Design Exploration and Analysis of Carbon-Infiltrated Carbon Nanotube Vascular Stents

Darrell John Skousen
Brigham Young University - Provo

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Design Exploration and Analysis of Carbon-Infiltrated Carbon Nanotube Vascular Stents

Darrell J. Skousen

A thesis submitted to the faculty of Brigham Young University in partial fulfillment of the requirements for the degree of Master of Science

Anton E. Bowden, Chair
Brian D. Jensen
Larry L. Howell

Department of Mechanical Engineering
Brigham Young University
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ABSTRACT

Design Exploration and Analysis of Carbon-Infiltrated Carbon Nanotube Vascular Stents

Darrell J. Skousen
Department of Mechanical Engineering, BYU
Master of Science

The purpose of this research was to design, develop, and test coronary stent designs composed of carbon-infiltrated carbon nanotubes (CI-CNTs). Coronary stents currently have two major complications: restenosis and thrombosis. CI-CNT stents have potential to address both of these issues, and therefore may provide improved clinical outcomes. CI-CNT stent geometry is patterned using high-resolution photolithography that provide advantages in design possibilities.

To develop a coronary stent, a standard design process was followed including: background, design specifications, concept generation, development, analysis, and testing. Background research was first completed and general design specifications for coronary stent performance were compiled. Multiple design concepts were generated, evaluated, and finally a design was selected.

This stent design was further developed and optimized using analytical tools along with finite element analysis. This stent design used tapered struts in repeating segments to reduce stress and improve radial force. The design was modeled and analyzed as both a flat geometry as well as in a cylindrical configuration. Mechanics of materials equations and geometry specific finite element analysis were used to guide the final coronary stent design.

The stent design was tested mechanically, and additional tests were performed to verify the blood compatibility of the CI-CNT material. The flat version of the stent design was manufactured and mechanically tested to verify performance. The performance of the cylindrical stent configuration was analyzed using an FE model of an atherosclerotic artery. This arterial FE model was created and validated by analyzing balloon angioplasty of a common stainless steel stent. The biocompatibility of CI-CNTs was explored and studied. Blood compatibility testing of CI-CNT samples was performed with results comparable in performance to stainless steel. A method of stent deployment was planned, and several other stent design concepts were analyzed.

This research demonstrates that a functioning coronary stent can be manufactured from CI-CNTs. The optimized design has potential to address problems currently associated with stents. However, a major challenge for CI-CNT stent designs is meeting the design requirement of sufficient radial force. CI-CNT stents also need to have excellent blood compatibility to justify being used in stent applications.

Keywords: coronary stent, carbon nanotubes, blood compatibility, finite element analysis, compliant mechanism, pyrolytic carbon
ACKNOWLEDGMENTS

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# TABLE OF CONTENTS

**LIST OF TABLES** ................................................................. vi

**LIST OF FIGURES** ............................................................... vii

Chapter 1 Introduction ............................................................ 1
  1.1 Objective .............................................................................. 1
  1.2 Thesis Outline ................................................................. 1
  1.3 Background ..................................................................... 2
  1.4 Treatment ........................................................................... 3
    1.4.1 Percutaneous Coronary Intervention (PCI) ......................... 3
    1.4.2 Drug Eluting Stents ...................................................... 4
  1.5 PCI Performance and Challenges ........................................... 4
  1.6 Materials ........................................................................... 7
    1.6.1 Application of Pyrolytic Carbon .................................. 7
    1.6.2 CI-CNT Fabrication .................................................... 8
  1.7 Coronary Artery Characteristics .......................................... 9
  1.8 Mechanical Performance .................................................. 9
  1.9 Stent Applications ........................................................... 10
  1.10 Conclusion ................................................................. 11

Chapter 2 Coronary Stent Design, Optimization, and Analysis .......... 12
  2.1 Abstract ............................................................................ 12
  2.2 Introduction ....................................................................... 12
  2.3 Design Specifications ........................................................ 13
  2.4 Stent Design ...................................................................... 14
    2.4.1 Stent Segment Optimization ...................................... 17
    2.4.2 Stent Segment Results ............................................... 18
    2.4.3 Finite Element Analysis ............................................ 19
  2.5 Tapered Maximum Force Design ........................................ 21
    2.5.1 Design Optimization ................................................. 21
    2.5.2 TMF Design Mechanical Testing Analysis .................... 24
  2.6 Cylindrical Stent Design .................................................. 26
    2.6.1 Bending Analysis ....................................................... 27
  2.7 Arterial Response ............................................................ 28
    2.7.1 Arterial Model .......................................................... 28
    2.7.2 Stainless Steel Stent Arterial Response ....................... 32
    2.7.3 TMF Stent Arterial Response .................................... 33
  2.8 Conclusion and Recommendations ..................................... 34
  2.9 Acknowledgments ........................................................... 35

Chapter 3 Blood Compatibility Testing of CI-CNTs .......................... 36
  3.1 Introduction ................................................................. 36
LIST OF TABLES

1.1 Bare metal stenting vs balloon angioplasty [1]. ................................. 5
1.2 Bx Velocity Stent Clinical Trial Results [2]. .................................... 7
1.3 Taxus Stent Clinical Trial Results [3]. ............................................. 7

2.1 FEA results for basic stent segment compared to calculations using mechanics of materials equations in MATLAB. ............................. 20
2.2 Table of mechanical testing results for 7 samples including: nanotube depth, displacement to failure, max force, elastic modulus, max compressive stress and strain, max tensile stress and strain, and the percent compression to failure. .... 26

3.1 Table of results of the three groups of testing (G1, G2, G3) each with 2 or 3 experiments. ................................................................. 44
LIST OF FIGURES

1.2 Coronary stents are mounted on a balloon and positioned in a clogged artery. The balloon is inflated causing the stent to permanently expand. The balloon is removed but the stent remains in the body holding the artery open [5]. ..................... 4
1.3 In-stent restenosis is the result of intimal proliferation in and around a coronary stent [6]. ................................................................. 6
1.4 The upper pathway shows the possible outcomes for balloon angioplasty with no stent. The lower pathway shows the pathway with a stent implanted [6]. ............ 6
1.5 Pyrolytic carbon is used in many different biomedical applications including heart valves [7]. ................................................................. 8

2.1 The upper pathway shows the possible outcomes for balloon angioplasty with no stent. The lower pathway shows the pathway with a stent implanted. ............... 14
2.2 A coronary stent has repeating segments in both the circumferential and longitudinal directions [8]. ......................................................... 15
2.3 A basic stent segment can be described by five parameters: strut thickness, strut angle, strut length, end radius, and end radius angle. ............................. 16
2.4 A basic stent segment can be analyzed into four equivalent fixed-free sections, where the end radius is split and fixed and the strut is split and left free. ............ 17
2.5 The quarter segment can be analyzed in two parts, a straight beam and a partial ring. 18
2.6 Optimization of the basic stent segment with maximum force as the objective. Feasible region is shaded in the upper left section. Each grid intersection point represents an individual design. In this plot, the radius and radius angle were held constant while the thickness and strut angle were variables. The feasible design space is in the upper left section with an optimum of: Length (1 mm), Thickness (.025 mm), Theta (30 deg), Radius (.05 mm), and Phi (80 deg). ................. 19
2.7 Stent mesh used for FEA ............................................................... 20
2.8 Left: Stent stresses at the end radius showed high tensile stresses at the outer edge (red), and high compressive stresses at the inside edge (blue). Right: The highest tensile stress occurred at the filleted connection of strut to end radius. .......... 21
2.9 Two adjacent segments of the tapered maximum force (TMF) design in the uncompressed configuration. ...................................................... 23
2.10 FEA of the TMF design reveals that the tensile stresses (1st principal) are spread out more uniformly. The design does not clash together even under a 65% compression. ...................................................... 23
2.11 Flat version of a full stent using the TMF design. This design was manufactured and used in mechanical compression testing. .......................... 24
2.12 Mechanical setup for compression testing a flat stent geometry. Left: uncompressed stent. Right: Fully compressed stent. ............................... 25
2.13 CAD model of a full 3D cylindrical version of the 3 mm TMF design. Has 6 rows with 12 repeating segments. ........................................... 27
2.14 FEA of the cylindrical TMF design shows that the tensile stresses (1st principal) are slightly higher on the outside edges. The design does not clash when compressed from a 3.2 mm diameter down to 1.2 mm.

2.15 FE bending analysis of the TMF cylindrical design.


2.17 Selected model dimensions (mm). Left: Arterial model with no pressure. Right: Arterial model with 100 mm Hg internal pressure.

2.18 Left: CAD model of an atherosclerotic artery. Right: ANSYS mesh of the imported arterial model.

2.19 Graph of the predicted pressure vs diameter response of the atherosclerotic artery model.

2.20 1/4 cylinder arterial model with a stainless steel stent.

2.21 Arterial response to stent angioplasty using a ‘Cordis BX Velocity’ stent.

2.22 Arterial response to stent angioplasty using a TMF stent design (1st principal stress).

3.1 Formvar (left) has high level of fully spread, clustered platelets. PyC (right) has well spread, not clustered platelets [9].

3.2 Forcefield test unit comprised of stainless steel tubing and 2 sections of pyrolytic carbon tubing (treatment and control) [10].

3.3 Images of the results of the first group of testing (G1).

3.4 Images of the results of the second group of testing (G2).

3.5 Images of the results of the third group of testing (G3).

3.6 Results of the three groups of testing (G1, G2, G3) each with 2 or 3 experiments. The CI-CNT samples were manufactured under differing conditions in each group.

4.1 Merit Medical ALIMAXX-B biliary stent being deployed [11].

4.2 Method for stent mounting. The stent is forced through the funnel into the mounting catheter.

4.3 Section view of the stent cramped and mounted into the sheath.

4.4 The locking stent concept can achieve much higher radial force than a typical stent design.

4.5 The push stent design is forced into the target lesion using a tapered cone.

4.6 Torsional spring-like connection between stent struts can spread out stresses.

4.7 Highly flexible slinky-like stent design, is compressed by twisting the stent.

4.8 Stent concept with struts with a wavy geometry that nest together during compression.

A.1 Stent segments can be connected in-line with each other, or in an opposite configuration.

A.2 It may be possible to use stainless steel struts to plastically expand the stent but use PyC to hold contact the arterial wall.

A.3 It may be beneficial to connect stent segments sideways, or to use two thinner connections.
A.4 It may be possible to have locking design that has multiple sizes using a sort of staircase design.
CHAPTER 1. INTRODUCTION

1.1 Objective

The purpose of this research is to design, develop, and test coronary stent designs made of carbon-infiltrated carbon nanotubes (CI-CNTs). Research on the current performance of vascular stents was completed. Requirements for stent performance and methods for analyzing the stent mechanical properties were also determined. Stent designs were generated and developed. FEA and mechanical testing were performed to verify stent properties.

The specific objectives of this research are:

1. Design: Determine the required performance of a coronary stent. Generate concepts, and select a basic design for a stent composed of CI-CNTs.

2. Develop: Optimize a basic repeating stent segment for a flat design. Use the optimized segment to complete and analyze a full 3-dimensional cylindrical stent design.

3. Test: Analyze the stent design using analytical tools and using a finite element analysis. Manufacture samples and mechanically test a flat version of the coronary stent. Perform blood compatibility testing of CI-CNT material to predict stent biocompatibility.

1.2 Thesis Outline

This thesis is broken into five chapters. Chapter 1 provides background information on the use of vascular stents, as well as information on the design requirements for coronary stents. Chapter 2 includes the bulk of the research for this thesis. It includes the development of a coronary stent design, methods for analyzing stents, finite element analysis of both flat and cylindrical designs, and results of mechanical testing. Chapter 3 includes information on the biocompatibility of pyrolytic carbon as well as results of blood compatibility testing of CI-CNT samples. Chapter 4
includes additional research on stent delivery systems as well as other design concepts. Chapter 5 includes a summary of contributions along with discussion of the thesis research.

1.3 Background

Cardiovascular disease is responsible for nearly one-third of all deaths in the world and resulted in 17 million deaths in 2008 [12]. This disease results in over 800,000 deaths per year in the U.S. and has an estimated cost of $503 billion per year with 51% of those deaths being the result of coronary heart disease (CHD) [13].

The coronary arteries wrap around the heart and supply blood to the heart tissue. CHD is a condition where the heart tissue isn’t receiving sufficient oxygen due to a reduced blood supply or increased myocardial oxygen demand or both. Lack of oxygen in the heart tissue can lead to heart failure and death. Coronary artery disease is the most common cause of CHD and is caused by a narrowing and hardening of the coronary arteries due to the buildup of plaque on the inner arterial walls (atherosclerosis) (Figure 1.1) [6]. As the arteries narrow, the blood flow is reduced causing the heart to strain, which is felt by pain in the chest, fatigue, and shortness of breath. Plaque may rupture or form a blood clot (thrombosis) that may break off from the vessel and completely occlude the artery causing a heart attack.
1.4 Treatment

Proper treatment of CHD can greatly decrease the risk of complications and death. If detected early, CHD can be successfully treated by lifestyle changes including dieting, exercise, and managing stress and other harmful behaviors. Also, drug therapy including the use of anti-coagulants (blood thinners) to lower cholesterol and blood pressure can help prevent CHD related complications.

Often, non-invasive methods are insufficient, and a more direct approach must be taken. One of the first methods, and also one of the most common methods for treating severe CHD is coronary artery bypass grafting [6]. This is a traumatic surgery (open-heart surgery) where the chest is opened up and veins or arteries from other parts of the body are grafted to the coronary artery system bypassing the diseased areas.

1.4.1 Percutaneous Coronary Intervention (PCI)

Over the past 30 years a much less invasive method for treating CHD has been developed with considerable success. This method is called percutaneous coronary intervention (PCI). For this treatment, an incision is typically made in the femoral artery in the thigh. A catheter is inserted into the femoral artery and guided into the aorta to the desired coronary artery branch. A guidewire (typically 0.014”) is advanced through the catheter and into the coronary artery to the diseased vessel. A balloon catheter is advanced over the guidewire and positioned in the narrowed vessel. The balloon is inflated for a short period of time, crushing and permanently deforming the plaque and expanding the artery [6].

