A Comparative Assessment of Deformation
Characteristics of Self-Expanding Venous Stents

by

Masoud Hejazi

B.Sc., Shiraz University, 2015

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF APPLIED SCIENCE

in

THE FACULTY OF GRADUATE AND POSTDOCTORAL STUDIES

(Mechanical Engineering)

THE UNIVERSITY OF BRITISH COLUMBIA

(Vancouver)

January 2018

© Masoud Hejazi, 2018
Abstract

Stents are medical devices that are widely used to treat vascular diseases through endovascular surgery. This minimally invasive surgery provides a faster recovery and fewer complications in comparison to other types of treatments. This device is available in various sizes and designs for deployment in a variety of blood vessels. The deformation characteristics of a stent contribute in a successful stent deployment and its long-term performance. A particular vascular disease and its location in the blood circulatory system require a stent with certain deformation characteristics. Accordingly, by studying these parameters for different stent designs, we can identify the most suitable stent for each type of disease.

The main objective of this thesis is to develop an analytical method that predicts the deformation characteristics of self-expanding venous stents. The presented analytical method in this thesis is desirable for design, optimization and comparative assessments with less computation time and cost in comparison to finite element simulation. The unit-cell study forms the framework of the presented analytical method, which allows the analysis of the radial pressure, compliance, and foreshortening. The developed analytical method relies on two critical stages: 1. Defining the deformation characteristics in terms of unit-cell deformation mechanism. 2. Correlating unit-cell deformation mechanism to strut bending mechanics. These two stages are respectively validated through axisymmetric FE simulation and unit-cell FE simulation. The precision and accuracy of the method were found acceptable. Collapse, another critical deformation mode, was studied through the axisymmetric FE simulation. The structural instability and compliance contribute to the collapse deformation.

Four different venous stent designs (Cook Vena, Cook Z, Luminexx, and Wallstent) are evaluated in terms of collapse, foreshortening, radial pressure, and compliance. Steel stents (Cook Z and Wallstent) are less compliant than Nitinol stents (Luminexx and Wallstent) and are more reliable to treat localized blood clots. The Nitinol stents are more efficient to be deployed close to body joints. Luminexx and Wallstent apply larger radial pressure and are the most reasonable choices for vital veins. If the final length of stent is critical (e.g. deployment close to branch orifice), Cook Z can be the best choice.
**Lay Summary**

Stents are medical devices that are widely used to treat artery and vein diseases. For the stent deployment, a surgery is performed through a small incision, which provides less complications and faster recovery. Due to the desirable clinical outcomes, stents are one of the most valuable medical devices that occupy a significant portion of market demand. These devices are available in various sizes and designs for deployment in variety of vessels. Most of the available designs in the market are off-labeled, which means that they are not specified to be used in a particular artery or vein. The stent deformation characteristics determine its clinical performance when the stent is deployed within a vessel. The present thesis investigates the deformation characteristics of four different stent designs to find the desirable features of these stents. Finally, the thesis introduces the capability of each design to treat different artery and vein diseases.
Preface

This thesis entitled “A Comparative Assessment of Deformation Characteristics of Self-Expanding Venous Stents” presents the original research conducted by Masoud Hejazi under the supervision of Prof. Sassani and Prof. Phani. The proposed methodology in this manuscript is original, unpublished and independent work by the author.
# Table of Contents

Abstract ................................................................................................................................. ii
Lay Summary .......................................................................................................................... iii
Preface .................................................................................................................................. iv
Table of Contents .................................................................................................................... v
List of Tables ............................................................................................................................ vii
List of Figures .......................................................................................................................... viii
List of Symbols ........................................................................................................................ x
Glossary ................................................................................................................................. xii
Acknowledgements ................................................................................................................ xiii
Introduction ............................................................................................................................ 1
  1.1 Motivation ......................................................................................................................... 1
  1.2 Venous Stenting ................................................................................................................. 4
    1.2.1 Anatomy and Physiopathology Challenges ................................................................. 4
    1.2.2 Mechanical Performance Challenges ........................................................................ 7
  1.3 Mechanics of Self-Expanding Stents ............................................................................... 10
  1.4 Research Objectives and Outlines .................................................................................. 16
The Analytical Unit-cell Study of Venous Stents ................................................................. 18
  2.1 Introduction ....................................................................................................................... 18
  2.2 Lattice Mechanics of Stent .............................................................................................. 19
  2.3 Analytical Approach to Study Expansion of Nitinol Stents ............................................. 25
    2.3.1 Analytical Solution Regarding Bending of Nitinol Stent ........................................... 25
    2.3.2 Nitinol Strut Bending (Cook Vena & Luminexx) ....................................................... 28
  2.4 Analytical Approach to Study Expansion of Steel Stents ............................................... 30
    2.4.1 Cook Z Strut Bending ................................................................................................. 30
    2.4.2 Wallstent Expansion ................................................................................................. 31
  2.5 Results and Discussion ................................................................................................... 33
  2.6 Conclusions ...................................................................................................................... 34
Unit-cell Study: Finite Element Analysis of Expansion of Self-Expanding Stents

