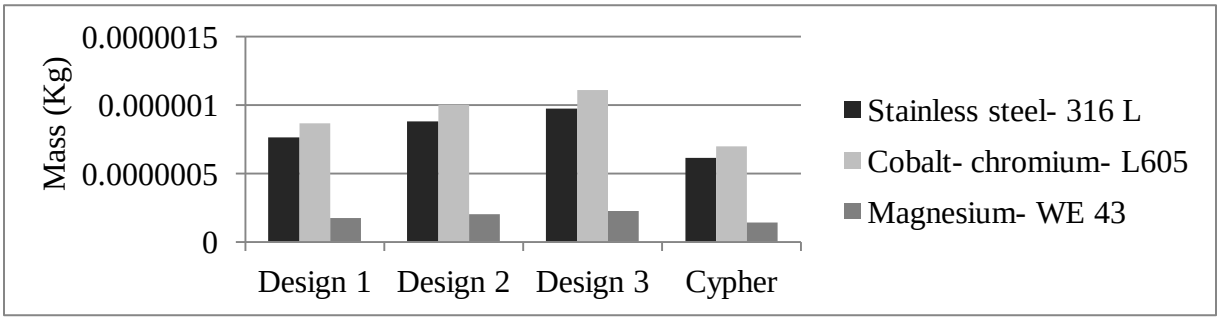


Figure 43. Mass of stent designs.

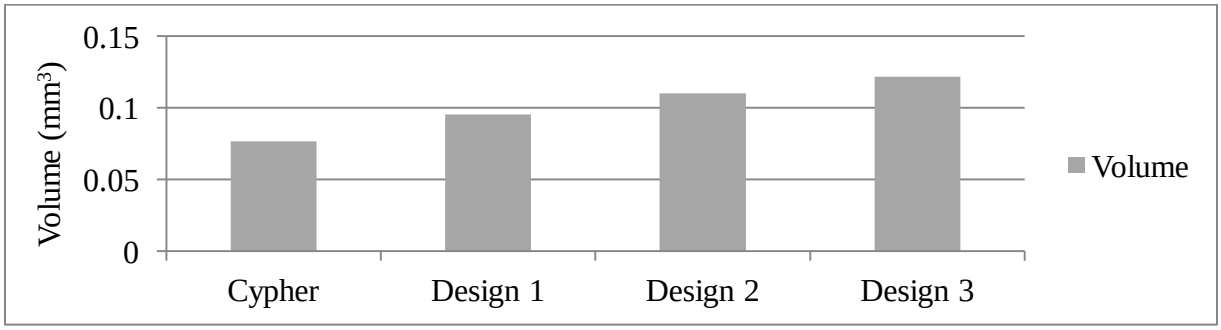


Figure 44. Volume of stents.

Figure 43 depicts the mass values of design 1, 2, 3 and Cypher stents. These values are compared with stainless steel, cobalt-chromium and magnesium biomaterials. The stents with cobalt-chromium has highest mass followed by stents with stainless steel. Stents with magnesium have low mass values as the density of the material is lowest compared to other two materials. Designs 2 and 3 have higher mass compared to other designs. Volume of the stents is shown in Figure 44. Cypher has lowest volume compared to other designs and design 3 has highest volume. High density materials such as cobalt-chromium are good to design thin strut stents. The biomaterial has low amounts of stainless steel composition, so it is MRI compatible as well as radiopaque.

5.4 Results and Discussion

The research conducts simulation analysis during the deployment state of stents. The simulations are carried to test two types of performances of novel stent designs. The two tests are:

i) Comparison of the results of von Mises stress, strain and total deformation of novel designs with the results of Cypher stent.

ii) Comparison of the von Mises stress, strain and total deformation of novel designs with significant magnesium alloys.

5.4.1 Stress/strain analysis and comparison with Cypher stent. The biomaterials considered in this analysis are stainless steel 316L, cobalt-chromium L605 and magnesium WE43. The novel stent designs results are compared with Cypher stent results. Cypher stent is made of stainless steel 316L but analysis is conducted with different biomaterials to compare the behavior of stent with novel stent designs.

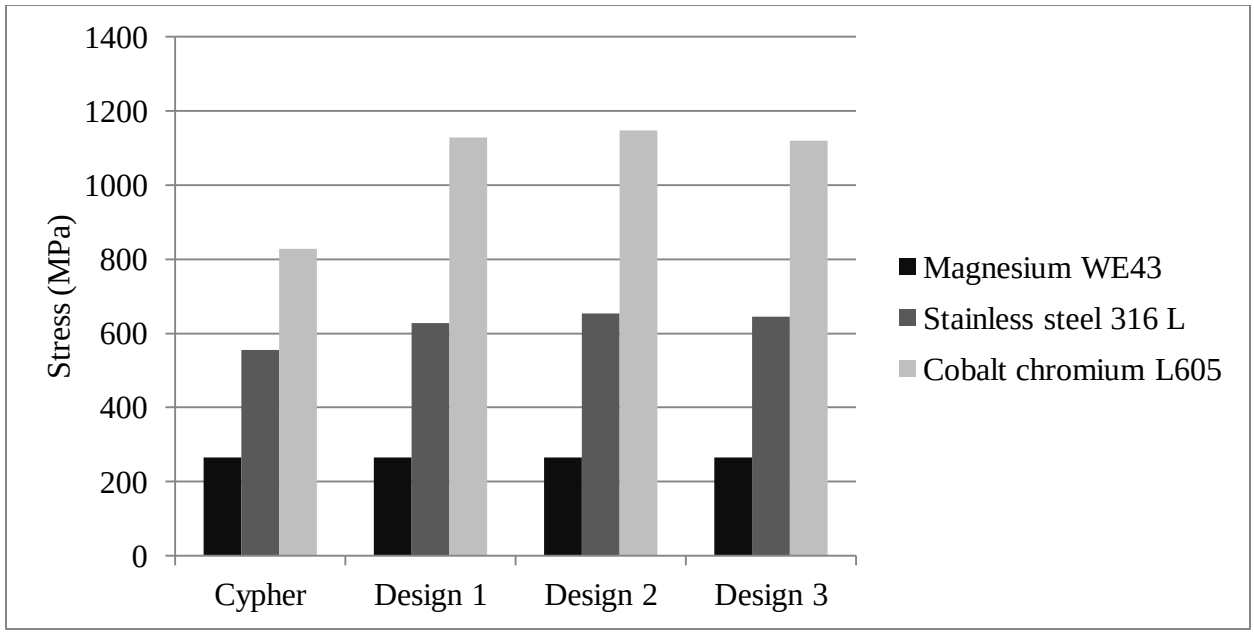


Figure 45. Comparison of von Mises stress with Cypher stent.

The results of stress, strain and total deformation of designs 1, 2, 3 and Cypher at 1.01-2.03 MPa pressures are provided in Appendix D.