After balloon dilation, another balloon with a stent mounted on it is placed in the affected artery. A stent is a cylindrical scaffold wire mesh, typically made of stainless steel. The stent is deployed by inflating the balloon, causing the stent to expand and plastically deform. The balloon is removed but the stent stays in place pushing against the artery wall keeping the artery open permanently (Figure 1.2).
Figure 1.2: Coronary stents are mounted on a balloon and positioned in a clogged artery. The balloon is inflated causing the stent to permanently expand. The balloon is removed but the stent remains in the body holding the artery open [5].

1.4.2 Drug Eluting Stents

Over the past 10 years, drug-eluting stents (DES) have been introduced. These stents are similar in design to bare-metal stents, but they also are coated with anti-proliferative drugs. These drugs release directly to the affected arteries to improve blood compatibility and reduce complications.

1.5 PCI Performance and Challenges

There are two major complications associated with PCI: restenosis and thrombosis. Restenosis is much more common than thrombosis but is also less lethal. Restenosis is defined as the renarrowing of the diseased vessel after PCI, and usually occurs within a few months [6]. Binary restenosis is defined as the reduction in the minimal lumen diameter by greater than 50%, and is usually measured during an angiogram. Clinical restenosis is defined as the rate of repeat revascularization of the same vessel after successful PCI. Binary restenosis rates are typically higher than clinical rates (Table 1.1), but are also more difficult to measure, since this requires a follow-up angiogram for each patient.

Restenosis from balloon angioplasty is caused by a combination of early elastic recoil, negative remodeling, and neointimal formation. Early elastic recoil occurs immediately after balloon dilation, and is due to the elastic properties of the plaque and arteries. Late lumen loss
Table 1.1: Bare metal stenting vs balloon angioplasty [1].

<table>
<thead>
<tr>
<th>Bare-Metal Stent Versus Balloon Angioplasty (7 Months)</th>
<th>Angioplasty</th>
<th>Bare-Metal Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference-vessel diameter (mm)</td>
<td>3.01±0.46</td>
<td>2.99±0.45</td>
</tr>
<tr>
<td>Minimal lumen diameter (mm)</td>
<td>1.08±0.31</td>
<td>1.07±0.33</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>64±10%</td>
<td>64±10%</td>
</tr>
<tr>
<td>After procedure minimal luminal diameter (mm)</td>
<td>2.05±0.33</td>
<td>2.48±0.39</td>
</tr>
<tr>
<td>Follow up minimal luminal diameter (mm)</td>
<td>1.73±0.55</td>
<td>1.82±0.64</td>
</tr>
<tr>
<td>Target lesion revascularization (%)</td>
<td>23.3%</td>
<td>13.5%</td>
</tr>
<tr>
<td>Binary restenosis rate</td>
<td>32%</td>
<td>22%</td>
</tr>
</tbody>
</table>

In balloon angioplasty is caused by neointima formation (20-30%) and negative remodeling (70-80%) [14, 15]. Neointima formation (sometimes referred to as intimal hyperplasia) is caused by smooth muscle cell migration and proliferation. Negative remodeling is not completely understood, and results in a concentric compression of the outer layer of the blood vessel and may be related to a thickening of the artery wall [16].

Table 1.1 shows the results of a large clinical trial showing the performance of bare-metal stents against balloon angioplasty alone. Balloon angioplasty alone has a binary restenosis rate of 25-60%, while bare-metal stents have reduced restenosis to 10-30% [6].

In vascular stents, the elastic recoil and negative remodeling are prevented and in-stent restenosis is almost entirely caused by neointimal hyperplasia inside the stented coronary artery (Figure 1.3). This is mainly due to vessel wall injury causing an inflammatory response and delayed endothelial healing of the stented segment [6, 17]. Figure 1.4 shows the possible outcomes of stent and balloon angioplasty. The stent struts cause an inflammatory reaction which is related to the trauma done to the vessel wall during PCI. The degree of injury during the procedure has been shown to correlate with the degree of intimal hyperplasia [18, 19].

Two common drug-eluting coronary stents that have been studied in several clinical trials are the Cordis BX Velocity (Table 1.2) and the Boston Scientific TAXUS stent (Table 1.3). In two large clinical trials (1000+ patients), the TAXUS and BX Velocity stents greatly improved the restenosis results as indicated in the target lesion revascularization (TLR) rates (Approx. 16% for bare-metal stents and 4% for DES). These clinical trials are of single non-complex lesions and are a best case scenario for stent results. From 1-year clinical trial results, DES have nearly completely prevented restenosis from occurring in non-complex lesions [6].
Figure 1.3: In-stent restenosis is the result of intimal proliferation in and around a coronary stent [6].

Figure 1.4: The upper pathway shows the possible outcomes for balloon angioplasty with no stent. The lower pathway shows the pathway with a stent implanted [6].
Coronary thrombosis is defined as the formation of a blood clot inside of a coronary artery, which can completely occlude the vessel causing myocardial infarction (heart attack). Thrombosis rates within a year after stent angioplasty are typically less than 1% in clinical trials [2,3]. It is very rare for thrombosis to occur in bare-metal stents after a month. However, even though drug-eluting stents have drastically improved restenosis rates, they have resulted in an increase in late term (after 1 month) thrombosis events [20–22]. Due to the high fatality rate associated with coronary thrombosis, this is a major concern with drug-eluting stents.

### 1.6 Materials

#### 1.6.1 Application of Pyrolytic Carbon

Ceramics are often useful in biomedical devices because of their excellent biocompatibility. Pyrolytic carbon (PyC) is a biocompatible ceramic that is resistant to blood clotting. PyC is a
Figure 1.5: Pyrolytic carbon is used in many different biomedical applications including heart valves [7].

A popular material for biomedical implant devices, and has been used in more than 4 million heart valves with over 25 different design configurations [10].

The blood compatibility of PyC has been tested extensively and has been shown to perform as well as or better than stainless steel and titanium [23–25]. There is also interesting research into further improving its blood compatibility through protein adsorption treatment [10].

Due to its brittle nature, PyC is difficult to use as a stent material. However, several stents have been developed made of stainless steel or cobalt-chrome with a carbon coating to help improve blood compatibility [26, 27].

The majority of stent materials, with the exception of nitinol, must undergo large plastic deformation in order to deploy in a blood vessel. It is difficult to design a stent composed entirely of a ceramic material such as PyC that also has the mechanical performance necessary to successfully treat CHD.

1.6.2 CI-CNT Fabrication

A form of PyC has been developed at BYU that allows high manufacturing tolerances (1-3 micron) and also has excellent mechanical properties. This form of PyC is known as carbon-
infiltrated carbon nanotubes (CI-CNTs). It is manufactured by growing a forest of carbon-nanotubes and then infiltrating the carbon nanotubes with carbon graphite.

Using MEMS manufacturing processes, a mask can be made with a detailed 2-dimensional geometry. Carbon-nanotubes are grown vertically extruding the 2-dimensional geometry into a 3-dimensional carbon-nanotube forest. The forest is then infiltrated with carbon graphite by a vapor deposition method. The mechanical properties as well as the mass is dominated by the filler material [28]. The biocompatible properties of the CI-CNTs is expected to be similar to other methods of manufacturing PyC.

1.7 Coronary Artery Characteristics

For the majority of published clinical trials, only three coronary arteries were used in angioplasty procedures: left anterior descending, left circumflex, and right coronary arteries. From three major clinical trials the percentage of lesions were left anterior descending (42%), left circumflex (27%), and right coronary artery (31%). The average reference vessel of three major clinical trials was 2.77 mm, with a minimal lumen diameter before treatment of 0.91 mm. The average lesion length was 14.2 mm [2, 29, 30].

1.8 Mechanical Performance

Coronary stents must be able to expand to approximately three times their original diameter [31]. The stent must have a crimped (compressed) profile as small as possible. Typically, a coronary stent profile is 1.2 mm or less. This allows the stent to be easily manipulated and positioned in the body. Since the minimum lumen diameter is often close to 1 mm, a larger stent profile would make it very difficult to insert into a clogged artery. The stent must be able to expand up to 2.5 to 4.0 mm to keep the stent open.

Bending stiffness is also critical for stent delivery. A less stiff stent is desirable because it is easier to manipulate and move through tortuous anatomy. However, a lower bending stiffness is often a competing requirement with a high radial stiffness. Several methods and tests have been developed to determine the mechanical performance of coronary stents [31].
1.9 Stent Applications

Coronary stents are a very common type of stent; however, there are many other uses and possibilities for CI-CNT stents. Essentially, any vessel in the human body can become occluded and cause complications. Nearly any occluded vessel can be treated with angioplasty and stenting, including the biliary duct, ureter, and many other vessels.

Several stent applications are listed below:

**Ureteral Stents**

Ureteral stents are used to allow urine drainage through the ureter when it becomes blocked, preventing damage to the kidney. One major problem with current ureteral stents is encrustation where bacteria form a biofilm layer on the stent surface. These encrustations can cause stent obstruction and impaired urine flow [32]. The Dolcera market analysis for ureteral stents estimates that 92,000 stents are used a year for kidney stones, kidney transplants, and urinary incontinence [33].

**Prostatic Stents**

Prostatic stents are used to allow drainage of urine for men. Often this is caused by an enlarged prostate that pushes against the urethra blocking it. These stents are often made of titanium or titanium alloys [34].

**Esophageal Stents**

Esophageal stents are used to relieve difficulty in swallowing, often because of esophageal carcinoma (cancer in or near the esophagus). Stents are made from both plastic and metal [35].

**Biliary Stent**

Biliary stents are placed in the bile ducts to treat obstructions and allow drainage of bile. Several conditions cause bile duct obstruction, including cancer of pancreas, gallbladder, and other surrounding organs. Also gallstones and injury to the gallbladder during removal surgery can constrict the bile duct. These stents are made of both plastic and metal.

**Femoropopliteal Stents**

Stents are placed in the superficial femoral and popliteal arteries to allow better blood flow to the legs. Claudication (pain in the leg brought on by walking) is more common in the elderly, and can be relieved by angioplasty and stenting. Both nitinol and stainless steel stents have been used, although angioplasty alone seems to deliver as good of results as stenting [36]. Cook
Medical has recently developed the Zilver PTX DES that has shown to perform better than bare metal stents [37].

While coronary stents are the most common type of stents and represent the largest market, it is possible that CI-CNT stents will have advantages in other stent applications. Several of these applications have similar challenges as coronary stents such as insufficient material biocompatibility. With proper design and development these issues could potentially be improved by using CI-CNTs.

1.10 Conclusion

From this research, it is clear that while coronary stents perform fairly well, there is room for improved performance that CI-CNT stents may provide. This background information was necessary to understand the performance requirements and to benchmark the current success of coronary stents. This research was used to design, develop, and test CI-CNT stents.
CHAPTER 2.  CORONARY STENT DESIGN, OPTIMIZATION, AND ANALYSIS

2.1 Abstract

In this chapter, coronary stent designs composed of CI-CNTs were developed and analyzed. There is a need for new stent designs that can improve on complications that currently affect coronary stents including restenosis and thrombosis. General design specifications for coronary stents were researched and compiled to evaluate stent performance. Stent design concepts were generated and evaluated.

One stent design was further developed and optimized using analytical tools along with finite-element analysis. This stent design was modeled and analyzed in both a flat geometry as well as cylindrical. The flat design was manufactured and mechanically tested to verify performance. An FE model of an atherosclerotic artery was created and used to predict performance of the cylindrical stent design.

2.2 Introduction

Coronary stenting can greatly reduce complications in coronary artery disease. However, as with all implanted materials, the biocompatibility of the materials has a large effect on performance. Arterial restenosis and thrombosis are two serious complications that can occur after stent angioplasty and are mainly due to the biocompatibility of the stent material, stent geometry, and the degree of injury caused during insertion [16, 18, 19].

Drug-eluting stents (DES) have been introduced that have proven to reduce the occurrence of restenosis [2, 3]. DES are often coated with an anti-proliferative drug that releases over a relatively short time (1-3 months) [38, 39]. A coronary stent that can improve blood compatibility without the use of anti-proliferative drugs could improve stent performance.

\footnote{Parts of this chapter will be submitted in a journal article.}
Carbon Infiltrated Carbon Nanotubes (CI-CNTs) is a material that has been developed recently. It has excellent flexibility and elastic strain to failure, but exhibits almost no plasticity [40]. Its material composition is a form of pyrolytic carbon, which has been shown to have relatively good blood compatibility [9, 24].

The majority of vascular stents used are made of stainless steel, cobalt chrome, or nitinol. These stents, with the exception of nitinol, are manufactured in a crimped state (low profile). They are inserted into the coronary artery mounted on balloon catheter and are plastically deformed outward using balloon angioplasty to open the occluded coronary artery.

2.3 Design Specifications

The FDA has outlined many of the required attributes of vascular stents including: radial stiffness/force, stent recoil, stress/strain analysis, biocompatibility and many other attributes [41]. Of these, the radial stiffness/force and the stress/strain analysis are critical to a functional stent design. Biocompatibility is also critical but is usually tested in-vitro, whereas mechanical properties can be studied using finite-element analysis (FEA) as well as mechanical testing.

Stent radial stiffness and radial strength determine the ability of the stent to resist collapse under loads [41]. This is critical because of the necessary forces the stent must provide against the artery wall to prevent restenosis of the vessel after a procedure.

Restenosis from balloon angioplasty as described in Chapter 1 is caused by a combination of early elastic recoil, negative remodeling, and neointimal formation. Stents prevent elastic recoil and negative remodeling but neointimal hyperplasia is still a major problem. Figure 2.1 shows the possible outcomes of stent and balloon angioplasty.