3.1 Introduction .................................................................35
3.2 Simulation Parameters ..................................................35
3.3 FE Results and Comparison to Analytical Results ..................37
  3.3.1 Cook Vena ...............................................................38
  3.3.2 Luminexx ...............................................................40
  3.3.3 Cook Z .................................................................43
  3.3.4 Wallstent ...............................................................45
3.4 Discussions ....................................................................47
3.5 Conclusions ....................................................................51

Axisymmetric Finite Element Analysis of Stent Expansion ............52
4.1 Introduction .................................................................52
4.2 Method ..........................................................................53
4.3 Results ..........................................................................54
4.4 Discussions ....................................................................59
4.5 Conclusions ....................................................................62

Conclusions and Closing Remarks ...........................................63
  5.1 Conclusions of Present Work ..........................................63
  5.2 Limitations and Future Work ..........................................65
  5.3 Potential Applications ...................................................66
References ............................................................................67
List of Tables

Table 1.1: Different characteristics of Artery and Vein .................. 4
Table 2.1: Thermo-mechanical Properties of Nitinol ................... 27
Table 2.2: Mechanical Properties for steel ............................. 30
Table 3.1 Number of finite elements in a unit-cell (or wire for Wallstent)................................. 37
Table 4.1: Number of elements for axisymmetric FE simulation ...... 53
Table 4.2: Stents ranking, most suitable (1) to least suitable (4) ...... 61
List of Figures

Figure 1.1: Endovascular surgery procedure and devices .................... 2
Figure 1.2: Arteries and Veins differences ......................................... 3
Figure 1.3: Anatomy of the vein and the function of the venous valve ..... 5
Figure 1.4: Venous stenting procedure in five steps ............................ 6
Figure 1.5: Foreshortening of stent .................................................... 7
Figure 1.6: The collapse and recoil of the venous stent .......................... 10
Figure 1.7: The lattice structure of the stents ..................................... 11
Figure 1.8: Thermo-Mechanical behaviour of Nitinol ............................ 13
Figure 1.9: Shape Memory ability of Nitinol ....................................... 13
Figure 1.10: Candidate Stents .......................................................... 15
Figure 2.1: Mechanics of the stent unit-cell ...................................... 21
Figure 2.2: Expansion of stent, unit-cell and strut ............................... 23
Figure 2.3: Deflection curve of Nitinol beam .................................... 26
Figure 2.4: Cook Vena unit-cell and strut free body diagram ............... 29
Figure 2.5: The Luminexx unit-cell and strut free body diagram .......... 29
Figure 2.6: Cook z unit-cell and strut free body diagram ..................... 31
Figure 2.7: Foreshortening characteristic of four candidate stents versus
the radial strain during expansion .................................................. 34
Figure 3.1: FE Unit-cell Boundary Condition ...................................... 36
Figure 3.2: Cook Vena Stress contour (Mises Stress (MPa)) ................. 38
Figure 3.3: Comparison of Bending Characteristic for Cook Vena
expansion ....................................................................................... 39
Figure 3.4: Radial Pressure for Cook Vena ........................................ 40
Figure 3.5: Luminexx Stress contour (Mises Stress (MPa)) ................. 41
Figure 3.6: Shear angle in Luminexx ............................................... 41
Figure 3.7: Comparison of Bending Characteristic for Luminexx
expansion ....................................................................................... 42
Figure 3.8: Radial Pressure for Luminexx ........................................ 43
Figure 3.9: Cook Z Stress contour (Mises Stress (MPa)) ..................... 44
Figure 3.10: Comparison of Bending Characteristic for Cook Z
expansion ....................................................................................... 44
Figure 3.11: Radial Pressure for Cook Vena ..................................... 45
Figure 3.12: Wallstent Stress contour (Mises Stress (MPa)) ............... 46
Figure 3.13: Radial Pressure for Wallstent ....................................... 46
Figure 3.14: Final Values of Foreshortening .................................... 49
Figure 3.15: Radial Pressure of all Stents (Analytical Unit-cell study) .... 49
Figure 3.16: Compliance of all Stents (Analytical Unit-cell study) ……… 51
Figure 4.1: Axisymmetric FE simulation Boundary Conditions ………… 53
Figure 4.2: Schematic of collapse FE simulation …………………… 54
Figure 4.3: Cook Z Radial pressure Vs Diameter …………………… 55
Figure 4.4: Cook Vena Radial pressure Vs Diameter ………………… 55
Figure 4.5: Luminexx Radial pressure Vs Diameter ………………… 56
Figure 4.6: Force versus collapse displacement ratio ………………… 57
Figure 4.7: FE simulation for Cook Vena Collapse ………………… 57
Figure 4.8: FE simulation for Luminexx Collapse ………………… 58
Figure 4.9: FE simulation for Wallstent Collapse ………………… 58
Figure 4.10: FE simulation for Cook Z Collapse ………………… 59
Figure 4.11: Recommended venous stents for different locations ……… 62
## List of Symbols