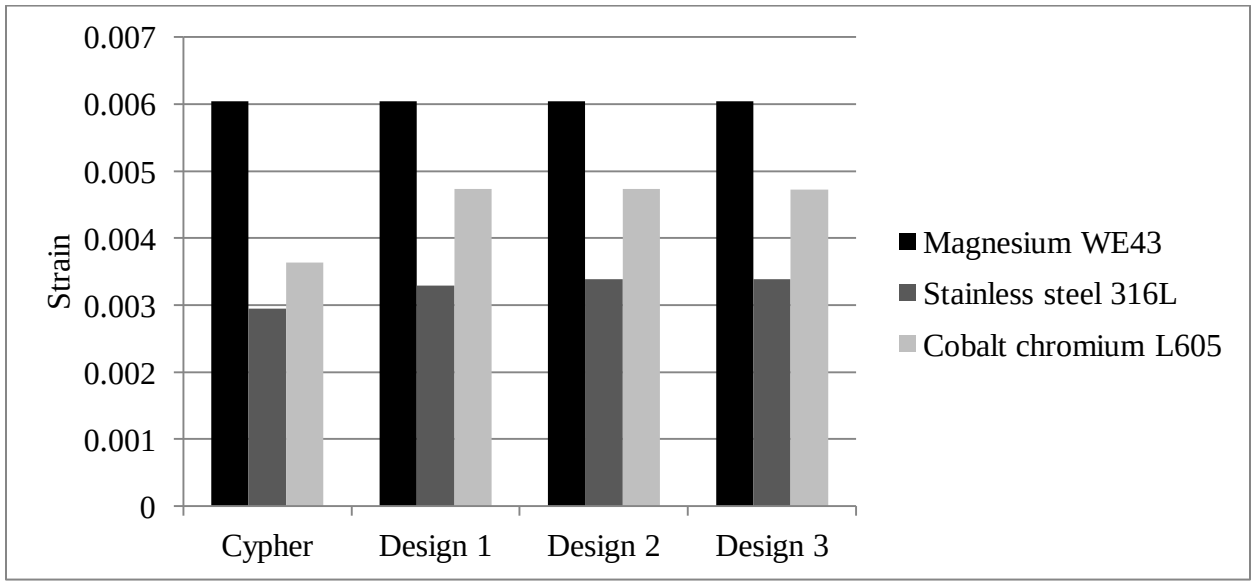


Figure 46. Comparison of von Mises strain with Cypher stent.

Figure 45 displays the von Mises stresses at 2.03 MPa pressure. In Figure 45, the stress values of designs are compared with stainless steel 316L, cobalt-chromium L605 and magnesium

WE43. All the designs with magnesium WE43 have almost same values of stress i.e., 265 MPa. Magnesium stents have significantly lower than stainless steel and cobalt chromium stents. The stress values of the stents are approximately equal to or higher than the yield strength values of the respective materials. Although, the designs with cobalt-chromium have high stress values, the values are between yield strength and ultimate tensile strength values of the material.

The strains of designs at 2.03 MPa are shown in Figure 46. Designs with magnesium have higher strain values compared to stainless steel and cobalt-chromium biomaterials. Designs with low strain values show better performances. Here, the stent designs with stainless steel and cobalt-chromium shows good results.

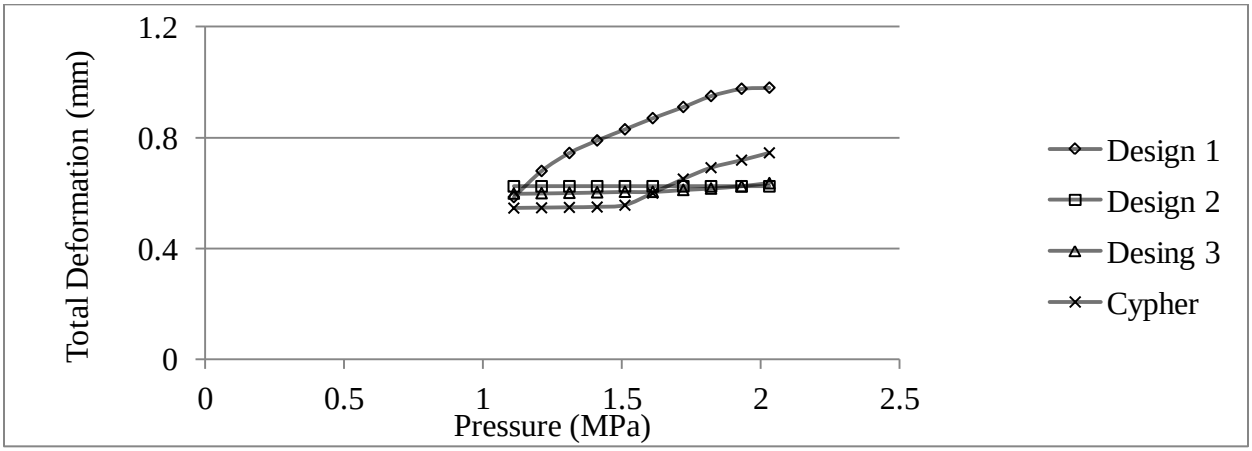


Figure 47. Comparison of total deformation with magnesium WE43

Flexibility is another parameter that significantly affects the functionality mechanism of stents. This parameter of the material influences the total deformation of the stents from crimped state to deployment state (i.e., 1.5 mm-3.0 mm). The total deformation of stent designs are shown in Figures 47, 48 and 49 for cobalt-chromium, stainless steel and magnesium biomaterials. These graphs show that designs 2 and 3 have constant deformation values during the application of pressures from 1.11-2.03 MPa for all the biomaterials. Design 1, gradually increased the deformation with increase in pressure values for magnesium but have constant

deformation values for SS and Co-Cr. Cypher stent has significant behavior compared to other designs as deformation gradually increased with the increase in application of pressure for all materials. Designs with different biomaterials have different deformation values but gradual increase in deformation is preferred in order to prevent vascular injuries while deploying stents in the arteries.

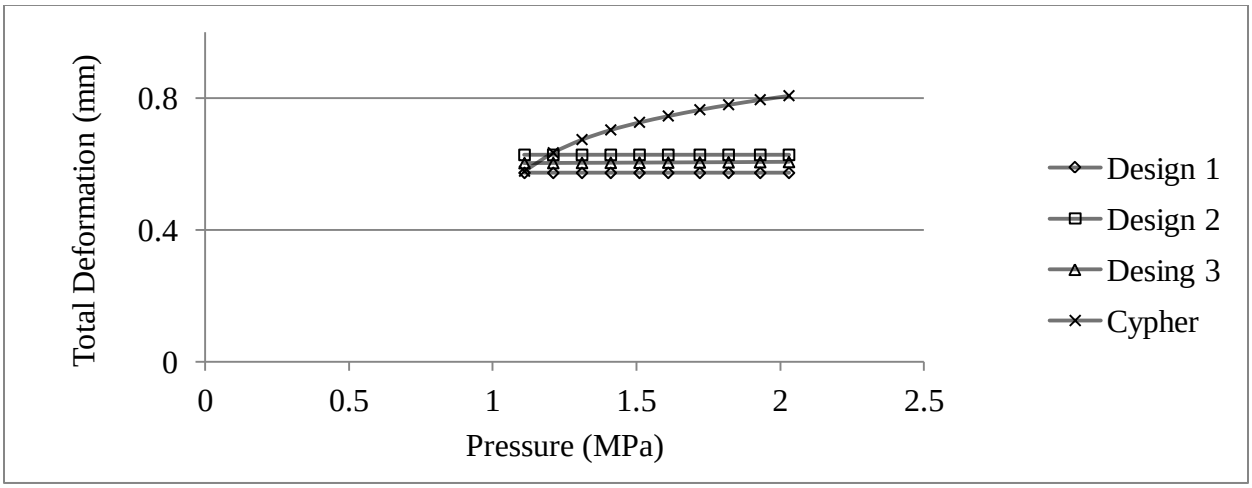


Figure 48. Comparison of total deformation with stainless steel 316L.