A coronary stent must be able to expand 2-4 times its original diameter. However, very few materials can withstand greater than 100% strain without failure. For this reason, coronary stents are designed with a geometry that allows a large geometrical expansion with a much smaller material strain.
Figure 2.1: The upper pathway shows the possible outcomes for balloon angioplasty with no stent. The lower pathway shows the pathway with a stent implanted.

### 2.4 Stent Design

As with the development of any new concept, a general process must be followed in order to develop a good design. This includes: defining the problem, background research, concept generation, concept selection and analysis, and prototyping and testing. Chapter 1 defines the problem and gives background research.

Our team performed concept generation and came up with many different design ideas. These concepts were discussed and examined and more improved designs were generated. Some of the more promising design concepts are provided in Chapter 4 and in Appendix A. Several designs had promising performance, but their delivery or functionality was significantly different than current stents. Several concepts included an ability to lock into an expanded configuration. However, these concepts cannot be delivered and implanted as easily as current coronary stents.

One of the most promising stent concepts has a similar design to current coronary stents, but is designed to provide maximum radial force. It is necessary to provide the maximum amount
of force due to the lower elastic modulus and ultimate strength of CI-CNTs compared to current stent materials.

Nearly all coronary stents have the same basic features as shown in Figure 2.2. Stents have thin struts that are connected in a zigzag pattern. The connection between the struts has a circular end radius to reduce the stress concentration at the connection. The struts and connection form a basic stent segment that is repeated circumferentially around the stent.

To simplify the geometry, a stent design can be reduced into a basic stent segment Figure 2.3. This basic segment can be described by five parameters: strut thickness, strut length, strut angle (theta), end radius, and end radius angle (phi). Phi is defined as the angle between the strut and the tangent line of the end radius (phi is zero when the strut and end radius are tangent).

Stent struts are very thin compared to the overall diameter of the stent. For this reason, for simple analyses the stent behaves like a thin-walled cylinder. The basic repeating stent segment is nearly flat, and the stresses and mechanical behavior are nearly identical between a flat segment, and a segment with a slight curvature. The design that was investigated and developed used this basic repeating segment to design the stent.

CI-CNTs are a brittle material that cannot withstand plastic deformation. For that reason, the stent can only undergo elastic deflection. Stainless steel and cobalt chrome stents are manufactured in a crimped state with diameter $\approx 1$ mm, and then plastically expanded to a diameter $\approx 3$ mm. Since CI-CNTs are fully elastic, the stent must be manufactured in its expanded shape, then
Figure 2.3: A basic stent segment can be described by five parameters: strut thickness, strut angle, strut length, end radius, and end radius angle.

compressed down for insertion into the arteries. After it has been positioned in the correct location, the stent is allowed to spring back to its original shape to hold the coronary artery open.

The design criteria of a fully elastic stent is substantially different than a plastically deformed stent. An optimized design is subject to a maximum allowable stress. From initial testing of the CI-CNT material, a maximum tensile stress of 100 MPa and a maximum compressive stress of 150 MPa can be expected [40]. A higher compressive strength is achieved because of the brittle nature of the CI-CNTs.

The stent is required to deflect from an initial diameter of 3 mm to a compressed diameter of 1 mm. This is equivalent to a 67% compression of each stent segment. A length of 1 mm was selected for the struts which is typical for coronary stents to allow longitudinal flexibility. By making the thickness very small, the stresses were lowered as much as necessary. However, as the thickness decreases so does the radial stiffness/force of the stent. Elastic stents inherently have a lower radial stiffness than plastically deformed stents, and therefore a maximum radial stiffness is optimal.
2.4.1 Stent Segment Optimization

The stresses and reaction forces for the basic stent segment can be calculated using mechanics of materials equations and the pseudo-rigid-body model for compliant mechanisms [42, 43]. Due to the symmetric nature of the basic stent segment, only a quarter of that segment is needed for analysis because the end radius can be split in two and fixed as shown in Figure 2.4.

This simplified model can be analyzed in two parts. First, the strut is chopped at the connection of the strut to the end radius. This strut can be represented as shown in Figure 2.5, with a force on one end being counteracted by an equal and opposite force at the other end as well as a bending moment. The second part is a partial ring that is fixed at one end, and loaded with the same force and moment as the strut at the other end.

The two conditions can be analyzed fairly easily. The forces and moments of the strut were calculated using the pseudo-rigid-body model. The stresses in the ring were calculated using thick curved beam equations which accurately predict higher compressive stresses on the inner radius of the ring. The stresses, forces, and deflections were calculated using MATLAB v.2012a (code attached in Appendix B).
Figure 2.5: The quarter segment can be analyzed in two parts, a straight beam and a partial ring.

2.4.2 Stent Segment Results

The basic stent segment was optimized using an exhaustive search method where each continuous variable was assigned discrete values at 5 degree increments for theta and phi, and at 5 micron increments for the radius and thickness. The tensile stresses at the outer edge of the ring and the compressive stresses at the inner edge of the ring as well as the reaction force were calculated for each combination of variables. The constraints allowed a tensile stress less than 80 MPa, a compressive stress less than 120 MPa, and no physical contact (clash) between the stent segments.

The stress concentration at the connection between the end radius and strut would result in high tensile stresses, and a fillet would be needed there in a final design. However, to make the analysis simpler to perform, the stresses at the connection were ignored. Later, in FE modeling a fillet was added and the stresses at the connection were analyzed.

The results of the optimization are shown in Figure 2.6 and led to several key stent design fundamentals. The thickness had large effect on both the stresses and the reaction force. A larger thickness increased both the stress and the force. Therefore, the optimal design had the largest possible thickness without exceeding the allowable stress.

The strut angle (theta) created higher forces when increased but much higher stresses. Therefore, the optimal strut angle was the smallest possible angle that could be achieved without the segments clashing before reaching a 67% compression.
Figure 2.6: Optimization of the basic stent segment with maximum force as the objective. Feasible region is shaded in the upper left section. Each grid intersection point represents an individual design. In this plot, the radius and radius angle were held constant while the thickness and strut angle were variables. The feasible design space is in the upper left section with an optimum of: Length (1 mm), Thickness (.025 mm), Theta (30 deg), Radius (.05 mm), and Phi (80 deg).

The end radius had lower stresses when the radius was larger. However, clash generally occurred when the end radii of adjacent stent segments were larger causing them to run into each other. Therefore, a more optimal design had a smaller radius. The smaller the radius, the more the end radius behaved like a thick curved beam. As the radius was reduced the compressive stresses on the inner edge of the radius became too high limiting how small the radius could be.

The connection angle (phi), had a small effect on stress. A larger phi lowered the stresses, but if it became too large, the two struts would clash. The optimal parameters for this specific set of parameters are: Length (1 mm), Thickness (.025 mm), Theta (30 deg), Radius (.05 mm), and Phi (80 deg). A radial depth of .025 mm was used to determine the reaction forces.

2.4.3 Finite Element Analysis

The basic stent segment was analyzed with FEA using ANSYS V.13.0 software. The stent was modeled as a solid volume with fillets added at the sharp connection between the end radius and the strut (Figure 2.7). The basic stent segment was modeled using 21,700 Solid185 elements.
Table 2.1: FEA results for basic stent segment compared to calculations using mechanics of materials equations in MATLAB.

<table>
<thead>
<tr>
<th>Description</th>
<th># of Elements</th>
<th>Max Tensile Stress (MPa)</th>
<th>Max Compress Stress (MPa)</th>
<th>Reaction Force (mN)</th>
<th>Deflection (mm)</th>
<th>Element Type</th>
<th>1st P Stress (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanics Equations</td>
<td>N/A</td>
<td>78.3</td>
<td>-112</td>
<td>0.405</td>
<td>0.401</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>FEA, Control</td>
<td>21,708</td>
<td>75.7</td>
<td>-105</td>
<td>0.410</td>
<td>0.401</td>
<td>Solid185</td>
<td>88.5</td>
</tr>
<tr>
<td>FEA, Fine Mesh</td>
<td>172,656</td>
<td>78.3</td>
<td>-110</td>
<td>0.409</td>
<td>0.401</td>
<td>Solid185</td>
<td>92.9</td>
</tr>
<tr>
<td>FEA, Solid186</td>
<td>21,708</td>
<td>81</td>
<td>-116</td>
<td>0.409</td>
<td>0.401</td>
<td>Solid186</td>
<td>96.9</td>
</tr>
</tbody>
</table>

Table 2.1 compares the results of the FE analysis to the results from the mechanics of materials equations in MATLAB.

The max tensile and compressive stresses occur at the outer and inner edges of the end radius, respectively, as predicted by the hand calculations. Three FE analyses were run on the basic stent segment: a control mesh of 21,700 elements, a fine mesh with 172,600 elements, and also using the higher order Solid186 20-node brick with 21,700 elements. Table 2.1 shows that the results of the FEA and the hand calculations had good agreement on the predicted stresses (within 4%). Also, increasing the element size did not significantly change the FEA results. The reaction forces showed excellent agreement as well. Displacement was used as the input and is equivalent to 67% compression of the stent segment.
The FEA analysis revealed that the tensile stresses at the filleted connection were higher than at the end radius. The 1st principal stress was 88.5 MPa, considerably higher than 75.7 MPa.

2.5 Tapered Maximum Force Design

FEA of the basic stent segment in the previous section showed good agreement with the predicted stresses and forces. However, the five parameter design was a very simple approach to optimizing the stent geometry. The basic design had several flaws including high stress concentrations at the end radius and filleted connection. It also had a low reaction force which would give the stent a low radial stiffness. The basic design could be improved using FEA techniques. The following sections describe the optimization process used to improve the stent geometry, as well as the results of mechanically testing manufactured samples of the final design.

2.5.1 Design Optimization

To improve the stent design, a tapered beam was used instead of a beam with constant thickness. For the same deflection, a thinner beam has less stress than a thicker beam. Also, for the same force, a thin beam will deflect more than a thick beam. These principles were used to taper the beam in a way that spread the stress out more uniformly.
A potential problem with the five parameter design is that adjacent segments could clash together under smaller deflections than desirable. The segments clashed usually at only one location while the rest of the geometry had large gaps between segments. To improve this, the struts were changed from being straight to slightly curved.

Due to the added complexity of tapering and non-straight geometry, mechanics of materials equations were impossible to apply to analyze the stresses and forces. The only method that could be used to quickly and efficiently improve the design is FEA. Fortunately, for simple geometries the FEA had already shown to agree with the predicted results. It could reasonably be expected to have accurate results when applied to more complex geometries.

Since this design is used in a cylindrical stent geometry, a few modifications to the design specifications were made. Also, since this design was finalized several months after the five parameter design, our understanding of the design specifications as well as the material properties improved.

This stent was designed for a coronary artery with an unoccluded inner diameter of 3 mm (reference diameter). For this diameter, the stent was designed to have 12 circumferentially repeating segments. An initial outer diameter of 3.2 mm and a compressed diameter of 1.2 mm were chosen resulting in a compression of 65%. The stent radial depth was chosen to be 100 microns, which is in the typical range for coronary stents. Also, with a better understanding of the material properties of CI-CNTs, higher compressive stresses were allowed. The stent was designed to have a max compressive stress of 180 MPa and a max tensile stress of 90 MPa.

A manual trial and error approach was used to optimize the tapering and curvature of the stent design. An automated approach would have been very difficult and time consuming to attempt to program. Also, the concepts for an improved design were discovered using trial and error methods. The design is simple enough that ANSYS was able solve each design iteration in a few minutes.

After many analyses were performed, a final design was selected where trial and error could no longer improve the design. It was named the tapered maximum force (TMF) design and two adjacent segments are shown in Figure 2.9.

FEA of the stent design shows that the stresses were much more uniformly spread out across the stent surface (Figure 2.10). Adjacent stent segments did not clash together. Even though
Figure 2.9: Two adjacent segments of the tapered maximum force (TMF) design in the uncompressed configuration.

Figure 2.10: FEA of the TMF design reveals that the tensile stresses (1st principal) are spread out more uniformly. The design does not clash together even under a 65% compression.

the struts were curved initially, when they were compressed they become nearly flat. The max tensile stress was 82.1 MPa, with a max compressive stress of 165 MPa. The reaction force was 9.1 mN. Even after accounting for a change in radial depth and the overall length of the stent segments, the TMF stent design showed more than a 3 fold increase in the reaction force over to the original design while only slightly increasing the maximum tensile stress.
2.5.2 TMF Design Mechanical Testing Analysis

After the TMF design was completed, mechanical testing was needed to verify the mechanical performance matched the performance predicted from FEA. Kris Jones contributed to this research in designing and constructing a method for testing, manufacturing test samples, and conducting and analyzing the mechanical tests.

To test the TMF design, a flat version of a full stent was generated in SolidWorks (Figure 2.11). This version included 12 stent segments repeated in each row, and 6 rows connected together. This is a flat version of a 3 mm diameter by 13 mm long coronary stent.

A mask was created and the design was manufactured using standard techniques described in Chapter 1. A method for holding the flat stent in place was developed and constructed. In this method, the stent was held in place while an Instron test machine compressed the flat stent recording both force and displacement (Figure 2.12).

Due to complex geometry of the stent design, it was impossible to calculate the elastic modulus, ultimate strength, or ultimate strain directly from the force/displacement data. Also, due to the variability in CI-CNT material properties, the elastic modulus cannot be assumed to be certain value, although it is typically near 10 GPa. The ultimate strength is generally near 150 MPa [40].

The only method to calculate the elastic modulus and ultimate strength was through an iterative process using FEA. In this process, the flat stent was compressed and the force/displacement
data from the Instron was recorded. In ANSYS, an identical test was performed using an initial guess of 10 GPa for the elastic modulus. This modulus was then adjusted until the predicted force/displacement in ANSYS matched with the results measured using the Instron.