- $A^{of}$: Austenite final temperature (K)
- $A^{os}$: Austenite start temperature (K)
- $C$: Compliance (1/MPa)
- $D$: Diameter of the stent (mm)
- $E^A$: Austenite elastic modules (GPa)
- $E^M$: Martensite elastic modules (GPa)
- $F_s$: Strut force (N)
- $F_\theta$: Bending force (N)
- $H^c$: Constant of Nitinol phase transformation
- $l$: Length of the strut (mm)
- $L$: Total length of the stent (mm)
- $M^{os}$: Martensite start temperature (K)
- $M^{of}$: Martensite final temperature (K)
- $M_\theta$: Joint Moment in the circumferential direction
- $M_r$: Joint Moment in the radial direction
- $n_c$: Number of circumferential unit-cells
- $n_a$: Number of axial unit-cells
$P$  Radial Pressure (Pa)

$P_s$  Strut Pressure (Pa)

$t$  Thickness of the strut (mm)
## Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
<td>Balloon Expandable</td>
</tr>
<tr>
<td>FE</td>
<td>Finite Element</td>
</tr>
<tr>
<td>FEA</td>
<td>Finite Element Analysis</td>
</tr>
<tr>
<td>SE</td>
<td>Self-expanding</td>
</tr>
<tr>
<td>SMA</td>
<td>Shape Memory Alloy</td>
</tr>
<tr>
<td>UC</td>
<td>Unit-cell</td>
</tr>
</tbody>
</table>
Acknowledgements

First of all, I would like to express my sincere gratitude to my supervisors, Professor Sassani and Prof. Phani, for all their solid support, precious advice, and warm friendship. Prof. Sassani means to me more than a supportive supervisor, he is truly my older wise friend and a father not only for me but also for all of his international students when they are far from their family. Meeting Dr. Phani was one of my greatest pleasures, he taught me how to always look at a bigger picture. He also provides me the requirements to conduct a biomedical piece of research, which has always been one of my dreams.

I would also like to thank other faculty members at UBC, particularly Dr. Joël Gagnon, who generously spending time with me and providing me with his constructive advice.

I would like to extend my gratitude to my friends and colleagues Mr. Masoud Haghi Kashani and Mr. Abbas Hosseini who helped to evolve this project.

On top of that, my special thanks belong to my lovely parents, my brother and my best friend Sahba Mozaffarian, who unconditionally and wholeheartedly supported me throughout my life by providing me with endless love, enthusiastic encouragement, and lifelong dedication.
“Parents were the only ones obligated to love you; from the rest of the world you had to earn it.” Ann Brashares.