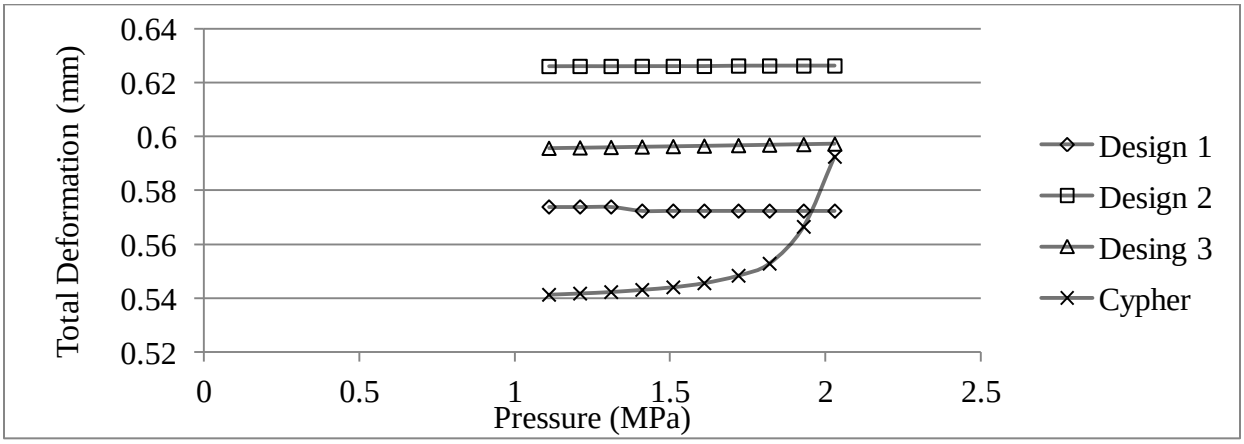


Figure 49. Comparison of total deformation with cobalt-chromium L605.

From stress, strain and total deformation graphs, Cypher with SS and Co-Cr has good results, i.e., low strain and gradual deformation of the design.

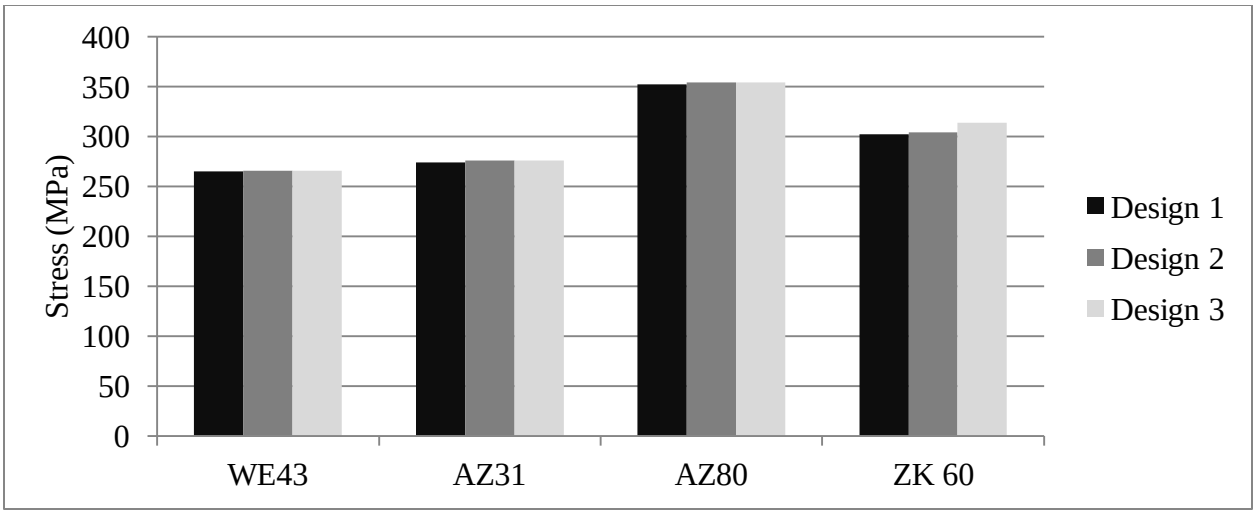


Figure 50. Comparison of stress with magnesium alloys

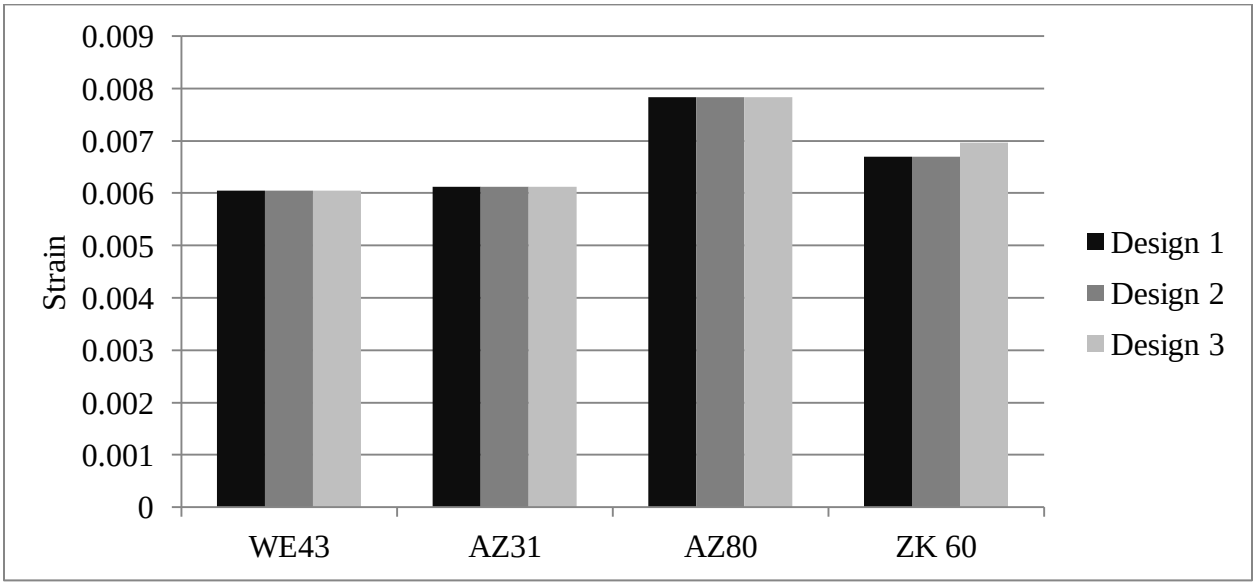


Figure 51. Comparison of strain with magnesium alloys.

5.4.2 Stress/ strain analysis of designs with magnesium alloys. Novel designs are tested with magnesium alloys WE43, AZ31, AZ80 and ZK60. The results are compared to summarize the performance of stents with magnesium alloys and to select best magnesium alloy. Designs 1, 2 and 3 are analyzed with magnesium alloys and stresses graph is shown in Figure 50. From the graph, the designs have stress values between yield strength and tensile strength of respective materials. Designs with WE43 have lower stress values than other materials. Stent

designs with magnesium AZ80 has higher stress values compared to other material designs. The trend is same for the strain values of the designs. The strains of the designs are shown in Figure 51.