Once the elastic modulus was determined, the ultimate strength and strain could be calculated. This was done by using a camera to record the mechanical testing. Using the camera, and also comparing to the Instron data, the initial mechanical failure of the stent was determined. The displacement of the stent at failure was then recorded and input into ANSYS to determine the maximum stresses and strains at failure.

Seven stent samples were manufactured and tested using this process. The results are compiled in Table 2.2. The results show that the average modulus of elasticity was close to 10 GPa, which was expected. However, the overall performance was worse than desired. The average compression before failure was 33.5%. This is half of what is needed for a functioning stent. The tensile stress at failure only averaged 55.1 MPa.

In the complete stent design there are over a hundred locations of higher stress. For most tested samples, only one or two locations would fail early while most of the stent stayed intact. For a complex stent geometry with many regions under high stress, the stent will typically fail at a manufacturing defect causing a local stress concentration. It is likely that with improved manufacturing techniques and quality control, the number and severity of manufacturing defects can be reduced. If this is improved, then the percent compression before failure should be increased significantly. An advantage of this stent design is that it can be tested non-destructively to ensure
performance. The stent can be fully compressed several times after manufacturing to ensure that it has no significant defects. If the stent fails during these tests then it will be discarded; if it doesn’t fail, the stent will have proven its mechanical strength.

### 2.6 Cylindrical Stent Design

The same TMF geometry used in the previous section was used as a template for developing a cylindrical stent design. Using the wrap function in SolidWorks this template was embossed onto a 3 mm cylinder. The embossed sketch was extruded outward radially 0.1 mm. This extrusion was repeated 11 times in a circular pattern resulting in a cylindrical ring with an inner diameter of 3 mm and an outer diameter of 3.2 mm (Figure 2.13). This ring was repeated longitudinally 5 times. Each ring was connected longitudinally to the next ring with several thin flexible connections. These connections allow the stent to bend and curve as it is guided through the arteries to the intended vessel.

Due to the cylindrical nature of the stent, when radially compressed the stresses on the outer edges are slightly higher than the inside edges. For this reason and because of the addition of the segment connectors, the maximum tensile and compressive stresses are slightly higher than the flat design. The compression resulted in a max tensile stress of 93.9 MPa and a compressive stress of 171 MPa (Figure 2.14).

<table>
<thead>
<tr>
<th>Sample #</th>
<th>Depth (mm)</th>
<th>Displacement (mm)</th>
<th>Max Force (mN)</th>
<th>Elastic Mod E (Gpa)</th>
<th>Max compr σ (Mpa)</th>
<th>Max Tensile σ (Mpa)</th>
<th>Max Comp ε (%)</th>
<th>Max Tensile ε (%)</th>
<th>Percent Compression</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.254</td>
<td>3.56</td>
<td>71.2</td>
<td>8.2</td>
<td>90.2</td>
<td>44.9</td>
<td>1.10%</td>
<td>0.55%</td>
<td>36.5%</td>
</tr>
<tr>
<td>2</td>
<td>0.279</td>
<td>3.03</td>
<td>70.6</td>
<td>9.5</td>
<td>94.4</td>
<td>47.0</td>
<td>0.99%</td>
<td>0.49%</td>
<td>31.1%</td>
</tr>
<tr>
<td>3</td>
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<td>3.74</td>
<td>234.4</td>
<td>12.3</td>
<td>142.0</td>
<td>70.7</td>
<td>1.15%</td>
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</tr>
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<td>0.33%</td>
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<td>11.5</td>
<td>174.2</td>
<td>86.7</td>
<td>1.51%</td>
<td>0.75%</td>
<td>50.3%</td>
</tr>
<tr>
<td>7</td>
<td>0.521</td>
<td>1.46</td>
<td>96.5</td>
<td>13.3</td>
<td>68.9</td>
<td>34.3</td>
<td>0.52%</td>
<td>0.26%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td></td>
<td>0.459</td>
<td>3.26</td>
<td>147.3</td>
<td>10.6</td>
<td>10.7</td>
<td>55.1</td>
<td>1.04%</td>
</tr>
<tr>
<td>St Dev</td>
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<td></td>
<td>0.134</td>
<td>1.24</td>
<td>88.1</td>
<td>2.2</td>
<td>46.6</td>
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<td>7.6</td>
<td>50.5</td>
<td>25.1</td>
<td>0.52%</td>
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<tr>
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<td>249.7</td>
<td>13.3</td>
<td>174.2</td>
<td>86.7</td>
<td>1.51%</td>
</tr>
</tbody>
</table>

Table 2.2: Table of mechanical testing results for 7 samples including: nanotube depth, displacement to failure, max force, elastic modulus, max compressive stress and strain, max tensile stress and strain, and the percent compression to failure.
Figure 2.13: CAD model of a full 3D cylindrical version of the 3 mm TMF design. Has 6 rows with 12 repeating segments.

Figure 2.14: FEA of the cylindrical TMF design shows that the tensile stresses (1st principal) are slightly higher on the outside edges. The design does not clash when compressed from a 3.2 mm diameter down to 1.2 mm.

2.6.1 Bending Analysis

When a stent is inserted into a patient and guided to a target artery, it often must pass through tortuous vessels. Therefore, one of the most important properties of a stent is that it can bend easily and can be guided to a vessel. While a lower stiffness in the CI-CNT stent designs is a disadvantage in keeping an artery open, this lower stiffness is a major advantage over stainless steel and other metallic stents in bending through tortuous vessels.

A simple bending analysis of the TMF design was performed. The initial analyses revealed that high stresses can occur in the connection between stent segment rows during bending.
connection was modified to reduce those stresses and allow for sufficient flexibility to pass through a bend in a coronary artery. The maximum stress predicted was 110 MPa, and the result is shown in Figure 2.15.

2.7 Arterial Response

In order to predict the performance of a stent before it is manufactured, FE models of a clogged coronary artery have been used in stent analyses [44–46]. These models are an extremely useful and inexpensive way to predict stent performance in a clogged artery. A model of an atherosclerotic artery was developed and is described in the following sections. This model was validated using an FEA of a stainless steel stent. The TMF design was also analyzed using this model.

2.7.1 Arterial Model

A normal sized coronary artery was selected for this model. A reference diameter of 3 mm, meaning the inner lumen diameter of an unclogged artery is approximately 3 mm, is a common size for coronary stents. When the lumen of a clogged artery has been reduced to 1 mm or less, the artery typically will need to be revascularized [2,29,30].

The design specifications for coronary stents specify that a stent must keep the artery open to allow blood flow to the heart. The arterial inner diameter is measured as an indicator of blood
flow. Plaque accumulation on the inside wall blocks blood flow. Angioplasty expands the artery elastically and the plaque both plastically and elastically. After angioplasty, a stent is expanded to keep the artery open. Due to the elastic nature of the artery, sufficient radial force is needed to keep the artery open.

In order to predict the arterial response, an FE model of an atherosclerotic artery similar to those used in other stent analyses was created [44, 45]. In both of these studies, the artery and plaque were modeled as 0.5 mm thick hollow concentric cylinders. This is a simple, common model for stent design.

In one study, a plaque ID of 2 mm with a 3 mm arterial ID was used [44]. In another study, a plaque ID of 1.5 mm and an arterial ID of 2.5 mm was used [45]. These IDs are of the artery under no internal pressure. Arterial blood pressure generally oscillates from 80 (diastolic) to 120 (systolic) mm Hg, giving an average of 100 mm Hg constant pressure in the artery. The arterial ID under this pressure is significantly larger than at rest.

Coronary artery reference IDs typically range from 2.5 to 4 mm. Clinical trials for recently developed stents usually begin with a simple scenario of stenting a single lesion in an average sized vessels. The typical size in these clinical trials is a reference size of about 3 mm with a pre-dilation minimal lumen diameter of about 1 mm and a post-dilation lumen diameter of about 2 mm [47].

The reason for the difference in diameters is that the reference diameter refers to the inner lumen diameter without any plaque growth. With plaque growth, the minimum diameter is...
reduced. During dilation the balloon permanently deforms the plaque and artery lining leaving a minimal diameter of roughly 2 mm (Figure 2.16).

The finite element arterial model had the following dimensions at rest: Artery OD- 3.75 mm, Artery ID- 2.75 mm, Plaque OD- 2.75 mm, Plaque ID- 1.75 mm (Figure 2.17), length 6 mm. The plaque in this model represents the plaque following pre-dilation after it has been plastically compressed.

While many different sizes of arteries could be analyzed, these dimensions were chosen for two reasons. First, when applying an internal pressure of 100 mm Hg, the plaque ID expands to 2.02 mm, and the artery ID expands to 2.95 mm (Figure 2.17). This is very close to the average size for clinical trials. Also, the CI-CNT stent is designed for a 3 mm reference diameter artery.

The material parameters assigned to the arterial tissues are critical for an accurate analysis. For this analysis, we used the parameters given by Migliavacca in their analysis, which used parameters calculated from the testing of biological tissues by Salunke [44, 48]. The mechanical behavior of the artery and plaque were modeled using a strain energy equation for the hyperelastic isotropic constitutive model of the following form:

\[ U = C_1 \ast (I_1 - 3) + C_2 \ast (I_2 - 3)^2 + C_3 \ast (I_2 - 3)^3 \]  \( (2.1) \)

\[ I_1 = \lambda_1^2 + \lambda_2^2 + \lambda_3^2, \quad I_2 = \lambda_1^2 \lambda_2^2 + \lambda_2^2 \lambda_3^2 + \lambda_3^2 \lambda_1^2 \]  \( (2.2) \)
In this constitutive model, $I_1$ and $I_2$ are strain invariants, and $\lambda_1$, $\lambda_2$, and $\lambda_3$ represent the stretch in each principal direction. For the arterial model, the following coefficients were used: $C_1 = 0.019513$ MPa, $C_2 = 0$, $C_3 = 0.02976$ MPa. For the plaque: $C_1 = 0.04$ MPa, $C_2 = 0.003$ MPa, $C_3 = 0.02976$ MPa.

The model was generated in SolidWorks, and imported into ANSYS for analysis. Due to the symmetric nature of the artery and plaque, only a quarter cylinder was used. The plaque and artery were joined together sharing the same nodes. 6432 elements were used in the model mesh (Figure 2.18). The solver accounted for large deflections due to the high pressure testing.

Pressure was applied to the inner surface of the plaque expanding the artery. Incremental pressure steps were applied and the resulting diameters were recorded. Figure 2.19 shows the results.
2.7.2 Stainless Steel Stent Arterial Response

Even though this arterial model is very similar to those used in other analyses, validation of the FE model was still necessary. To validate this model, a commonly used stainless steel stent was modeled and analyzed to predict the artery’s response.

The selected stent was the ‘Cordis BX Velocity’ which has been used in other similar analyses [49]. The stent is made of 316L stainless steel. Its unexpanded outer diameter is 1.18 mm and it has a strut thickness of 0.14 mm (Figure 2.20). The material properties of the stent used are those of Liang and include: Elastic modulus = 201 GPa, Poisson ratio = 0.3, yield stress = 330 MPa, limit stress = 750 MPa [45].

Pressure was applied to the inside area of the stent forcing it to expand outward to model the balloon expansion in vivo. ANSYS contact elements were used at the interface between the stent outside surface and the inner surface of the plaque. Solid185 elements were used allowing plasticity with yielding beginning to occur at 330 MPa.

The stent was expanded outward to a diameter of 3.30 mm. The plaque expanded to 3.30 mm only when in contact with the stent, in other locations it expanded less. When the pressure was removed from the stent inner surface, the stent experienced elastic recoil reducing it to a diameter of 3.19 mm, and leaving the final minimum lumen diameter of the artery at 2.71 mm. The final state is shown in Figure 2.21.
The results of this analysis gave us confidence in the FE arterial model. Several clinical trials using the ‘Cordis BX Velocity’ stent have been performed, giving information on the lumen diameters of the target arteries before and after revascularization [2, 50]. In the 2003 study by Moses [2], the mean diameter of the reference vessel was 2.80 mm. This is slightly less than the 2.95 mm reference diameter of the FE arterial model under 100 mmHg pressure. After the procedure, the minimum luminal diameter was 2.68 mm. This is slightly less than the minimum lumen diameter of 2.71 mm predicted by the FE model.

The fact that there is good agreement between what the arterial model predicts and what is expected from clinical trials gave us confidence that this model could be used to help predict the performance of the TMF stent design as well as other designs being developed.

2.7.3 TMF Stent Arterial Response

The performance of a 1/4 section of the TMF stent design was analyzed using the FE arterial model. For this design, the stent was compressed to its crimped diameter of 1.2 mm by applying a pressure on the outer surface of the stent. The stent was then moved into the artery and the pressure on the stent was removed allowing the stent to push out against the artery wall. The artery was pressurized at 100 mmHg, and had an initial minimum lumen diameter of 2.00 mm.
After the stent was released the artery expanded to have a minimum lumen diameter of 2.05 mm (Figure 2.22).

One other stent design was also analyzed using this method. This design was developed previously by Kris Jones and has an auxetic nature to allow high radial expansion without causing a decrease in longitudinal length. Using the same methods as with TMF arterial analysis, this auxetic stent enlarged the artery from an initial minimal lumen diameter of 2.006 mm to 2.011 mm.

2.8 Conclusion and Recommendations

This research provides a design for a full cylindrical coronary stent. The performance has been predicted through FEA, and initial mechanical testing has been performed. One area of concern is the ability of the TMF stent to meet the radial force/stiffness design requirements including preventing restenosis. It is clear from the arterial response analysis that the TMF design provides significantly less radial force than a stainless steel stent. This results in a smaller lumen
diameter, that could result in restenosis if negative remodeling or neointimal growth occur. This issue is discussed further in Chapter 5.