In dedication to my beloved Parents
Chapter 1

Introduction

1.1 Motivation

Vascular stents are small mesh-like tubes, which are placed inside diseased blood vessels to retrieve their healthy function. The stent can be treated as a lattice, where a geometric unit-cell is repeated in the circumferential and axial directions of a cylindrical stent [1]. Since the physiology and the structure of different vessels are not identical, each stent is precisely designed for a specific type of vessel and its related disease to provide a more efficient deployment through endovascular surgery. This minimally invasive surgery provides faster recovery and fewer complications. The desirable outcomes of endovascular surgery have drawn more attention to stent design and applications over the past decade.

The surgery starts with a small incision in wrist, arm or leg followed by inserting a guidewire that will be navigated inside the blood vessel to the diseased area (Figure 1.1). The delivery device includes a sheath, the stent, and a balloon. The two major categories of stents are balloon-expandable and self-expanding stents. As shown in Figure 1.1, the inflating balloon applies pressure on the interior surface of the stent and deploy the balloon-expandable stent in place, on the other hand, the self-expanding stent will expand automatically after uncovering the sheath on its exterior surface. The residual stresses and shape memory characteristic of the self-expanding stent are responsible for the expansion.
1.1 Motivation

Figure 1.1: Endovascular surgery procedure and devices. a) Stent entry locations, b) Self-expanding Stent, c) Balloon-expandable Stent. Open access images from Cook Medical INC.

The vein and artery are two major categories of blood vessels and have different functions and mechanical properties (Figure 1.2 and Table 1.1). These differences arise due to their physiological functions and histological structure. For instance, the artery has more flow rate and its function is to carry the blood to the organs, on the other hand, vein plays the role of a reservoir for blood circulatory system.

Based on the mechanical properties, anatomy and the physiology of the vessel, its corresponding stent has to meet requirements for safe performance. The biological and mechanical response of a vessel to its stent is another fact that should be considered for long-term performance of the stent. Venous stents are designed for venous disease treatment, and in comparison to arterial stents, the venous stent has not been sufficiently investigated. The required properties for venous stents are not necessarily same as an arterial stent. Thus, it is not always effective to treat a venous disease by an arterial stent. This thesis studies the mechanical features of four popular types of venous stents and introduces a new approach toward studying mechanics of self-expanding stents. Currently, Finite Element Analysis (FEA) is the most popular method to analyze the expansion of
self-expanding stents. Knowing the fact that designing a new device sometimes requires a large number of numerical simulations, FEA is not an efficient method in terms of computation time and cost. Consequently, a new method, which can be less expensive, easier to employ, and more time efficient, is desirable. Analytical method can be an appropriate alternative approach, which has faster computation time and is easier to be used in various coding software.

Figure 1.2: Arteries and Veins differences. a) Anatomy, b) Elasticity, c) Blood flow, d) Structure. [2]
Table 1.1: Different characteristics of Artery and Vein.

<table>
<thead>
<tr>
<th></th>
<th>Vein</th>
<th>Artery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (mmHg)</td>
<td>5-10</td>
<td>80-120</td>
</tr>
<tr>
<td>Blood Flow</td>
<td>Steady</td>
<td>Pulsatile</td>
</tr>
<tr>
<td>Structure</td>
<td>Compliant</td>
<td>Stiff</td>
</tr>
</tbody>
</table>

1.2 Venous Stenting

1.2.1 Anatomy and Physiopathology Challenges

The venous system of a human body refers to the veins that drain into the right side of the heart. At any given moment, almost 70 percent of the blood is in the venous system. Accordingly, the venous system in addition to carrying blood to the heart, play the role of a reservoir [2]. Veins are very compliant which means that they are capable of accommodating substantial volume expansion (Figure 1.2). Naturally, a vein experiences significant volume variation during daily activities such as dehydration and hydration of the body. If the stent expansion fails to cover the expansion of the vein (i.e., the vein expands more than its stent), the contact between stent and vessel wall will be lost, and the blood flow causes the stent migration (undesirable displacement of the stent after surgery) [3, 4]. Therefore, the expansion rate of the stent must at least cover the natural expansion rate of the vessel.