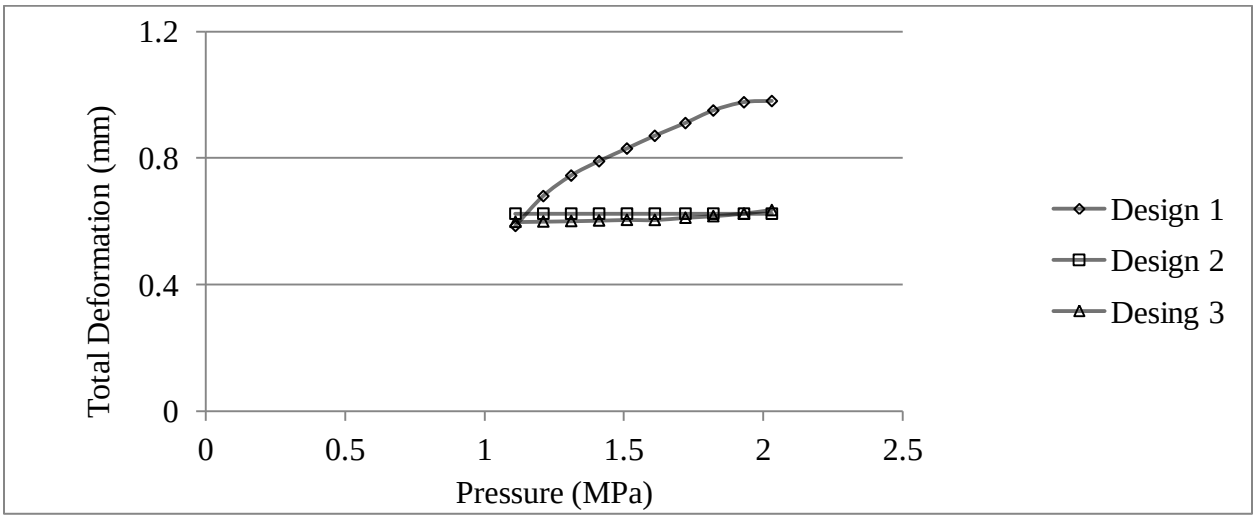


Figure 52. Comparison of total deformation with magnesium WE43.

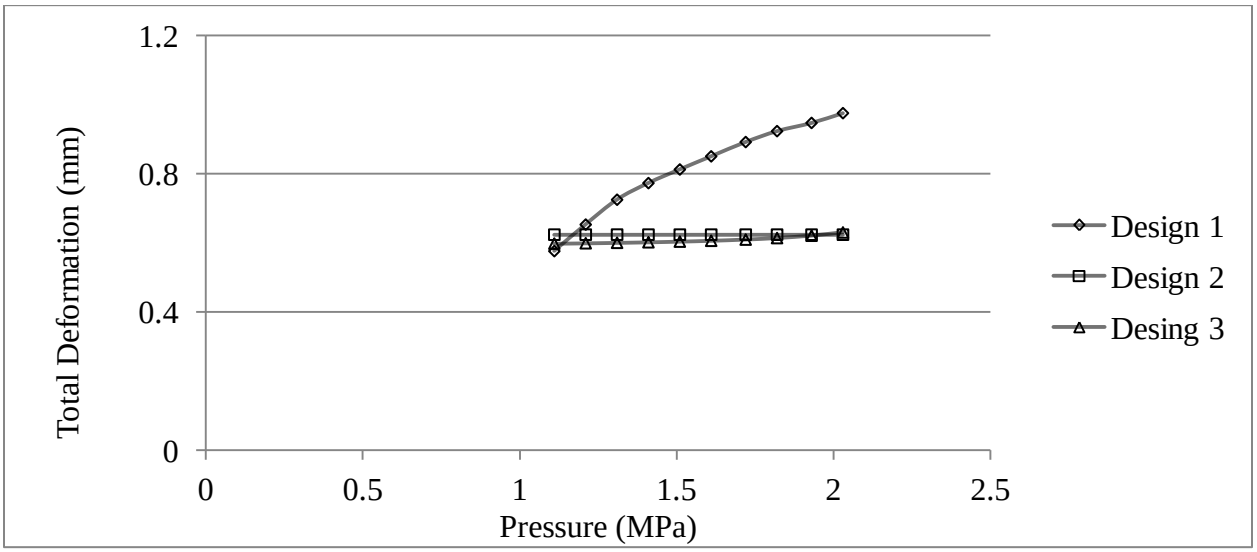


Figure 53. Comparison of total deformation with magnesium AZ31.

The total deformation values of the stent designs for magnesium alloys WE43, AZ31, AZ80, ZK60 at 1.11-2.03 MPa are shown in Figures 52, 53, 54 and 55 respectively. In all the analyses the deformation values of designs 2 and 3 are constant while deformation of design 1

gradually increased with the increase in pressure. The deformation values of design 1 for materials AZ80 and ZK60 are constant for few pressure values but gradually increased with increase in pressure.

From the total deformation graphs of magnesium alloys, design 1 with WE 43 and AZ 31 alloys show promising results i.e., gradual deformation with increase in pressure.

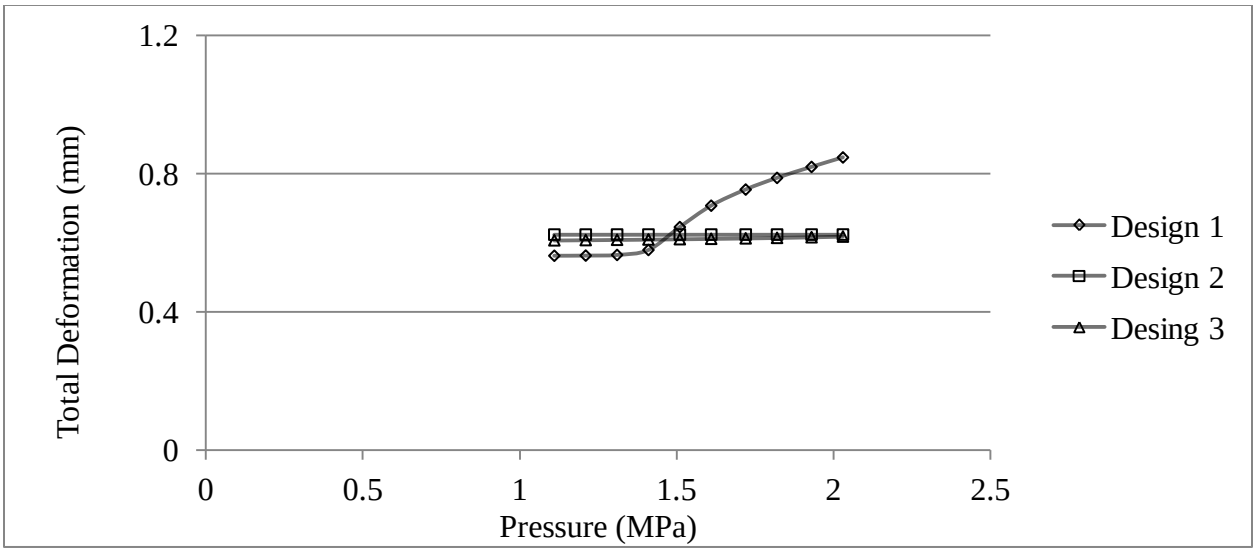


Figure 54. Comparison of total deformation with magnesium AZ80.

Design1 with magnesium WE43 and AZ31 biomaterials are recommended from the stress, strain and total deformation results.

From the two types of simulation tests conducted in this research, it reveals that different struts structures behave distinctly with the application of same magnitude of pressure. This study has considered the deployment state of stents; however, the stents has to be evaluated in crimped state with balloon, artery and plaque environment.