2.9 Acknowledgments

We acknowledge Clarke Capital Partners for their support and funding in part of this work. We also thank Kristopher Jones for his collaboration in this work.
CHAPTER 3. BLOOD COMPATIBILITY TESTING OF CI-CNTS

Along with the design and testing from Chapter 2, the blood compatibility of CI-CNTs needed to be researched and tested. Many studies have been conducted on the blood compatibility of pyrolytic carbon which is very similar to the CI-CNT material used in this research. A summary of those studies is included in this chapter. In addition, blood compatibility testing was performed on CI-CNT samples manufactured for this research.

3.1 Introduction

The only known material that is completely compatible with blood is the inner lining of arteries and veins known as the endothelium. The endothelium is an active material that is constantly releasing biologically active agents that inhibit the blood’s thrombotic response. The main goal of any blood compatible material is to limit the thrombotic response and allow endothelial cells to cover the material limiting further thrombosis.

Pyrolytic carbon (PyC) is relatively thromboresistant material that is used in millions of mechanical heart-valves [10]. PyC is a possible candidate material for coronary stenting. However, data is needed to quantify PyCs blood compatibility and specifically its resistance to thromboembolization.

Current data for measuring the blood compatibility of PyC as well as many other materials is often limited to tests using stagnant blood for in vitro testing. These tests measure the amount of thrombus generated over a period of time. Somewhat superior to these tests are experiments where blood flows over the material at velocities and shear rates similar to in vivo conditions. However, both types of testing are limited because they only examine the amount of thrombus formed, not the amount of emboli that are released.

\[1\] Much of this chapter will be included in a journal paper submission
The causes of material blood compatibility are understood somewhat, but many theories are still debated. Thrombin generation and platelet activation cause intimal hyperplasia or tissue in-growth, and can lead to restenosis and increased risk of thrombosis. Initial proteins adsorbed by a material contacting the blood are believed to affect the platelet adhesion and interaction. Protein adsorption is favored by electrostatic and hydrophobic interactions between the material surface and the adsorbed protein. Albumin is an inert protein; it is predicted that when it is adsorbed onto material surfaces it will induce less platelet adhesion and activation compared to other plasma proteins, such as gamma-globulin and fibrinogen [51].

Animal studies of carbon-coated vascular prostheses showed improved patency rates. However, surface irregularities can contribute to poor performance. Endothelial cells release biologically active agents that limit the thrombotic response. Growing endothelial cells on synthetic surfaces has been tried to generate a thromboresistant material [51]. Prosthesis coating with endothelial cells is an important factor for implant patency. It is important to know the mechanisms regulating endothelium adhesion [25].

PyC has many characteristics which are unusual for biomaterials including hydrophobicity, high surface energy, and surface roughness. These properties lead to rapid tight binding of proteins. It is hypothesized that albumin in the blood is rapidly adsorbed on the material surface which passivates it from platelet adhesion. Also, once albumin is absorbed it is predicted that there is little turnover from other plasma proteins that can lead to platelet activation [9]. Platelet response to PyC is unusual because it has extensive platelet adhesion and a high level of platelet spreading but has minimal platelet activation and aggregation [23].

PyC has excellent durability and sufficient thromboresistance when used in mechanical heart-valve prosthetics. Valvular prosthetics composed of PyC structural components have clinically superior levels of thromboembolic complications compared with valves made of other materials. However, PyC valve patients need chronic anticoagulation using Warfarin, and are generally given aspirin to inhibit platelet activation. This can lead to problems if patients have bleeding disorders because their clotting response is impaired [9].
3.2 Blood Compatibility Research

There have been several studies comparing the blood compatibility of PyC to other bio-
compatible materials such as titanium.

In one study, PyC heart valve leaflets were compared to Formvar. The samples were bathed
in column-washed platelet suspension that included bovine serum albumin and incubated for 45
min at body temperature. SEM images (Figure 3.1) showed that the platelets were well spread on
the PyC, but were not highly clustered.

It is possible that well spread platelets form a monolayer that resists further platelet adhe-
sion and thrombus formation. From the study, the extensive platelet spreading closely follows the
PyC contours. A tight monolayer of spread platelets is expected to have high strength adhesion
that would minimize embolization of the layer [9].

Another study implanted samples of PyC, titanium and cobalt-chromium into sheep vena
cava. In that study they found that the PyC had significantly larger thrombus area, and the platelet
activation was similar. This study indicated that PyC may not perform better than titanium and
cobalt chromium [24].

Another study indicated that the good anti-thrombogenic properties of PyC might be due
to the fact that it adsorbs very little Hageman factor compared to titanium and other materials.
Hageman factor is known to activate a coagulation cascade following platelet surface contact. A
low level of adsorption of albumin does not seem to contribute to PyC blood compatibility. A
high correlation was found between the total adsorbed protein content and the number of adherent platelets. However, the activation of platelets did not depend on the amount of adsorbed protein, but is probable that it depends on the composition of the adsorbed proteins [52].

3.3 Blood Compatibility Improvements

An ideal blood compatible material would have both hydrophobic and hydrophilic properties where it could attract proteins that increase biocompatibility and repel components that activate platelets. ATS Medical developed a technology to attract a molecular layer of charged proteins and lipids to the surface of PyC. To attract these components, a modulated low-voltage signal is applied directly to PyC while it is in contact with circulating blood. They hypothesized that the attracted blood proteins and lipids would create a surface passive to platelet activation [10].

They conducted a study where a patient’s blood passed through a flow tube that had test samples in series. The setup had a PyC tube with the applied electric treatment followed by a control PyC tube followed by a stainless steel tube (Figure 3.2) [10].

An electric current treatment was applied to the samples for an allotted treatment time and then blood was allowed to flow freely for the rest of the time. The results showed that the control PyC samples had more than 10 times the area of platelet adhesion. Visually they are easily distinguishable.

It is possible that this treatment or similar methods can reduce platelet adhesion and subsequent thrombosis. This treatment also has the advantage of local effects, and does not alter the systemic coagulation system like an anticoagulant drug. It is postulated that the electrically stim-
ulated PyC attracts charged blood proteins such as albumin and fibrinogen and phospholipids to passivate the surface. It is likely that if these proteins are adsorbed, then coagulating proteins such as Hageman factor will not adsorb to the surface. It is also possible the electric charge can alter the fibrinogen receptors to inhibit further binding. However, some studies have shown that a pulsing electric voltage can induce platelet activation [10].

The study by Slaughter had some very interesting results. Certainly, the thrombogenic properties of PyC can be altered by using an electrical surface treatment. They predict that this is because the charged surface attracts charged molecules such as albumin and fibronectin. The visual results are very apparent between the control and treatment samples.

The existing studies that have been performed are lacking several important factors to determine whether PyC will be a good material for a coronary stent. Nearly all of the existing studies only look at and characterize the extent of platelet activation and thrombosis without addressing embolization.

3.4 Blood Compatibility Testing

Although there have been several studies on the blood compatibility of PyC, it was still necessary to test the blood compatibility of the CI-CNT materials. Several initial tests were carried out and more tests are in process. All samples were manufactured and processed by Jordan Tanner. Thrombodyne, Inc carried out all the blood compatibility testing. My role was in coordinating and supervising blood compatibility tests.

Three groups of material samples were analyzed using the same blood compatibility testing method. The method used is a standard procedure at Thrombodyne where heparinized blood flows over material samples, and the amount of thrombus formation is quantified. The manufactured samples had a 0.91 mm square cross section and were approximately 4 cm long. Multiple materials were tested in parallel to compare a new biomaterial to a known control sample.

The initial test group was a direct test between stainless steel and CI-CNTs. However, the results from the first group had high variability and another group with various surface treatments of CI-CNTs was tested. This second group gave more useful results, but more data was desired. A final third group was tested using refined manufacturing processes for CI-CNTs. We have the
most confidence in this final group of samples and have included its results as well as the first two groups.

Group 1 had two materials: CI-CNTs and stainless steel 316L. The CI-CNT samples had a growth period of 25 min, and an infiltration period of 30 min. This was one of the initial manufacturing runs, and some of the manufacturing processes and parameters were still being refined. The second material, stainless steel, is a common material used in coronary stents and was used as a control. The stainless steel bars were cut out of a 0.91 mm sheet using wire EDM and then manually sanded using 400 grit sand paper. No sanding or treatment was done to the CI-CNT samples.

Three samples of each material were tested in the first group. The results are shown in Table 3.1 and in Figure 3.3. This testing showed that for a small sample size the stainless steel seemed to perform somewhat better than the CI-CNT samples. The sample size is small and the variability between tests was high so more testing was performed.

A second group of samples were manufactured. In this group, three different surface treatments were used to try to improve the blood compatibility of the samples. The first surface treatment used a thermal oxidation method where the samples were heated in an oven while air flows over the sample oxidizing the surface. The second surface treatment was to manually polish the CI-CNT samples using wet 2000-grit sandpaper. The third treatment was an oxygen plasma etch for 35 minutes in an etching chamber. The infiltration time was also increased to 60 minutes.
Two experiments with one sample of each CI-CNT material/treatment were tested in a head-to-head comparison against the same stainless steel samples as in group 1. The results are shown in Table 3.1 and in Figure 3.4. These results showed more promise for the CI-CNT material compared to the stainless steel. The thermal oxidation treatment appeared to yield better results, while the plasma etch treatment seemed to worsen the thromboresistance. In both test runs, the CI-CNT materials had comparable blood compatibility to stainless steel. However, from examining the samples using SEM imaging, it appeared that the samples had been infiltrated for too long causing surface abnormalities.

A third group of samples were manufactured to gain further blood compatibility data. In this group, the manufacturing processes were very closely monitored and the infiltration time was decreased to 30 minutes to prevent over-infiltration. The CI-CNT materials were treated in the
same manner as in group 2. Three samples in each group were compared directly to stainless steel to test blood compatibility.

The results of group 3 are shown in Table 3.1 and in Figure 3.5. This group of samples yielded somewhat different results than group 2. The plasma etch treatment was still the worst, but the untreated CI-CNT samples actually outperformed any other group overall. This is encouraging news considering that it is much simpler to not apply any treatments to the samples. If the CI-CNT material has the best blood compatibility without any surface treatment it makes it a more desirable biomaterial. It also appears to be equivalent too or better than the stainless steel samples.

These tests represent initial attempts to quantify the blood compatibility of CI-CNT materials compared to stainless steel. These tests had small sample sizes and there still is insufficient
Table 3.1: Table of results of the three groups of testing (G1, G2, G3) each with 2 or 3 experiments.

<table>
<thead>
<tr>
<th></th>
<th>Stainless Steel 316L</th>
<th>CI-CNT Untreated</th>
<th>Thermal Oxidation</th>
<th>Manual Polish</th>
<th>Plasma Etch</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1 E1</td>
<td>11,832</td>
<td>13,899</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G1 E2</td>
<td>8,183</td>
<td>17,088</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G1 E3</td>
<td>1,727</td>
<td>19,950</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G2 E1</td>
<td>34,356</td>
<td>43,593</td>
<td>23,825</td>
<td>24,763</td>
<td>56,448</td>
</tr>
<tr>
<td>G2 E2</td>
<td>17,307</td>
<td>31,957</td>
<td>23,053</td>
<td>47,693</td>
<td>69,004</td>
</tr>
<tr>
<td>G3 E1</td>
<td>6,415</td>
<td>4,027</td>
<td>12,774</td>
<td>8,561</td>
<td>23,128</td>
</tr>
<tr>
<td>G3 E2</td>
<td>1,173</td>
<td>1,313</td>
<td>2,505</td>
<td>1,049</td>
<td>8,516</td>
</tr>
<tr>
<td>G3 E3</td>
<td>22,337</td>
<td>3,315</td>
<td>8,481</td>
<td>10,788</td>
<td>14,158</td>
</tr>
</tbody>
</table>

Figure 3.6: Results of the three groups of testing (G1, G2, G3) each with 2 or 3 experiments. The CI-CNT samples were manufactured under differing conditions in each group.

![Blood Compatibility Results Comparison](image)

data to draw definite conclusions. Also, in these tests the stainless steel was not electropolished which is the general treatment for stainless steel implants. Further tests with larger sample sizes comparing CI-CNT materials to electropolished stainless steel 316L samples will be performed to better quantify the blood compatibility of CI-CNTs.
3.5 Acknowledgments

We acknowledge the contributions of Jordan Tanner who completed the manufacturing and treatment of the CI-CNT samples, and also Dr. Sivaprasad ”SP” Sukavaneshvar who conducted the blood compatibility testing at Thrombodyne, Inc.
CHAPTER 4. ADDITIONAL RESEARCH

The research included in this chapter was important to the overall success of the project, but did not fit in well in either of the previous chapters. The first part of this chapter is focused on developing a delivery system to guide and deploy a CI-CNT stent in a target vessel. The second part is devoted to other design concepts that were not used in the TMF design but were analyzed and have potential to be used in other applications.

4.1 Delivery System

Once a stent has been developed and manufactured there must be a way to deploy it. As described in Chapter 1, in order to deploy a coronary stent, a stent delivery system with a balloon is needed. For a typical coronary stent, a balloon is used to expand the stent radially outward plastically deforming the stent in the desired location.

However, stents that do not undergo plastic deformation must have a different deployment mechanism. Superelastic nitinol stents are an example of a stent that uses elastic properties to expand outward from an initially cramped position. These stents are manufactured in an expanded state and then elastically compressed and inserted into a catheter sheath. In order to deploy the stent, a second smaller catheter is placed inside the sheath. This inside catheter is held in place while the outer sheath is retracted allowing the stent to expand outward forcing the vessel open (Figure 4.1).