The structure of blood vessels consists of three biological layers: Tunica Adventitia, Tunica Media (the thickest layer) and Tunica Intima (the thinnest layer) respectively from outside to inside (Figure 1.3). The Tunica Media (the
1.2 Venous Stenting

A muscular layer that structured by elastic fiber represents the mechanical properties of the vessel. It is significantly less muscular in veins in comparison to arteries, and it provides distensibility of the vein. Since the stent has a direct contact with the blood substance and Tunica Intima, the blood-stent and Tunica Intima-stent chemical interactions are another design restriction. By conducting in vivo experiments, Palmaz demonstrated that the concentration of the stent alloy (or oxide of the alloy) in the blood could reach a toxic limit and the stresses that applied to the vessel by the deployed stent causes hyperplasia (the unnatural enlargement of the vessel) [5].

![Diagram of the vein and venous valve](image)

**Figure 1.3:** Anatomy of the vein and the function of the venous valve. Above: the venous valve open. Below: the venous valve close. Open Source figure from Wikipedia.

The venous valve (one way flaps that periodically occupy interiors of the vein) acts as a check valve to guarantee the unidirectional blood flow to the heart (Figure 1.3). The deployment of the venous stent will interrupt the function of the venous valve and cause deep reflux disease [6]. The deep reflux disease, also known as venous insufficiency, is a medical condition affecting the circulation of blood in the lower extremities. This adverse influence of venous stenting has not been addressed yet, and it seems that it does not have any solution. This is
because of the fact that it is highly possible to deploy a stent close to the venous valve. It is worth noting that almost 40% of patients suffer from deep reflux after venous stenting [6].

Thrombosed vein is one of the disease, which is typically treated through stent deployment (Figure 1.4). Thrombosis is a common venous disease referred to the formation of a blood clot within a vein. When a blood vessel is injured, the body attempt to form a blood clot at injury location to prevent blood loss. Even when the blood vessel is not injured, the blood clot may form in the body under certain conditions. The blood clot obstructs the blood flow through the circulatory system. The thrombosis is a serious disease, and its fatality and incidence rate is respectively 0.117% and 12% among normal population [7, 8]. Retrieving the blood flow requires endovascular surgery and venous stenting. In some cases, the surgeon extracts the blood clot through endovascular surgery, but the more preferred procedure is to deploy a venous stent. The stent pushes the blood clot against the vein wall and makes the lumen wide open. See Figure 1.4.

Figure 1.4: Venous stenting procedure in five steps (1 to 5). Open source image from www.pinterest.com.
1.2.2 Mechanical Performance Challenges

Venous stenting has a number of challenges. First, the stent must cover the entire thrombosed region; otherwise, the treatment is not complete. This challenge at the first stage may seem not an issue, but considering stent expansion mechanism, will change this assumption. Usually, when stent starts its expansion, the length of the stent will change, and at the final stage of the deployment, it may deviate significantly from the initial length (Figure 1.5). Shrinking in length of the stent weakens the precision of the surgery and in some cases, requires the deployment of another stent. Regarding this characteristic, foreshortening parameter is defined as the percentage change of stent length (Equation (1.1)) [9]. According to the stent structure, the length of the stent may also become longer during expansion, which can connect additional healthy regions of the vessel to the stent. This performance is not desirable because of the fact that a stent is a foreign object to the body and it is more appropriate to minimize the interaction region between the stent and the vessel.

![Figure 1.5: Foreshortening of stent. a) Initial stage, b) Deployed stage; Initial length ($L_0$), Deployed length (L)](image)
1.2 Venous Stenting

Foreshortening = \( \frac{L_0 - L}{L_0} \times 100 \) \hspace{1cm} (1.1) \[9\]

Tan et al. investigated the influence of the stent unit-cell geometry on foreshortening of balloon-expandable stents \[9\]. They conducted expansion test on different types of stents that had different geometrical unit-cells. Among six different stents, four had positive foreshortening (stent length decreased during expansion), and two of them had negative foreshortening (stent length get longer during expansion). Douglas et al. introduced kinematic, Finite Element and analytical methods to study the expansion mechanism of the stent \[10\]. They also employed these methods to predict the foreshortening of the same six stents in Tan et al. work and compared them to experimental results.