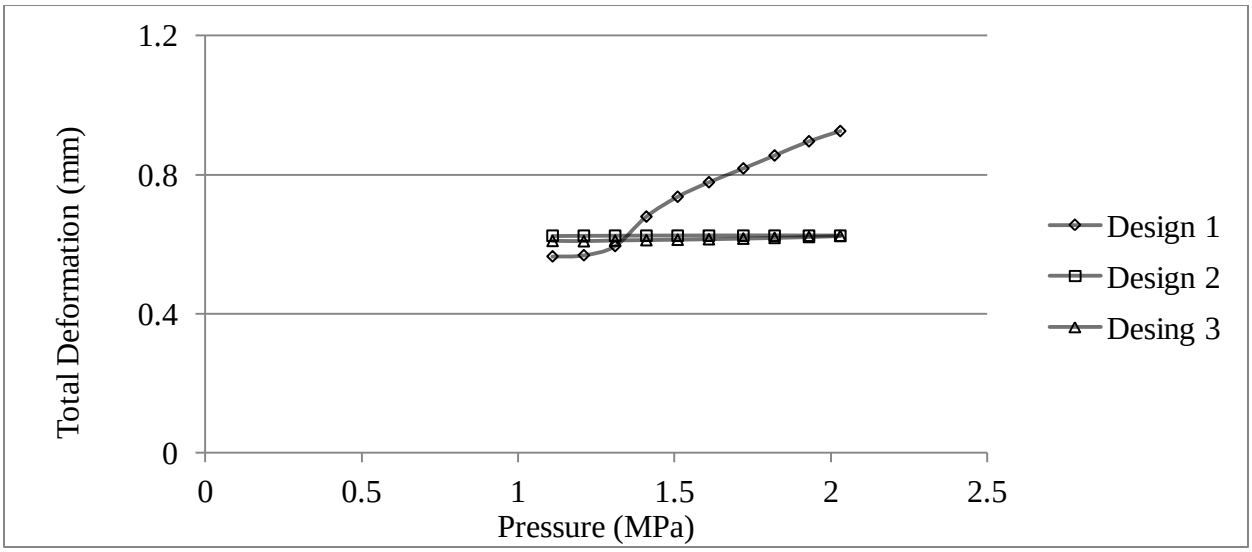


Figure 55. Comparison of total deformation with magnesium ZK60

5.5 Conclusion

The designs are tested with bio-materials and compared with Cypher stent. The amount of pressure applied radially on the stents is same, but the strut designs are distinct for each stent design. So, the behavior of the stents changes with different patterns of designs. From the results it is recommended to have design 1 with magnesium WE43 or AZ31. The methodology introduced in this research is tested with few aspects of coronary stents. However, the designs have to be analyzed with parameters such as foreshortening, dogboning, radial recoil, longitudinal recoil and coverage area. The simulation software provides cost effective solutions. Hence, the research in the future could be concentrated on above aspects. Conclusions and future work on the research are summarized in chapter 6.

CHAPTER 6

Conclusion and Future Work

6.1 Research Overview

Product development methodology is essential for any class of products to understand the concepts and resources necessary in an industry. The methodology composes of market or consumer needs, concepts, material requirements and feasible resources to optimize time, cost and quality of the products and to deploy the product in the market within short time frame. This concept is widely known as concurrent engineering; in which all the phases of the product are considered during idea generation stage to condense the lead time and opt for cost efficient techniques.

Hence, this study contributes product development methodology of coronary stents composed with concepts and resources to enhance decision making processes and to promote time efficient methods. The new methodology acknowledges the conceptual design phase, detailed design phase and manufacturing processes of coronary stents.

Conceptual design phase includes material, form, pattern, geometry, coating and software. Detailed design phase involves with crimping, deployment, performance and software. Manufacturing processes are compromised of traditional and modern methods. All these phases are considered during the introduction of stent concepts i.e., product development phase to optimize time and cost.

6.1.1 Execution of Methodology. The conceptual design phase and detailed design phase of product development methodology are executed by adopting the concepts to design and simulate the novel stents that are introduced in this research.

The designs are modeled with crimped diameter in Solidworks software and simulated in Ansys Workbench software. These stent designs are simulated with biomaterials such as stainless steel 316 L, cobalt-chromium L605 and magnesium alloys.

Restenting is possible with a biodegradable material and magnesium is a leading biodegradable material. Hence, various magnesium alloys are considered to evaluate the novel stent designs in this study. The research is conducted to select the appropriate magnesium alloy so; the variations in strut designs and materials are simulated and optimized using Ansys software.

The novel designs are compared with Cypher stent (Johnson & Johnson Co.) results and design 1 with magnesium WE43 or AZ31 are recommended from the study of simulation results. These materials have shown better results compared to other materials.

Many manufacturing methods are described in the methodology and water jet laser manufacturing method is encouraged because of the precision cut and elimination of surface treatments as this method is free from formation of oxidation layers and burrs.

6.2 Future Work

A detailed research on the following aspects of stents is required to assess the product development methodology introduced in this study.

6.2.1 Crimping. Although most studies introduce the stents designed in crimped state, these could be designed in expanded state i.e.., 3 mm and perform the simulation procedure by crimping the stents to 1.5 mm. During this course, the study helps to observe stent behavior parameters such as stress, strain and total deformation.

6.2.2 Strut connectors. The novel stent designs could be improved by remodeling with distinct ‘N’, ‘S’ and ‘W’ shape strut connectors to study the flexibility of stent expansion states.

6.2.3 Biodegradability. Simulation studies could be conducted to perform the analysis on the materials to address the time frame of the biodegradability of magnesium alloys.

6.2.4 Functionality evaluation. Researchers engage in evaluating the parameters of stents such as dogboning, foreshortening, longitudinal recoil and radial recoil. These parameters are evolved during deployment procedure hence; artery and plaque could be added to the simulation environment to study the functionality of the stents. The parameters discussed here are affected by metal-to-artery ratio factor. This is also a primary aspect considered to prevent thrombosis after deployment of stent.

6.2.5 Fluid flow analysis. This analysis involves with an artery and plaque in the simulation environment. The analysis could be conducted to study the flow of fluids/blood along with the amount of drug release.

6.2.6 Transient analysis. The above mentioned finite element analyses could be performed as function of time.

6.2.7 Prototype evaluation. Prototypes can be manufactured and tested with different strut thicknesses to estimate the deployment pressure essential to expand the stent.

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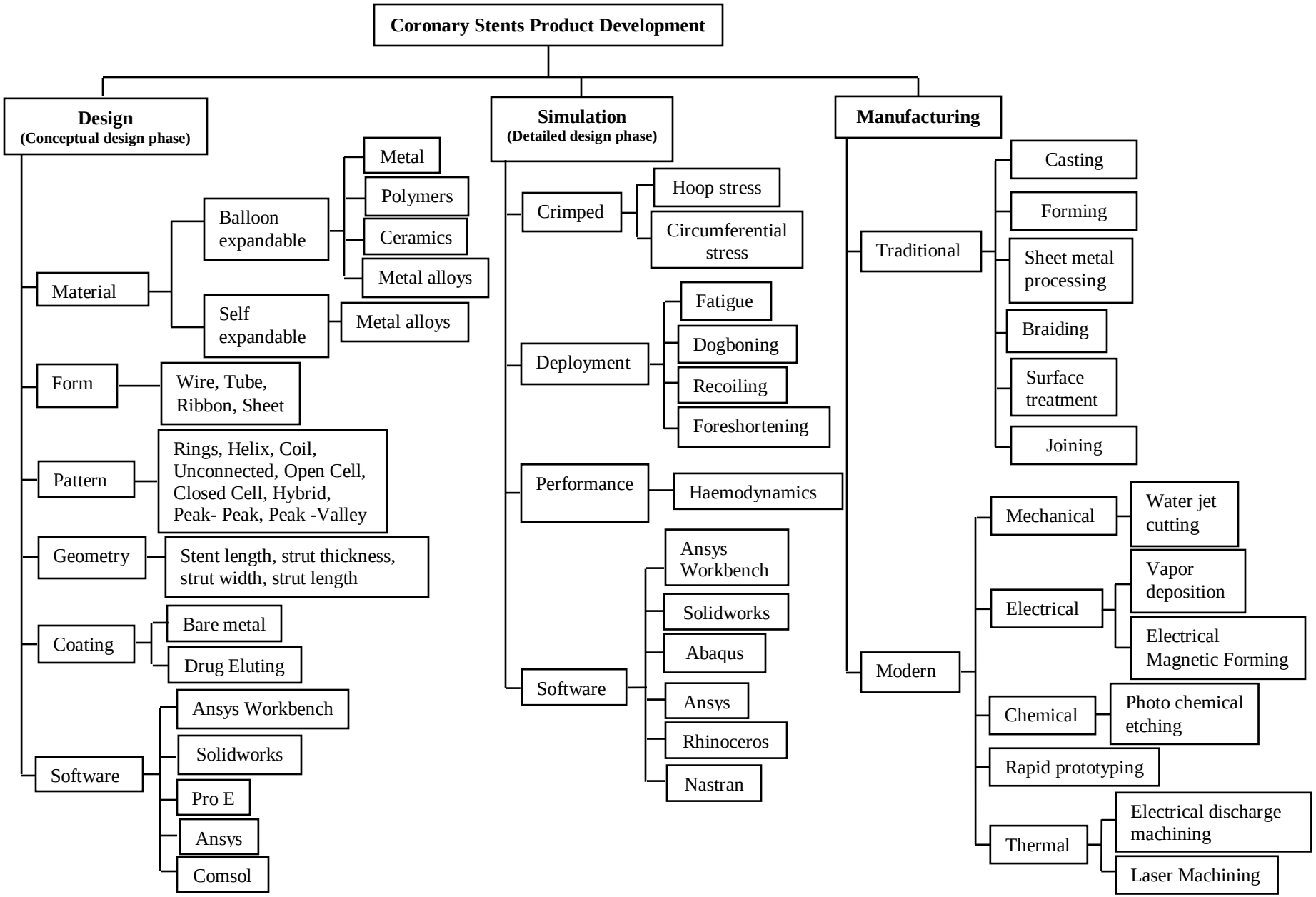
Appendix A