A similar process could be used in deploying the TMF stent design. An initial concept is shown in Figure 4.2. In this concept, a funnel like fixture is placed at the end of the sheath catheter. The stent will be forced through the funnel into the sheath catheter. The stent will be placed deep enough into the sheath catheter that the funnel can be removed without also removing or damaging the stent. The funnel will be removed and the stent will be pushed fully into the sheath.
To deploy the stent, an inner catheter would be placed inside the sheath. The inner catheter would have an OD only slightly smaller than the ID of the sheath. Once the stent has been positioned in the target vessel, the sheath would be retracted while holding the inner catheter in place. This would force the stent out of the sheath, and the stent would expand elastically against the artery inner wall.
4.2 Concept Development

Many concepts were generated and discussed in the initial selection and development of a stent geometry. Some of these concepts were for an entire stent design, while others were only for certain parts of the stent design (for example, concepts on how to connect one strut to another). The following stent design concepts were all investigated to see their potential advantages as well as disadvantages.

4.2.1 Locking Stent

One of the major disadvantages of using CI-CNTs in stents is that they cannot produce as much radial force to keep clogged arteries open. One possible solution is to have the stent lock into place. By locking into place, the stent can greatly increase the radial force and while lowering the stress.

Figure 4.4 shows an example of a locking design. This view of the stent is in the locked position. In order to compress, the rectangle segments would be displaced out of plane. Then the entire stent could be 50% compressed forming a two layer stent with the rectangles in one layer and the stent segments in another layer.

There are a few disadvantages associated with this concept. First of all, these designs can only be compressed to a maximum of 50%. Generally, it is preferable to have the stent compress more than that to make it easier to insert.
Another disadvantage is that currently used coronary stents (including the TMF design) can be used to treat a range of arterial sizes. This design can only be used for one artery size. If the artery is too big, the stent may not help or may be dislodged. If the artery is too small, the stent may be unable to deploy, or could damage the artery.

The most difficult challenge of this concept is due to the fact that not all clogged artery lumen areas are circular. The plaque may form an oval, or it may have much more plaque in one location and none in another. This will cause a non-uniform pressure on the stent which could cause it too buckle similar to crushing a soda can. It also may be impossible to get the stent to lock in place if the lesion is an unusual shape. Stent buckling is a very dangerous failure mode causing immediate thrombosis with high fatality rates.

### 4.2.2 Push Stent

The push stent is another concept similar to the locking stent. In this concept, the stent would not need to be compressed to be inserted. The stent would be manufactured at the desired size as shown in Figure 4.5. A mounting catheter with a tapered cone at the end would be used to insert the stent. It would be positioned at the target lesion, and then would be pushed into position. The tapered cone will expand the artery as the stent is being inserted.
This stent design would have sufficient radial force to hold open even arteries that have severe calcified lesions. It also would perform well in non-round lesions. It would need to have slots cut out as shown to allow the stent to flex and bend as it is guided to the target lesion.

The disadvantages of this design severely limit its use. First, since it must stay at its full diameter during insertion, it will be very difficult to insert. Also, if the lesion is very small or calcified it may be impossible to push the stent forward with enough force to insert it.

It also suffers in that it can only fit one size of lesion. If the lesion is too small or big, the stent will not perform as well. However, in certain cases this design may outperform other stents, especially when the stent material is highly blood compatible but not very flexible.

4.2.3 **Torsional Spring Coil**

This concept was designed to help reduce stresses that occur at the end connection between two stent struts. Typically, stent struts are essentially a straight segment that is repeated in a zigzag pattern and connected by a circular section. This circular section will have high stresses during compression as shown in Chapter 2. To reduce those stresses, the length of the end circular section was lengthened and then wrapped around itself similar to a torsional spring. This allows the stresses to be spread out over a much longer length, reducing the maximum stress.

The torsional design does indeed lower stresses, however it also results in high tensile stresses due to the unusual geometry and stress concentrations. Also, due to the large nature of the torsional springs, the struts must be spaced out farther apart so that the springs do not clash into
Figure 4.6: Torsional spring-like connection between stent struts can spread out stresses.

Figure 4.7: Highly flexible slinky-like stent design, is compressed by twisting the stent.

each other during compression. This also increases stresses. Overall, it did not seem to help the
design improve performance.

4.2.4 Slinky Stent

Another concept that was thought of is similar to a slinky. In this concept, the stent is
compressed by twisting it, and is expanded by untwisting it. This type of a design would be
extremely flexible and could be easily guided to the target artery. It could also provide very high
radial forces to keep the artery open.
This stent would be difficult to deploy. It takes many twists in order to get a significant amount of compression. To deploy the stent, some sort of rapid rotational device would be needed to deploy it in a reasonable amount of time. The main disadvantage is that the wall thickness of the stent must be very thin to reduce the stress sufficiently for compression. It becomes so thin that buckling and other problems are likely to occur.

4.2.5 Nesting Stent

Another design concept is where the stent struts would have a wavy geometry where adjacent struts would nest together. This would increase the effective length of the struts allowing more compression with less material strain. However, due to the curvy nature, the stress concentration that arise cause more of a stress increase than is reduced by the extra length.

4.2.6 Design Concepts

Many other concepts were generated and investigated. Some of those concepts are included in Appendix A.
CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary of Contributions

This thesis contributes in areas of design, development, and testing of a new coronary stent. The major contributions of this thesis are: design specifications and concept generation and selection, optimization of a stent segment and a completed design of a full cylindrical coronary stent, analysis of stent performance using mechanics of materials equations and FEA, blood compatibility research and testing.

5.1.1 Design Specifications and Selection

Information was needed to describe the properties and performance of vascular stents in treating cardiovascular disease. The sizes and shapes of stents were discovered. Critical stent requirements were determined including having sufficient radial force to hold a clogged artery open. A method of deployment was created. The performance of current bare metal and drug-eluting stents was quantified to have a benchmark for stent performance. This research was critical in helping evaluate stent concepts and designs to predict their success.

Especially during the initial stages of this research, many concepts were generated and evaluated. These concepts were explored and improved ideas were generated. As our understanding of the design requirements improved, other concepts and designs were generated and analyzed. One design was fully completed, and several other designs also have potential to be used as well.

5.1.2 Coronary Stent Development and Optimization

The selected stent design was completed and analyzed. First, a basic repeating segment was optimized using an exhaustive search method in MATLAB. Then, this segment was further
optimized using FEA. Finally, a full 3-dimensional cylindrical geometry was generated including connections between stent struts and a method for insertion into the body.

5.1.3 Finite Element Methods and Testing

The TMF stent design was analyzed several different ways. Using MATLAB, a computational analysis of stresses and forces performed. The performance of this design was also evaluated using FEA. To help evaluate the performance of a stent design, an atherosclerotic arterial model was created in ANSYS. This model includes a plaque area that represents an average lesion. This model was validated by testing a stainless steel stent design with known performance and verifying the results. The CI-CNT stent designs can be easily inserted into this model and analyzed in ANSYS to predict their performance. A current stent design can also be explored using different material properties to see how it affects the results (for example, if the elastic modulus is 20 GPa instead of 10 GPa).

5.1.4 Blood Compatibility Testing

Information is needed to predict the biocompatibility of any medical device before it is implanted. The current studies on the blood compatibility of pyrolytic carbon were researched and summarized. Methods for testing the blood compatibility of the CI-CNTs material used in the stent designs were determined. We collaborated with two blood compatibility testing laboratories including Ken Solen’s group at BYU, as well as Thrombodyne to perform testing. Blood compatibility testing has been and will continue to be tested and some of the results are included in this thesis.

5.2 Discussion

This thesis work presents a coronary stent design that has been developed, optimized, and tested. The hope of this research is that it will be used to develop a new stent product to improve medical treatments. An improved stent design could be used to save lives and improve quality of life. However, the performance of these designs must be examined critically to compare to existing coronary stents.
This research answers many questions about the performance of the CI-CNT stent designs. There are two open questions that this research partially addressed but are worthy of further research: how much radial force is enough, and is the blood compatibility good enough. These two questions are critical to stent success and are discussed in the following sections.

5.2.1 How Much Radial Force is Enough?

The primary function of a stent is to prevent the artery from closing off following balloon angioplasty. When the artery is closed off quickly (heart attack) it is highly fatal. If the artery closes off slowly (restenosis) then the artery will need to be revascularized. This is a non-fatal but unfavorable outcome, and currently occurs in a significant percentage of procedures.

As described in the background section, restenosis is caused by three factors: elastic recoil of the artery following balloon expansion, negative remodeling of the artery causing the arterial ID to shrink, and intimal tissue growth further occluding the vessel. However, our current understanding of the relative extent that each of these three factors contributes to restenosis is incomplete. In general, existing coronary stents have made substantial progress in addressing the first two causes, although they often have difficulty preventing intimal hyperplasia.

The TMF stent design was optimized to provide as much radial force as possible to keep the artery open within the design space described previously. However, the lower material toughness (strain energy to failure) of the CI-CNT material constrains the magnitude of elastic recoil resisted by the TMF design. The magnitude of radial force required to maintain sufficient vessel lumen is currently unknown. It is likely that the TMF design will outperform existing stents in preventing intimal tissue growth. Implanting the TMF stent will also be less traumatic to the coronary artery which will further reduce the intimal hyperplasia response.

If future work determines that higher radial force is needed to maintain the lumen of the blood vessel, there are opportunities to improve the CI-CNT material properties. It is likely that with improved manufacturing processes the elastic modulus and strength of the CI-CNT material could be improved, increasing the stent radial force. Also, in future research, carbon nanotubes could be aligned in multiple directions which would greatly increase the stiffness and strength of CI-CNTs. Another approach for improving radial force may be in developing alternative design
concepts that include a locking mechanism to provide greater force (some of these are presented in Chapter 4 and in the Appendix A of this thesis).

In many cases, existing stents appear to have more radial force than is necessary to keep an artery open. In most cases, balloon angioplasty alone prevents restenosis due to the small amount of negative remodeling and intimal hyperplasia that occurs. In all cases, balloon angioplasty alone prevents restenosis for short duration. If the stent could remain in this open state permanently there would be no complications. This indicates that even if a stent does not fully prevent artery elastic recoil, if it can eliminate negative remodeling and intimal hyperplasia it will prevent restenosis. It is possible that this design or similar designs will be best used in targeted applications in coronary stenting, and possibly in other vascular areas.

5.2.2 Is the Blood Compatibility Good Enough?

The blood compatibility of the CI-CNTs is critical for stent performance. Initial blood compatibility testing indicates that the CI-CNT material has similar properties to stainless steel. Also, these tests have shown that the blood compatibility of the CI-CNT material is sensitive to manufacturing technique. The most recent set of tests (Group 3) confirms that the material may be able to outperform stainless steel by a significant margin. However, there is still substantial work to be done before the potential for blood compatibility improvements can be determined.

The majority of coronary stents used currently are drug-eluting stents. Drug-eluting stents are an active material releasing anti-thrombic drugs locally to inhibit the blood’s response and improve compatibility. In general, it is difficult for a passive material such as CI-CNTs to compete with an active material. However, it is possible to improve the biocompatibility of CI-CNTs in ways that cannot be done to stainless steel or other stent materials. One unique advantage that CI-CNTs have is the ability to be infiltrated with polymers including drug-eluting resorbable polymers due to the porous nature of CI-CNTs. Bare-metal stents do not have this ability. They can only be coated with a polymer that will wear off and eventually disappear. This ability to be infused with anti-thrombic resorbable polymers could lead to a major advantage over bare-metal stents.

It is also possible to drastically improve the blood compatibility of CI-CNTs using a process similar to the electrically treated pyrolytic carbon described in Chapter 3. This relatively new technology developed to manufacture stent geometries made of CI-CNTs combined with the
recent technique of improving blood compatibility could produce a vascular stent capable of out-performing any other stent in targeted applications. However, the technique for improving blood compatibility is not fully developed, and additional research would be required to investigate this potential.

5.3 Conclusion

This research has produced a promising CI-CNT stent design, along with methods to predict the performance of various stent geometries. Initial mechanical testing and blood compatibility studies are encouraging. There is also information provided on stent performance requirements, along with research on the necessary blood compatibility. Additional research in both design and blood compatibility are needed before commercialization of CI-CNT stent technology.
REFERENCES


Figure A.1: Stent segments can be connected in-line with each other, or in an opposite configuration.
Figure A.2: It may be possible to use stainless steel struts to plastically expand the stent but use PyC to hold contact the arterial wall.
Figure A.3: It may be beneficial to connect stent segments sideways, or to use two thinner connections.
Figure A.4: It may be possible to have locking design that has multiple sizes using a sort of staircase design.
APPENDIX B.  BASIC STENT ANALYSIS MATLAB CODE

% Darrell Skousen
% Stent Segment Analysis
clc
clear

%Input Parameters
theta = [30]*pi/180;
R = [.05]*10^-3;
phi = [80]*pi/180;
L = [1]*10^-3;
thick = [25]*10^-6;
depth = .025E-3;

%Test Parameters
F = .405E-3;

for i = 1:1
  for j = 1:1
    for k = 1:1
      for m = 1:1
        for n = 1:1
          %Calculated Parameters
          phi2(i,k) = theta(i) - 2*phi(k) + pi;
          phi3(i,k) = phi(k) - theta(i)/2;
          phi4(i,k) = 2*pi - phi2(i,k);
          phi5(i,k) = pi/2 - phi2(i,k)/2;
          alpha2(i,k) = phi4(i,k) - phi5(i,k);
          alpha1(i,k) = -phi5(i,k);
          L1(i,m) = L(m)/2*cos(theta(i)/2);
          % Mc(i,m) = F*L1(i,m);
          Mc(i,m) = F*L(m)/2;
          cp(i,k) = cos(phi5(i,k));
          sp(i,k) = sin(phi5(i,k));
          int(i,k) = phi4(i,k)/2;
          I(n) = depth*thick(n)^3/12;

68
E = 10E9;
A(n) = depth*thick(n);

% Calculate deflection of circle
Dc(i,j,k,m,n) = F*R(j)/(E*A(n))*(cp(i,k)^2*(int(i,k)/2-sin(2*int(i,k))/4)+2*sp(i,k)*cp(i,k)*(-cos(int(i,k)))-sin(int(i,k))^2/2)...% +sin(2*int(i,k))/2-Mc(i,m)*cp(i,k)*cos(int(i,k))+Mc(i,m)*sp(i,k)*(int(i,k)-sin(int(i,k)))+2*sp(i,k)*cp(i,k));