The second challenge in venous stenting is the vein compliance. The compliance is defined to examine the correlation between pressure variation and diameter change (Equation (1.2)).

\[
C = \frac{D_2 - D_1}{D_1 (P_2 - P_1)} \hspace{1cm} (1.2)
\]

In this equation, \( C \), \( D_1 \), \( D_2 \), \( P_1 \), \( P_2 \) are respectively compliance, initial diameter, final diameter, initial pressure and final pressure. As shown by Morris et al., who conducted an in vitro experiment on an Abdominal Aortic Aneurysm, the compliance mismatch is a contributing factor in stent migration \[11\]. Berry et al. investigated the advantages of compliance matching on arterial self-expandable stents \[12\]. By employing Finite Element Method, they concluded that matching compliance would improve the long-term performance of an arterial stent.

The venous stent applies pressure to the thrombosed vein to overcome the blood clot blockage and opens the occluded section. The pressure applied to the vein should be high enough to push against the blood clot but should not be too
large to avoid vein rupture. Archie and Green studied the vein rupture pressure and found a linear correlation between vein diameter and its rupture pressure \[13\]. Freeman et al. studied the optimal radial pressure for arterial stents and the influence of radial pressure on the biological response of the vessel \[14\]. The radial strength of the stent is highly related to the geometrical parameters such as thickness, length and the connections of the stent links; Snowhill et al. studied the correlation between these parameters and the radial pressure \[15\]. The radial pressure can affect the vessel wall mechanics, and the design parameters are contributing factor to the stress distribution on the vein wall. Bedoya et al. assessed the effect of stent design parameters on an artery wall and concluded that a uniform stress distribution on the vein wall is desirable to avoid the stress concentration and rupture \[16\].

The reaction pressure applied by vein and blood clot tend to recoil the stent (Figure 1.6). The recoil also may occure due to the spring-back effect of stent alloy after deployment \[10\]. As shown by Murphy et al. through clinical investigation, venous stents are more likely to experience collapse rather than recoil \[17\]. The stent collapse refers to the situation that reaction pressure of the vein clamps the stent (Figure 1.6). Furthermore, stents that are deployed in the veins near the body joints, especially knee, have to tolerate the natural deformation of the vein. The daily movement of body joints cause bending and torsion in the local veins, and if the stent experiences any buckling or failure, the patient should go under another surgery. Ghriallais and Bruzzi studied this issue through a Finite Element Analysis for the femoral artery close to knee \[18\].
1.3 Mechanics of Self-Expanding Stents

Figure 1.6: The collapse and recoil of the venous stent. a) Before stenting, b) Desirable stented vein, c) Recoil, d) Collapse

1.3 Mechanics of Self-Expanding Stents

Figure 1.7 depicts a generic structure of a stent. It is obvious that there is a geometrical unit-cell which can be repeated circumferentially and longitudinally to form the entire structure of the stent. This characteristic provides the chance to assume the stent as a lattice, which makes it possible to study the mechanical properties of a single unit-cell and generalize it to the entire structure by the aid of proper boundary conditions. In the balloon-expandable stents, the pressure of the balloon forces the stent to expand, but self-expanding stents expand automatically -to the desirable final diameter- because of the residual stresses or shape memory characteristics of shape memory alloy.
1.3 Mechanics of Self-Expanding Stents

The manufacturing process of the self-expanding stents is as follows:

1. Fabricating the structure of the stent at the nominal working diameter by laser cutting technology or metal forming techniques
2. Cooling the structure to the desirable temperature for compressing
3. Compressing the stent to the diameter which is required to install on the delivery device (up to one-twentieth of the nominal diameter)
4. Covering the stent with the delivery device sheath to keep the stent at compressed diameter

The stent will be deployed later by uncovering the sheath inside the vein. The self-expanding steel stents are designed to work at the elastic limit of the steel. Consequently, the elastic deformation in their structure recovers the desirable diameter. For the Nitinol stents, however, the shape memory characteristic of the alloy is responsible for the large restorable deformation.

Figure 1.7: The lattice structure of the stents.
Nitinol is a metal alloy of Nickel and Titanium, which is available in austenite, martensite or a combination of both phases. Temperature and the state of stress are contributing factors in defining the phase of nitinol. For medical devices, the phase is martensite and austenite respectively for temperatures less than $5^\circ C$ and more than $35^\circ C$, when the stress components are zero. As shown in Figure 1.8, the phase transition from austenite to martensite provides two elastic phases for Nitinol. Figure 1.8a illustrates the loading and unloading stress-strain curves for Nitinol at $35^\circ C$.