Product Development Methodology of Coronary Stents (Source: Stockel, 2002; Lally, 2006; Vaizasatya, 2013)



Appendix B

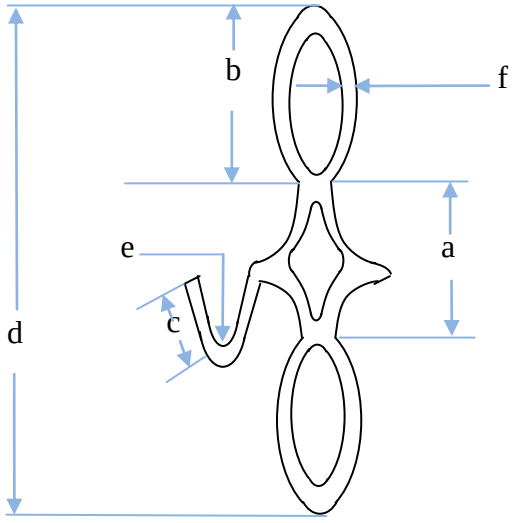


Figure B.1. Design 1.

Table B.1.

Geometrical Dimensions of Design 1

	Dimensions (mm)
a	0.556
b	0.724
c	0.15
d	2.017
e	0.093
f	0.1

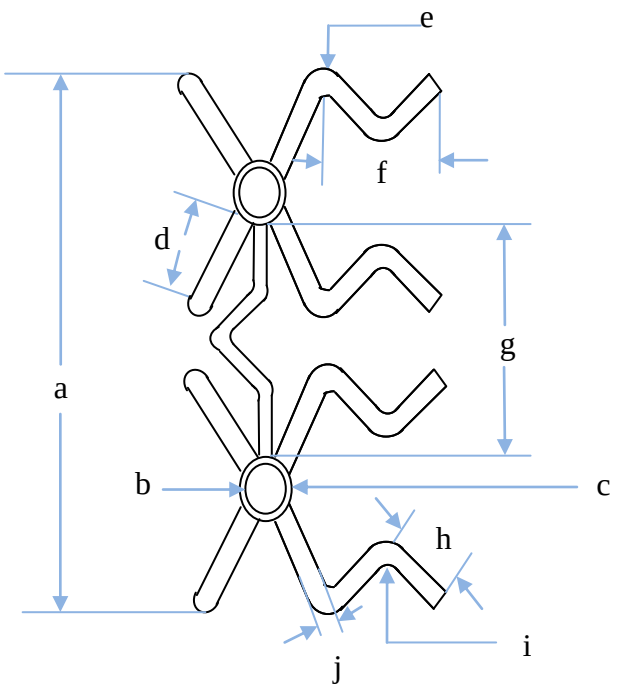


Figure B.2. Design 2.

Table B.2.

Geometrical Dimensions of Design 2

	Dimensions (mm)
a	1.95
b	0.045
c	0.096
d	0.347
e	0.08
f	0.308
g	0.915
h	0.09
i	0.022
j	0.08

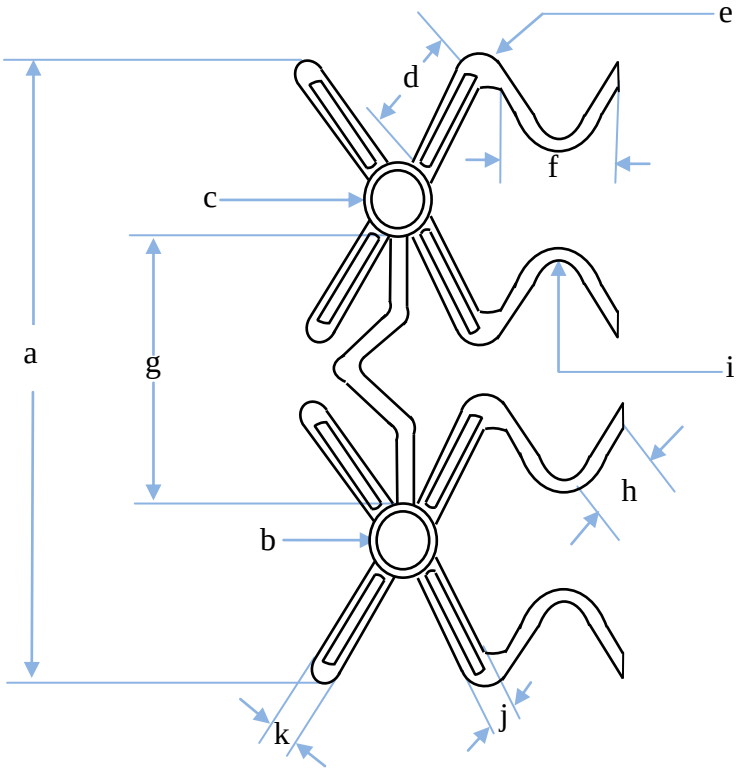


Figure B.3. Design 3.

Table B.3.

Geometrical Dimensions of Design 3

	Dimensions (mm)
a	1.966
b	0.057
c	0.122
d	0.29
e	0.088
f	0.234
g	0.855
h	0.1
i	0.053
j	0.032
k	0.12

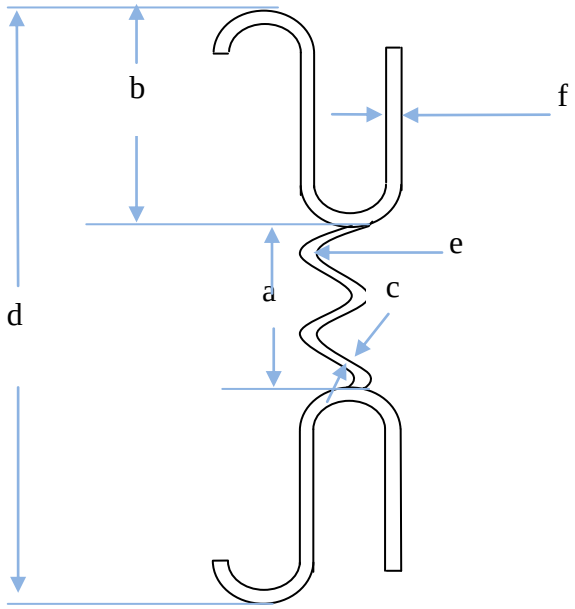


Figure B.4. Design 4.