Dc1 = F*R/(E*A)*(cp^2*(int/2-sin(2*int)/4)-2*sp*cp*(sin(int)^2/2)+sp^2*(int/2+sin(2*int)/4))...
+sin(2*int/2)+sp^2*(1.5*int-2*sin(int)+sin(2*int)/2)+Mc/(F*R)*cp*cos(int)-Mc/(F*R)*sp*(int-sin(int));

Dc2 = -(F*R/(E*A))*2*sp*cp+(F*R^3/(E*I))*Mc/(F*R)*cp;

Dc = -(Dc1-Dc2);

alpha_t(i,j,k,m,n) = Dc(i,j,k,m,n)/R(j);
alpha_degrees(i,j,k,m,n) = alpha_t(i,j,k,m,n).*180/pi

% check alpha_t
Mf=F*(L(m)/2+R(j));
Ro(i,m,n) = E*I(n)/Mf(i,m);
Lr(i,j,k) = R(j)*phi4(i,k)/2;
alpha_tm(i,j,k,m,n) = Lr(i,j,k)/Ro(i,m,n);
alpha_tm_deg(i,j,k,m,n) = Lr(i,j,k)/Ro(i,m,n)*180/pi

% Parameters for beam deflection
beta(i,j,k,m,n) = theta(i)/2-alpha_t(i,j,k,m,n);
Lp(m) = L(m)/2;
nn(i,j,k,m,n) = tan(beta(i,j,k,m,n));
phi_p(i,j,k,m,n) = beta(i,j,k,m,n) + pi/2;
ktheta = 2.65;
syms var
expr(i,j,k,m,n) = var - F*sin(phi_p(i,j,k,m,n)-var)*Lp(m)^2/(E*I(n)*ktheta);
thetaC(i,j,k,m,n) = solve(expr(i,j,k,m,n),var);
gamma(i,j,k,m,n) = (.8521 - .01829*nn(i,j,k,m,n));
c(i,j,k,m,n) = gamma(i,j,k,m,n)*Lp(m)*(1-cos(thetaC(i,j,k,m,n)));
b(i,j,k,m,n) = gamma(i,j,k,m,n)*Lp(m)*sin(thetaC(i,j,k,m,n));
Dp(i,j,k,m,n) = (c(i,j,k,m,n)^2 + b(i,j,k,m,n)^2)^.5;
beta_p(i,j,k,m,n) = tan(c(i,j,k,m,n)/b(i,j,k,m,n));
\[ Db(i,j,k,m,n) = Dp(i,j,k,m,n) \cdot \cos(\beta(i,j,k,m,n) - \beta_p(i,j,k,m,n)) \]
\[ \text{Db}(i,j,k,m,n) = \text{double}(\text{Db}(i,j,k,m,n)) \]
\[ Db_{\text{check}}(m,n) = F \cdot Lp(m)^3 / (3 \cdot E \cdot I(n)) \]
\[ \text{angle}_{\text{check}}(m,n) = F \cdot Lp(m)^2 / (2 \cdot E \cdot I(n)) \cdot 180 / \pi \]
\% Deflection due to angular deflection
\[ \theta_{\text{v}}(i,j,k,m,n) = \theta(i) / 2 - \alpha_t(i,j,k,m,n) \]
\[ \theta_{\text{v}}(i,j,k,m,n) = \theta(i) / 2 - \alpha_{tm}(i,j,k,m,n) \]
\[ \text{Dt}(i,m) = Lp(m) \cdot \sin(\theta(i) / 2) \]
\[ \text{Lt}(i,m) = Lp(m) \cdot \cos(\theta(i) / 2) \]
\[ \text{Lh}(i,j,k,m,n) = \text{Lt}(i,m) / \cos(\theta_{\text{v}}(i,j,k,m,n)) \]
\[ \text{Dv}(i,j,k,m,n) = \text{Lh}(i,j,k,m,n) \cdot \sin(\theta_{\text{v}}(i,j,k,m,n)) \]
\[ \text{Da}(i,j,k,m,n) = \text{Dt}(i,m) - \text{Dv}(i,j,k,m,n) \]
\[ \text{D1}(i,j,k,m,n) = \text{Da}(i,j,k,m,n) + \text{Db}(i,j,k,m,n) + \text{Dc}(i,j,k,m,n) \]
\[ \text{D4}(i,j,k,m,n) = \text{D1}(i,j,k,m,n) \cdot 4 \]
\% Stress
\[ Lm(j,m) = Lp(m) + 2 \cdot R(j) \]
\[ Lm(j,m) = Lp(m) + R(j) + R(j) \cdot \sin(\phi_4 / 2 - \pi / 2) \]
\[ M(j,m) = F \cdot Lm(j,m) \]
\[ \text{stress}_{\text{straight}}(j,m,n) = M(j,m) \cdot \text{thick}(n) / (2 \cdot I(n)) \]
\% Length ratios
\[ D_{\text{max}}(i,j,m) = 2 \cdot L(m) \cdot \sin(\theta(i) / 2) + 4 \cdot R(j) \cdot \sin(\theta(i) / 2) \]
\[ D_{\text{min}}(j) = 4 \cdot R(j) + 2 \cdot \text{thick}(n) \]
\[ D_{\text{ratio}}(i,j,m) = \text{Dmax}(i,j,m) / \text{Dmin}(j) \]
\[ D_{\text{comp}}(i,j,k,m,n) = (\text{Dmax}(i,j,m) - \text{D4}(i,j,k,m,n)) / \text{Dmax}(i,j,m) \]
\% Curved Beam Stress
\[ dA(r,n) = \text{depth} \cdot \log((R(j) + \text{thick}(n) / 2) / (R(j) - \text{thick}(n) / 2)) \]
\[ \text{rn}(j,n) = A(n) / dA(r,n) \]
\[ e(j,n) = R(j) - \text{rn}(j,n) \]
\[ \text{rt}(j,n) = R(j) + \text{thick}(n) / 2 \]
\[ \text{rc}(j,n) = R(j) - \text{thick}(n) / 2 \]
\[ \text{stresst}(j,m,n) = -M(j,m) \cdot (\text{rn}(j,n) - \text{rt}(j,n)) / (A(n) \cdot e(j,n) \cdot \text{rt}(j,n) - F / A(n)) \]
\[ \text{stressc}(j,m,n) = -M(j,m) \cdot (\text{rn}(j,n) - \text{rc}(j,n)) / (A(n) \cdot e(j,n) \cdot \text{rc}(j,n) - F / A(n)) \]
\% Optimize
\[ \text{Opt}(i,j,k,m,n) = D_{\text{comp}}(i,j,k,m,n) \cdot (\text{stresst}(j,m,n)) \cdot \text{Lm}(j,m) \]
end
end
end
end
stresst
stressc
D4
APPENDIX C. ANSYS CODE

C.1 TMF Stent Cylindrical Analysis

/CWD,'C:\Users\Darrell\Dropbox\Thesis\Thesis J'
FINISH
/clear
/PREP7
ET,1,SOLID185
MPTEMP,,,,,,,
MPTEMP,1,0
MPDATA,EX,1,,12.5E9
MPDATA,PRXY,1,,.3

~PARAIN,'Stent tapered curved select_b’,’x_t’,.SOLIDS,0,0
VSWEEP,1,20,39

FINISH

/SOLU
DA,100,UX,
DA,7,UZ,
DL,280, ,UY,
DL,8, ,UY,

SFA,20,1,PRES,25000
NLGEOM,ON
SOLVE

FINISH

/POST1
/DSCALE,1,1.0
/EFACET,1
C.2 TMF Stent Flat Analysis

/CWD,'C:\Users\Darrell\Dropbox\Thesis\Thesis J'
FINISH
FINISH
/clear
/PREP7
ET,1,SOLID185
MPTEMP,,,,,,,,
MPTEMP,1,0
MPDATA,EX,1,,10E9
MPDATA,PRXY,1,,.3
~PARAIN,'Stent tapered select_c','x_t',,SOLIDS,0,0
/NOPR
/GO
ESIZE,.000015,0,
CM_,_Y,VOLU
VSEL, , , , 1
CM_,_Y1,VOLU
CMSEL,S_,_Y
VSWEEP,_Y1
CMDELE_,_Y
CMDELE_,_Y1
CMDELE_,_Y2
finish

!Set boundary conditions and loads
/SOL
FLST,2,1,4,ORDE,1
FITEM,2,155
/GO
DL,P51X, ,UX,
FLST,2,1,4,ORDE,1
FITEM,2,155
/GO
DL,P51X, ,UY,
FLST,2,1,4,ORDE,1
FITEM,2,155
/GO
DL,P51X, ,UZ,
FLST,2,1,4,ORDE,1
C.3 Stent Basic Segment Analysis

!/CWD,’C:\Users\Darrell\Dropbox\Thesis\Thesis J’
FINISH
/clear
/Prep7
ET,1, SOLID186
!ET,1,SOLID187
MPTEMP,,,,,,,
MPTEMP,1,0
MPDATA,EX,1,,10E9
MPDATA,PRXY,1,,.3

!Define Parameters
pi=acos(-1)
theta=30*pi/180
rad=.05E-3
phi=80*pi/180
len=1E-3
thk=.025E-3
phi2=theta-2*phi+pi
ff=.05E-3
deep=.0125E-3
!Create Geometry
k,1,0,0,0
k,2,sin(theta/2)*len/2,-cos(theta/2)*len/2,0
KWPAVE,2
CSYS,4
k,3,rad*sin(phi2/2)*2,0,0
k,4,rad*sin(phi2/2),-rad-cos(phi2/2)*rad,0
LSTR,1,2
LARC,2,4,1,rad,
KWPAVE,3
CSYS,4
k,5,sin(theta/2)*len,cos(theta/2)*len,0
LARC,3,4,5,rad,
LSTR,3,5
KWPAVE,5
CSYS,4
k,6,rad*sin(phi2/2)*2,0,0
k,7,rad*sin(phi2/2),rad+rad*cos(phi2/2),0
KWPAVE,6
CSYS,4
k,8,sin(theta/2)*len/2,-cos(theta/2)*len/2,0
CSYS,0
WPAVE,0,0,0
CSYS,0
LARC,5,7,3,rad,
LARC,6,7,8,rad,
LSTR,6,8
LPLT
k,9,-cos(theta/2)*thk/2,-sin(theta/2)*thk/2,0
k,10,cos(theta/2)*thk/2,sin(theta/2)*thk/2,0
LSTR,9,1
LSTR,1,10
k,11,0,0,-deep
k,12,0,0,deep
LSTR,1,11
LSTR,1,12
ADrag,8,9,10
ADrag,8,9,11
AAdd,1,2,3,4
LFILLT,1,2,ff,,
LFILLT,3,4,ff,,
LFILLT,4,5,ff,,
LFILLT,6,7,ff,,
FLST,8,11,4

75
!Meshing Elements
ESIZE,thk/6
VSWEEP,12
!VMESH,12

FINISH
/SOL

dd=.4007*1E-3 !Deflection
!Fix one side
DL,13, ,UX,
DL,18, ,UX,
DL,13, ,UY,
DL,18, ,Uy,
DL,13, ,Uz,
DL,18, ,Uz,
DL,189, ,UX,-dd !Deflect other side
DL,191, ,UX,-dd
DL,189, ,Uy,
DL,191, ,Uy,
DL,189, ,Uz,
DL,191, ,Uz,

NLGEOM,ON !Turn on non-linear geometry
SOLVE
FINISH
/POST1
/DSCALE,1,1.0
PLNSOL, S,X, 0,1.0
C.4 TMF Stent Arterial Analysis

/CWD,'C:\Users\Darrell\Dropbox\Thesis\Thesis J'
FINISH
/clear
/PREP7
ET,1,SOLID185
MPTEMP,,,,,,,,
MPTEMP,1,0
!MPDATA,EX,3,,12.5E9
MPDATA,EX,3,,10E9
MPDATA,PRXY,3,,.3
!PP=25000
PP=20000
PP80=10.66E3
PP100=13.33E3
PP120=16.00E3

TB,HYPE,1,1,9,MOON
TBTEMP,0
TBDATA,,.019513E6,,,,
TBDATA,,,.02976E6,,

TB,HYPE,2,1,9,MOON
TBTEMP,0
TBDATA,,.04E6,,,,.003E6,
TBDATA,,,.02976E6,,

~PARAIN,'Arterial Model pyrolytic','x_t',,SOLIDS,0,0

VSEL,,,3
VATT,3,,1
VSWEEP,3,51,32
ALLSEL,ALL

VGLUE,1,2

ESIZE,.00015,0,

VSEL,,,1
VATT,1,,1
VSWEEP,1
ALLSEL,ALL
VSEL,,4
VATT,2,1
VSWEEP,4
ALLSEL,ALL

FINISH

/SOLU
!Nothing happening
DA,19,UX,
DA,126,UX,
DA,4,UX,
DA,112,UY,
DA,125,UY,
DA,2,UY,
DA,127,UZ,
DA,5,UZ,
DA,128,UZ,
DA,4,UZ,
LSWRITE,1,