Figure 1.8b depict the phase transition due to temperature variation. The $A^{os}$, $A^{of}$, $M^{os}$ and $M^{of}$ are respectively austenite start temperature, austenite final temperature, martensite start temperature and martensite final temperature. It should be noted that Figure 1.8a is only valid for the temperatures higher than $A^{os}(35^\circ C$ for medical devices). For the temperatures lower than $M^{os}$, the stress-strain curve is the same as ductile materials and nitinol experiences plastic deformations. However, it is possible to eliminate these permanent deformations if we increase the temperature up to $A^{os}$ again. In other words, although there is a large deformation and permanent strain at lower temperatures, it is possible to recover the original shape of the Nitinol. This characteristic provides shape memory ability (Figure 1.9). The Nitinol stents are fabricated at body temperature $37^\circ C$. They are compressed at a temperature less than $M^{os}$ (usually $5^\circ C$) and then are deployed at $37^\circ C$ to recover their original expanded shape.
1.3 Mechanics of Self-Expanding Stents

Figure 1.8: Thermo-Mechanical behaviour of Nitinol. a) Stress-strain Curve of Nitinol at $35^\circ C$. b) phase diagram of Nitinol. c) Stress-strain Curve of Nitinol at $5^\circ C$. d) Stress-strain Curve for shape memory effect

Figure 1.9: Shape Memory ability of Nitinol
1.3 Mechanics of Self-Expanding Stents

Nitinol stents have been studied in terms of fatigue failures, stent-vessel interaction and radial pressure and reported in the literature. A constitutive thermomechanical model is necessary for providing finite element framework. Bhattacharya studied the formation of martensite phase in the microstructure of shape memory alloys and its contribution to the shape memory effect [19]. Lagoudas et al. presented a thermos-mechanical constitutive model for Nitinol in detail [20]. Since the Nitinol material behaviour is not available in the material library of FE commercial software such as ABAQUS (Dassault Systemes Simulia Corp), it is required to develop a user material subroutine for finite element analysis of Nitinol. In this work, the ABAQUS user material subroutine (UMAT, Dassault Systemes Simulia Corp) has been written based on both Lagoudas et al. model and Auricchio-Taylor model [20] [21]. Jovicic et al. studied the fatigue of Nitinol arterial stents and introduced a computational method to predict the fatigue failure [22]. The influence of geometrical parameters on the radial pressure of self-expanding stents investigated by Garcia et al. [23]. They also proposed a brand new design for variable radial stiffness in stents; their stent radial stiffness varies along stent length to be more compatible with the radial stiffness of the vessel. Perrin et al. examined the factors and assumptions which should be taken into account for finite element analysis of self-expanding stents; they validated their model on three clinical cases [24]. Rebelo et al. provided the modeling assumption such as loading and boundary conditions for the unit-cell study of self-expanding stents; they also compared results of the unit-cell study to the full stent analysis in order to validate their assumptions [25].

The deformation characteristics, vessel-wall interaction and radial strength of self-expanding stents –especially arterial stents- has been investigated and reported in the literature. To study the mechanics of stents, most of the literature employed in-vitro experiments or finite element approach. The analytical
1.3 Mechanics of Self-Expanding Stents

approach is another method to study deformation characteristics of a stent. However, this approach mostly used for the balloon expandable ones. This is because of the fact that Nitinol mechanical behaviour (shape memory effect) brings some complications into the analytical study of mechanics of self-expanding stents, which are made of Nitinol. Consequently, there is a gap on analytical approach into the investigation of self-expanding stent mechanics. Another gap is revealed when we compare arterial and venous stents. While arterial stents have drawn more attention in the literature, investigation of venous stents seems to be overlooked. This thesis is composed to address these gaps with two essential objectives: 1. Studying deformation characteristics and the radial strength which contribute to the long-term performance of self-expanding venous stents, 2. Introducing an alternative approach toward investigating mechanics of self-expanding stents. We focus on four popular designs of self-expanding venous stents: Cook Vena, Luminexx, Cook Z and Wallstent (Figure 1.10).