Table B.4.

Geometrical Dimensions of Cypher

	Dimensions (mm)
a	0.8
b	1.1
c	0.1
d	3
e	0.1
f	0.1

Appendix C

Table C.1.

Mass of Stents (Kg)

Material	Design 1	Design 2	Design 3	Cypher
Stainless steel- 316 L	0.000000762	0.000000882	0.000000974	0.000000614
Cobalt- chromium- L605	0.000000866	0.000001003	0.000001108	0.000000699
Magnesium- WE43	0.000000174	0.000000202	0.000000223	0.000000141

Table C.2.

Volume of Stents (mm^3)

Stent	Volume
Cypher	0.076775
Design 1	0.09519
Design 2	0.11025
Design 3	0.12171

Appendix D

Stainless Steel (316 L). Cobalt- Chromium (L605) and Magnesium alloys: Stress, Strain. Total Deformation values of Stent Designs 1, 2, 3, & Cypher.

Design 1.

Table D.1.

Stainless Steel - 316 L

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	628.43	0.0032953	0.57219
1.11	628.43	0.0032953	0.57218
1.21	628.49	0.0032953	0.57211
1.31	628.49	0.0032953	0.5721
1.41	628.49	0.0032953	0.5721
1.51	628.46	0.0032953	0.57213
1.61	628.46	0.0032953	0.57212
1.72	628.49	0.0032953	0.57208
1.82	628.48	0.0032953	0.5721
1.93	628.5	0.0032953	0.57208
2.03	628.52	0.0032953	0.57208

Table D.2.

Cobalt- Chromium – L 605

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	1128.7	0.0047325	0.5724
1.11	1128.7	0.0047325	0.5739
1.21	1128.7	0.0047325	0.5739
1.31	1128.6	0.0047325	0.5739
1.41	1128.6	0.0047325	0.57238
1.51	1128.6	0.0047325	0.57238
1.61	1128.6	0.0047325	0.57237
1.72	1128.6	0.0047325	0.57237
1.82	1128.6	0.0047325	0.57236
1.93	1128.6	0.0047325	0.57236
2.03	1128.6	0.0047325	0.57236

Table D.3.

Magnesium – WE43

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	264.57	0.0060455	0.5655
1.11	265.07	0.0060455	0.58544
1.21	265.19	0.0060455	0.67966
1.31	265.25	0.0060455	0.74452
1.41	265.01	0.0060455	0.78982
1.51	264.79	0.0060455	0.8299
1.61	264.8	0.0060455	0.87022
1.72	264.69	0.0060455	0.91052
1.82	265.13	0.0060455	0.95019
1.93	265.3	0.0060455	0.9763
2.03	265.35	0.0060455	0.98019

Table D.4.

Magnesium – AZ31

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	274.64	0.0061199	0.56488
1.11	274.55	0.0061199	0.57641
1.21	274.67	0.0061199	0.65331
1.31	274.53	0.0061199	0.72525
1.41	274.21	0.0061199	0.77328
1.51	274.68	0.0061199	0.81273
1.61	274.78	0.0061199	0.85075
1.72	274.71	0.0061199	0.89214
1.82	274.6	0.0061199	0.9237
1.93	274.52	0.0061199	0.94747
2.03	274.24	0.0061199	0.9757

Table D.5.

Magnesium – AZ80

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	352.31	0.0078393	0.56236
1.11	352.3	0.0078393	0.56252
1.21	352.3	0.0078393	0.56301
1.31	352.22	0.0078393	0.56486
1.41	352.13	0.0078393	0.57916
1.51	352.13	0.0078393	0.6455
1.61	352.39	0.0078393	0.70741
1.72	352.86	0.0078393	0.7541
1.82	352.55	0.0078393	0.78777
1.93	352.36	0.0078393	0.81959
2.03	352.33	0.0078393	0.84701

Table D.6.

Magnesium – ZK60

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	302.61	0.0066985	0.56422
1.11	302.58	0.0066985	0.56489
1.21	302.53	0.0066985	0.56832
1.31	302.47	0.0066985	0.59468
1.41	302.72	0.0066985	0.67933
1.51	302.96	0.0066985	0.73636
1.61	303.13	0.0066985	0.77818
1.72	302.54	0.0066985	0.81788
1.82	302.64	0.0066985	0.85511
1.93	302.57	0.0066985	0.8959
2.03	302.47	0.0066985	0.92533

Design 2.

Table D.7.

Stainless Steel - 316 L

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	653	0.0033886	0.62675
1.11	653	0.0033886	0.62676
1.21	653	0.0033886	0.62673
1.31	653	0.0033886	0.62677
1.41	653	0.0033886	0.62676
1.51	653	0.0033886	0.62681
1.61	653	0.0033886	0.62682
1.72	653	0.0033886	0.62684
1.82	653	0.0033886	0.62685
1.93	653	0.0033886	0.62683
2.03	653	0.0033886	0.62683

Table D.8.

Cobalt- Chromium – L 605

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	1148	0.0047325	0.48944
1.11	1148	0.0047325	0.62601
1.21	1148	0.0047325	0.62603
1.31	1148	0.0047325	0.62602
1.41	1148	0.0047325	0.62604
1.51	1148	0.0047325	0.62605
1.61	1148	0.0047325	0.62606
1.72	1148	0.0047325	0.62618
1.82	1148	0.0047325	0.62619
1.93	1148	0.0047325	0.6262
2.03	1148	0.0047325	0.6262

Table D.9.

Magnesium – WE43

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	265.97	0.0060455	0.62414
1.11	265.97	0.0060455	0.62417
1.21	265.97	0.0060455	0.6242
1.31	265.97	0.0060455	0.62421
1.41	265.97	0.0060455	0.62423
1.51	265.97	0.0060455	0.62424
1.61	265.97	0.0060455	0.62421
1.72	265.97	0.0060455	0.6242
1.82	265.97	0.0060455	0.62418
1.93	265.97	0.0060455	0.62415
2.03	265.97	0.0060455	0.62411

Table D.10.

Magnesium – AZ31

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	275.97	0.0061199	0.62408
1.11	275.97	0.0061199	0.62411
1.21	275.97	0.0061199	0.62413
1.31	275.97	0.0061199	0.62416
1.41	275.97	0.0061199	0.62414
1.51	275.97	0.0061199	0.62415
1.61	275.97	0.0061199	0.62415
1.72	275.97	0.0061199	0.62415
1.82	275.97	0.0061199	0.62414
1.93	275.97	0.0061199	0.62412
2.03	275.97	0.0061199	0.62408

Table D.11.

Magnesium – AZ80

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	353.97	0.0078393	0.62369
1.11	353.97	0.0078393	0.62371
1.21	353.97	0.0078393	0.62374
1.31	353.97	0.0078393	0.62376
1.41	353.97	0.0078393	0.62378
1.51	353.97	0.0078393	0.6238
1.61	353.97	0.0078393	0.62382
1.72	353.97	0.0078393	0.62382
1.82	353.97	0.0078393	0.62383
1.93	353.97	0.0078393	0.62383
2.03	353.97	0.0078393	0.62386

Table D.12.