!Arterial pressure added to 80 mmHg
SFA,7,1,PRES,PP120
NLGEOM,ON
LSWRITE,2,

!Arterial pressure added to 120 mmHg
SFA,7,1,PRES,PP120
LSWRITE,3,

!Arterial pressure down to 100 mmHg
SFA,7,1,PRES,PP120
LSWRITE,4,

!Compress stent
DL,304, UZ,
DL,32, UZ,
SFA,32,1,PRES,PP
LSWRITE,5,

DL,304, UZ, -.0025
DL,32, ,UZ,-.0025
LSWRITE,6,

FINISH

/PREP7
!*    
!*  
/COM, CONTACT PAIR CREATION - START
CM,_NODECM,NODE
CM,_ELEMCM,ELEM
CM,_KPCM,KP
CM,_LINECM,LINE
CM,_AREACM,AREA
CM,_VOLUCM,VOLU
/GSAV,cwz,gsav,,temp
MP,MU,3,
MAT,3
MP,EMIS,3,7.8860905221e-031
R,3
REAL,3
ET,2,170
ET,3,174
R,3,,,1.0,0.1,0.0,
RMORE,,,1.0E20,0.0,1.0,
RMORE,0.0,0.1.0,,1.0,0.5
RMORE,0.1.0,1.0,0.0,,1.0
KEYOPT,3,4,0
KEYOPT,3,5,0
KEYOPT,3,7,0
KEYOPT,3,8,0
KEYOPT,3,9,0
KEYOPT,3,10,2
KEYOPT,3,11,0
KEYOPT,3,12,0
KEYOPT,3,2,0
KEYOPT,2,5,0
! Generate the target surface
ASEL,S,,,32
CM,_TARGET,AREA
TYPE,2
NSLA,S,1
ESLN,S,0
ESLL,U
ESEL,U,ENAME,,188,189
NSLE,A,CT2
ESURF
CMSEL,S,_ELEMCM
! Generate the contact surface
ASEL,S,,,7
CM,_CONTACT,AREA
TYPE,3
NSLA,S,1
ESLN,S,0
NSLE,A,CT2 ! CZMESH patch (fsk qt-40109 8/2008)
ESURF
ALLSEL
ESEL,ALL
ESEL,S,TYPE,,2
ESEL,A,TYPE,,3
ESEL,R,REAL,,3
/PSYMB,ESYS,1
/PNUM,TYPE,1
/NUM,1
EPLTOP
ESEL,ALL
ESEL,S,TYPE,,2
ESEL,A,TYPE,,3
ESEL,R,REAL,,3
CMSEL,A,_NODECM
CMDEL,_NODECM
CMSEL,A,_ELEMCM
CMDEL,_ELEMCM
CMSEL,S,_KPCM
CMDEL,_KPCM
CMSEL,S,_LINECM
CMDEL,_LINECM
CMSEL,S,_AREACM
CMDEL,_AREACM
CMSEL,S,_VOLUCM
CMDEL,_VOLUCM
/GRES,cwz,gsav
CMDEL,_TARGET
CMDEL,_CONTACT
/COM, CONTACT PAIR CREATION - END
/MREP,EPLTOP
/SOLU

SFA,32,1,PRES,PP*1/2
C.5 Stainless Stent Cylindrical Analysis

/LWRITE,7,

SFA,32,1,PRES,0
LSWRITE,8,

LSSOLVE,1,8,1

FINISH
/POST1
/DSCALE,1,1.0
/EFACET,1

PLNSOL, S,1, 2,1.0

~/PARAIN,'stainless balloon',x_t,,SOLIDS,0,0
ESIZE,.00004,0,

CM,_,Y,VOLU
VSEL, , , , 1
CM,_,Y1,VOLU
CHKMSH,'VOLU'
CMSEL,S,_,Y
VSWEP,_,Y1
CMDELE,_,Y
CMDELE,_,Y1
CMDELE,_,Y2

FINISH
/SOL

DA,13,UX,
DA,30,UY,

DK,40, , , ,0,UZ, , , , ,
LSWRITE,1,

FLST,2,9,5,ORDE,8
FITEM,2,1
FITEM,2,11
FITEM,2,-12
FITEM,2,14
FITEM,2,24
FITEM,2,-26
FITEM,2,37
FITEM,2,-38
SFA,P51X,1,PRES,1.2E6
LSWRITE,2,

FLST,2,9,5,ORDE,8
FITEM,2,1
FITEM,2,11
FITEM,2,-12
FITEM,2,14
FITEM,2,24
FITEM,2,-26
FITEM,2,37
FITEM,2,-38
C.6  Stainless Stent Arterial Analysis

/CWD,'C:\Users\Darrell\Dropbox\Thesis\Thesis J'
FINISH
/clear
/PREP7
ET,1,SOLID185
MPTEMP,,,,,,
MPTEMP,1,0
MPDATA,EX,1,,201E9
MPDATA,PRXY,1,,.3
PP=2E6
pi=3.14159
TBDE,PLAS1,1,,,
TB,PLAS,1,1,9,MISO
TBTEMP,0
TBPT,,0,0
TBPT,,0.0016418,3.3E+008
TBPT,,0.005,3.5E+008
TBPT,,0.01,3.7E+008
TBPT,,0.03,4.2E+008
TBPT,,0.1,5.5E+008
TBPT,,0.2,6.75E+008
TBPT,,0.3,7.25E+008
TBPT,,0.4,7.5E+008

~PARAIN,’stainless balloon’,’x_t’,,SOLIDS,0,0

ESIZE,.00009,0,

ndiv=8
FLST,5,6,4,ORDE,6
FITEM,5,11
FITEM,5,-12
FITEM,5,33
FITEM,5,-34
FITEM,5,61
FITEM,5,-62
CM,_Y,LINE
LSEL, , , ,P51X
CM,_Y1,LINE
CMSEL,,_Y
LESIZE,_Y1, , ,ndiv, , , ,1

ndiv2=6
LESIZE,37, , ,ndiv2, , , ,1
LESIZE,29, , ,ndiv2, , , ,1
LESIZE,8, , ,ndiv2, , , ,1
LESIZE,14, , ,ndiv2, , , ,1
LESIZE,65, , ,ndiv2, , , ,1
LESIZE,57, , ,ndiv2, , , ,1

VSWEEP,1

!Import artery and plaque

TB,HYPE,2,1,9,MOON
TBTEMP,0
TBDATA,,.019513E6,,,
TBDATA,,,.02976E6,,,

TB,HYPE,3,1,9,MOON
TBTEMP,0
TBDATA,,,,.04E6,,,,.003E6,
TBDATA,,,,.02976E6,,,

!ET,2,SOLID185
!MPTEMP,,,,,,,
!MPTEMP,1,0
!MPDATA,EX,2,,1E9
!MPDATA,PRXY,2,,.3

!ET,3,SOLID185
!MPTEMP,,,,,,,
!MPTEMP,1,0
!MPDATA,EX,3,,1E9
!MPDATA,PRXY,3,,.3

~PARAIN,'Arterial Model_b','x_t',,SOLIDS,0,0

VGLUE,2,3
ESIZE,.00012
dd1=.00024
dd2=.00012

LESIZE,92,dd2, , , , , ,1
LESIZE,100,dd2, , , , , ,1
LESIZE,89,dd2, , , , , ,1
LESIZE,96,dd2, , , , , ,1

LESIZE,101,dd1, , , , , ,1
LESIZE,103,dd1, , , , , ,1
LESIZE,102,dd1, , , , , ,1
LESIZE,104,dd1, , , , , ,1

LESIZE,81,dd1, , , , , ,1
LESIZE,83,dd1, , , , , ,1
LESIZE,85,dd1, , , , , ,1
LESIZE,87,dd1, , , , , ,1

VSEL,,,,2
VATT,2,,1,0
VSWEEP,2

85
VSEL,,,,4  
VATT,3,,1,0  
VSEL, , , , 4  
VSweep,4  

ALLSEL, ALL  

/COM, CONTACT PAIR CREATION - START  
CM,_NODECM,NODE  
CM,_ELEMCM,ELEM  
CM,_KPCM,KP  
CM,_LINECM,LINE  
CM,_AREACM,AREA  
CM,_VOLUCM,VOLU  
/GSAV,cwz,gsav,,temp  
MP,MU,1,  
MAT,1  
R,3  
REAL,3  
ET,2,170  
ET,3,174  
KEYOPT,3,9,0  
KEYOPT,3,10,2  
R,3,  
RMORE,  
RMORE,,0  
RMORE,0  

! Generate the target surface  
ASEL,S,,,8  
ASEL,A,,,9  
ASEL,A,,,10  
ASEL,A,,,21  
ASEL,A,,,22  
ASEL,A,,,23  
ASEL,A,,,34  
ASEL,A,,,35  
ASEL,A,,,36  
CM,_TARGET,AREA  
TYPE,2  
NSLA,S,1  
ESLN,S,0  
ESLL,U  
ESEL,U,ENAME,,188,189  
NSLE,A,CT2  
ESURF
CMSEL,S,_ELEMCM

! Generate the contact surface
ASEL,S,,,45
CM,_CONTACT,AREA
TYPE,3
NSLA,S,1
ESLN,S,0
NSLE,A,CT2 ! CZMESH patch (fsk qt-40109 8/2008)
ESURF
ALLSEL
ESEL,ALL
ESEL,S,TYPE,,2
ESEL,A,TYPE,,3
ESEL,R,REAL,,3
/PSYMB,ESYS,1
/PNUM>Type,1
/NUM,1
EPLOT
ESEL,ALL
ESEL,S,TYPE,,2
ESEL,A,TYPE,,3
ESEL,R,REAL,,3
CMSEL,A,_NODECM
CMDEL,_NODECM
CMSEL,A,_ELEMCM
CMDEL,_ELEMCM
CMSEL,S,_KPCM
CMDEL,_KPCM
CMSEL,S,_LINECM
CMDEL,_LINECM
CMSEL,S,_AREACM
CMDEL,_AREACM
CMSEL,S,_VOLUCM
CMDEL,_VOLUCM
/GRES,cwz,gsav
CMDEL,_TARGET
CMDEL,_CONTACT
/COM, CONTACT PAIR CREATION - END
/MREP,EPLOT
/COM, CONTACT PAIR PROPERTIES - START
RMODIF,3,3,.2
RMODIF,3,4,0.1
KEYOPT,3,4,2
/COM, CONTACT PAIR PROPERTIES - END
/MREP,EPLOT
!*Define loads
!*First Step
FINISH
/SOL

DA,51,UY,
DA,40,UY,
DA,30,UY,
DA,13,UX,
DA,52,UX,
DA,42,UX,

DA,53,UZ,
DA,43,UZ,
DA,54,UZ,
DA,44,UZ,

FINISH
/PREP7

!FLST,4,2,1,ORDE,2
!FITEM,4,354
!FITEM,4,2855
!CP,1,UZ,P51X

FLST,4,154,1,ORDE,18
FITEM,4,514
FITEM,4,-553
FITEM,4,680
FITEM,4,-681
FITEM,4,701
FITEM,4,721
FITEM,4,760
FITEM,4,-761
FITEM,4,781
FITEM,4,801
FITEM,4,1182
FITEM,4,-1201
FITEM,4,1582
FITEM,4,-1601
FITEM,4,2865
FITEM,4,-2867
FITEM,4,2925
FITEM,4,-2987

88
CP,2,UZ,P51X
FLST,4,154,1,ORDE,4
FITEM,4,554
FITEM,4,-641
FITEM,4,2742
FITEM,4,-2807
CP,3,UZ,P51X

FINISH
/SOL

D,486, ,0, , ,UZ, , , ,
!D,354, ,0, , ,UZ, , , ,
!D,2855, ,0, , ,UZ, , , ,

PP2=100000
SFA,45,1,PRES,PP2*.133
NLGEOM,ON
LSWRITE,1,

SFA,45,1,PRES,PP2
dd=.1
SFA,24,1,PRES,PP*dd
SFA,25,1,PRES,PP*dd
SFA,14,1,PRES,PP*dd
SFA,1,1,PRES,PP*dd
SFA,12,1,PRES,PP*dd
SFA,11,1,PRES,PP*dd
SFA,37,1,PRES,PP*dd
SFA,38,1,PRES,PP*dd
SFA,26,1,PRES,PP*dd
LSWRITE,2,

dd=.5
SFA,24,1,PRES,PP*dd
SFA,25,1,PRES,PP*dd
SFA,14,1,PRES,PP*dd
SFA,1,1,PRES,PP*dd
SFA,12,1,PRES,PP*dd
SFA,11,1,PRES,PP*dd
SFA,37,1,PRES,PP*dd
SFA,38,1,PRES,PP*dd
SFA,26,1,PRES,PP*dd
LSWRITE,3,
dd= .9
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 4,

dd= 1
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 5,

dd= 0
SFA, 45, 1, PRES, PP2*.9
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 6,

dd= 0
SFA, 45, 1, PRES, PP2*.8
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 7,

dd=0
SFA, 45, 1, PRES, PP2*.7
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 8,

dd=0
SFA, 45, 1, PRES, PP2*.6
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 9,

dd=0
SFA, 45, 1, PRES, PP2*.5
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 10,
dd=0
SFA, 45, 1, PRES, PP2*.4
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 11,

dd=0
SFA, 45, 1, PRES, PP2*.35
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 12,

dd=0
SFA, 45, 1, PRES, PP2*.3
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA, 1, 1, PRES, PP*dd
SFA, 12, 1, PRES, PP*dd
SFA, 11, 1, PRES, PP*dd
SFA, 37, 1, PRES, PP*dd
SFA, 38, 1, PRES, PP*dd
SFA, 26, 1, PRES, PP*dd
LSWRITE, 13,

dd=0
SFA, 45, 1, PRES, PP2*.25
SFA, 24, 1, PRES, PP*dd
SFA, 25, 1, PRES, PP*dd
SFA, 14, 1, PRES, PP*dd
SFA,1,1,PRES,PP*dd
SFA,12,1,PRES,PP*dd
SFA,11,1,PRES,PP*dd
SFA,37,1,PRES,PP*dd
SFA,38,1,PRES,PP*dd
SFA,26,1,PRES,PP*dd
LSWRITE,14,

dd=0
SFA,45,1,PRES,PP2*.2
LSWRITE,15,

!NSUBST,400,0,0
SFA,45,1,PRES,PP2*.1333
LSWRITE,16,

!Solve
LSSOLVE,1,16,1,

FINISH
/POST1
/DSCALE,1,1.0