Magnesium – ZK60

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	303.97	0.006698	0.62417
1.11	303.97	0.006698	0.62419
1.21	303.97	0.006698	0.62422
1.31	303.97	0.006698	0.62424
1.41	303.97	0.006698	0.62426
1.51	303.97	0.006698	0.62427
1.61	303.97	0.006698	0.62428
1.72	303.97	0.006698	0.62429
1.82	303.97	0.006698	0.62429
1.93	303.97	0.006698	0.62428
2.03	303.97	0.006698	0.62428

Design 3.

Table D.13.

Stainless Steel – 316L

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	645.77	0.0033886	0.60147
1.11	645.78	0.0033886	0.60178
1.21	645.78	0.0033886	0.60211
1.31	645.78	0.0033886	0.60244
1.41	645.79	0.0033886	0.60275
1.51	645.8	0.0033886	0.60314
1.61	645.8	0.0033886	0.60352
1.72	645.81	0.0033886	0.60396
1.82	645.82	0.0033886	0.60436
1.93	645.82	0.0033886	0.60485
2.03	645.83	0.0033886	0.60531

Table D.14.

Cobalt- Chromium – L 605

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	1120.3	0.0047199	0.5955
1.11	1120.3	0.0047199	0.59566
1.21	1120.3	0.0047199	0.59581
1.31	1120.3	0.0047199	0.59597
1.41	1120.3	0.0047199	0.59614
1.51	1120.3	0.0047199	0.5963
1.61	1120.4	0.0047199	0.59647
1.72	1120.4	0.0047199	0.59666
1.82	1120.4	0.0047199	0.59684
1.93	1120.4	0.0047199	0.59704
2.03	1120.4	0.0047199	0.59722

Table D.15.

Magnesium – WE43

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	266	0.0060455	0.59732
1.11	266	0.0060455	0.59837
1.21	266	0.0060455	0.59959
1.31	266	0.0060455	0.60101
1.41	266	0.0060455	0.60272
1.51	266	0.0060455	0.60483
1.61	266	0.0060455	0.60451
1.72	266	0.0060455	0.61144
1.82	266	0.0060455	0.6164
1.93	265.99	0.0060455	0.62449
2.03	265.99	0.0060455	0.6356

Table D.16.

Magnesium – AZ31

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	276	0.0061199	0.59724
1.11	276	0.0061199	0.59825
1.21	276	0.0061199	0.59935
1.31	276	0.0061199	0.60066
1.41	276	0.0061199	0.60222
1.51	276	0.0061199	0.60413
1.61	276	0.0061199	0.60653
1.72	275.99	0.0061199	0.61001
1.82	275.99	0.0061199	0.61432
1.93	275.99	0.0061199	0.62119
2.03	275.99	0.0061199	0.63051

Table D.17.

Magnesium – AZ80

Pressure (Mpa)	Stress (Mpa)	Strain (mm/mm)	Total Deformation (mm)
1.01	354	0.0078393	0.60655
1.11	354	0.0078393	0.60726
1.21	354	0.0078393	0.608
1.31	354	0.0078393	0.6088
1.41	354	0.0078393	0.60966
1.51	354	0.0078393	0.61062
1.61	354	0.0078393	0.61168
1.72	354	0.0078393	0.613
1.82	354	0.0078393	0.61438
1.93	354	0.0078393	0.61614
2.03	354	0.0078393	0.61805

Table D.18.

Magnesium – ZK60

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	303.98	0.0068042	0.60772
1.11	303.98	0.0067954	0.60947
1.21	303.98	0.0067998	0.60856
1.31	303.98	0.0067914	0.61047
1.41	303.98	0.0067876	0.61159
1.51	305.44	0.0067858	0.61283
1.61	307.1	0.0068213	0.61426
1.72	308.93	0.0068604	0.61608
1.82	310.61	0.0068961	0.61806
1.93	312.43	0.006935	0.62073
2.03	314.04	0.006969	0.62377

Cypher .

Table D.19.

Stainless Steel – 316L

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	481.46	0.0026264	0.55251
1.11	486.42	0.0026476	0.57726
1.21	503.8	0.0027206	0.63331
1.31	517.36	0.0027817	0.67317
1.41	527.02	0.002826	0.7026
1.51	534.25	0.0028591	0.72564
1.61	539.93	0.0028846	0.74491
1.72	545.12	0.002908	0.76381
1.82	549.25	0.002926	0.77906
1.93	552.37	0.002939	0.7942
2.03	554.88	0.0029484	0.80647

Table D.20.

Cobalt- Chromium – L 605

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	829.19	0.0035944	0.54098
1.11	828.59	0.0035918	0.54131
1.21	828.41	0.0035912	0.54176
1.31	828.41	0.0035914	0.54231
1.41	828.5	0.003592	0.54312
1.51	828.33	0.0035913	0.54408
1.61	828.34	0.0035913	0.54559
1.72	828.62	0.0035919	0.54839
1.82	828.38	0.0035933	0.55285
1.93	828.21	0.0036048	0.56652
2.03	828.75	0.0036332	0.59247

Table D.21.

Magnesium – WE43

Pressure (MPa)	Stress (MPa)	Strain (mm/mm)	Total Deformation (mm)
1.01	261.31	0.0060455	0.76132
1.11	261.33	0.0060455	0.54551
1.21	261.36	0.0060455	0.54662
1.31	261.41	0.0060455	0.54791
1.41	261.44	0.0060455	0.54936
1.51	261.42	0.0060455	0.55589
1.61	263.25	0.0060455	0.59938
1.72	265.19	0.0060455	0.65046
1.82	265.35	0.0060455	0.6913
1.93	265.39	0.0060455	0.71857
2.03	265.37	0.0060455	0.74502

Appendix E

List of publications during Ph.D. study

1. **Vaizasatya, A**., Veroneze, G., Li, Z. C., Martin, A., Xu, Z. "Coronary Stents: Novel Designs of stents and comparison with bio-compatible materials", International Conference on Production Research (ICPR), Iguassu Falls, Brazil, July 2013.
2. **Vaizasatya, A**., Veroneze, G., Li, Z. C., Xu, Z. "A Product Development Methodology: Design and Simulation of Coronary Stents", Design of Medical Devices Conference, Minneapolis, MN, April 2013.
3. **Vaizasatya, A**., Baisie, E. A., Xu, Z., Li, Z.C. "Design and Simulation of Coronary Stents", Industrial and Systems Engineering Research Conference (ISERC), Orlando, FL, May 2012.
4. Tabbak, S., **Vaizasatya, A.,** Wan, S., Li, Z.C., Stanfield, P. "Petri Nets Application and Implementation on New Service Development", Industrial and Systems Engineering Research Conference (ISERC), Orlando, FL, May 2012.
5. Bateni. H., **Vaizasatya, A**., Blaschak, M. J. "The Effect of 80 dB Environment Noise on Control of Posture in Healthy Young Adults", Human Factors and Ergonomics in Manufacturing and Service Industries, December 2011.
6. Wan, S., **Vaizasatya, A**., Li, Z. C. "Modeling and Simulation of Wind Energy Conversion System (WECS) Using Fuzzy Logic", Industrial Engineering Research Conference (IERC), Reno, NV, May 2011.
7. Bateni. H., **Vaizasatya, A**., Blaschak, M. J. "Affect of Intensive Environmental Noise of Human Postural Control", Poster presentation at Annual Meeting of American Society of Biomechanics Conference, Providence, RI, June 2010.

In Preparation:

1. **Vaizasatya, A**., Li, Z. C., Xu, Z. “A Study on Product Development Phases of Coronary Stents with Concurrent Engineering”.
2. **Vaizasatya, A**., Akangah, P., Li, Z. C., Xu, Z. “Simulation of Stents with Magnesium Alloys”.