Figure 1.10: Candidate stents. a) Cook Z, b) Wallstent, c) Cook Vena, d) Luminexx. Open source images from Bard PV, Cook Medical and Boston Scientific Co.
1.4 Research Objectives and Outlines

According to identified gaps among literature, this thesis study deformation characteristics and radial strength of self-expanding venous stents. In this study, we employ a new analytical method joint with finite element simulation. Furthermore, a comparative study of different venous stent design is considered in terms of the mechanics of the deformation characteristics and radial strength. The objectives of this research are defined as follows:

1. Defining an analytical approach toward studying mechanics of a self-expanding stent and its deformation characteristics
2. Validate the accuracy of the defined analytical method with finite element simulation of the stent expansion
3. Introduce the most efficient stent for different types of venous disease in various locations

Chapter 2 defines an analytical approach for analysing mechanics of self-expanding stents by treating a stent as a lattice structure. In this chapter, we define the deformation characteristics in terms of unit-cell deformation mechanism and also correlate unit-cell deformation mechanism to strut bending mechanics. Accordingly, the deformation characteristics of a stent is presented in terms of bending parameters of a unit-cell strut.

Chapter 3 employs finite element simulation to evaluate the analytical method in terms of correlating unit-cell deformation mechanism to strut bending mechanics. In addition, foreshortening, compliance and radial pressure of the stent will be determined based on the simulation of a unit-cell deformation mechanism.
The contents of chapter 4 employ axisymmetric FE simulation to evaluate the correlation between deformation characteristics and unit-cell deformation mechanism, which was defined in chapter 2. This chapter also studies the radial strength of a stent against collapse deformation through axisymmetric FE simulation.

Chapter 5 contains the conclusion and future work of this thesis. This chapter introduce the most efficient stent design for different types of venous diseases and the clinical significance of the comparative study. Furthermore, it explains the application and the limitation of the method presented in chapter 2.
Chapter 2

The Analytical Unit-cell Study of Venous Stents

2.1 Introduction

The lattice structure of a stent provides a context to perform the unit-cell study on the expansion mechanisms. The unit-cell study is beneficial for both FE and analytical methods. This approach can reduce the computational time in FE by reducing the number of elements. For the case of analytical approach, the unit-cell study provides a simpler model to study the mechanics of the stent. The FE analysis is the most popular method to study the mechanics of the self-expanding stents especially the Nitinol stents. Although FE is an accessible method, its computational time and cost are not well for design and optimization purposes. For instance, we need to run a number of simulations for different values of strut thickness to capture its effect on radial pressure. The fundamental problem with FE method is the fact that each simulation addresses a particular geometry and loading conditions and to change a parameter, it is needed to set up a new simulation. The effort in this chapter is to introduce an alternative approach, which studies the mechanics of stents and indeed be less expensive in terms of computational time and cost.

The first step in this approach (unit-cell study) is to define the stent unit-cell parameters such as its geometry and topology. Topology here means the unit-cells connections and their orientation relative to each other. Through unit-cell study, we can correlate the mechanics of the entire structure to the mechanics of a unit-cell. As a result, if we define a model that is capable of predicting the relationship between deformation and loading of the unit-cell, it indeed can predict the general deformation-loading correlation of the stent. The first objective of this chapter is to define the mechanical performance (foreshortening,
radial pressure, and compliance) of the stent in terms of the deformation characteristic of a unit-cell. Afterwards, we study the mechanics of each stent unit-cell regarding its material and geometry.

2.2 Lattice Mechanics of Stent

In this chapter, we assume that all the unit-cells have an exact identical geometry and dimension. Furthermore, unit-cells have been repeated periodically to form the entire structure of the stent. Consequently, the pressure distribution and deformation should be same for each unit-cell under uniform radial expansion. Figure 2.1a shows a generic stent structure at an arbitrary diameter and its correlated pressure \( P_s \) which will be applied by the vessel on the stent struts.

Since the stent structure has a cylindrical shape, it would be more practical to drive the equations of static equilibrium in a cylindrical coordinate system. By isolating a unit-cell from the entire structure and defining the corresponding forces at isolated joints, it is possible to investigate the static equilibrium for the unit-cell. Since there is no external loading in the direction of the \( z \)-axis, it is clear that there should not be any reaction forces in this direction. Because of axisymmetric loading conditions, the stent cannot have internal reactions which cause \( \tau_{\theta r}, \tau_{\theta z} \) shear components. Accordingly, there exist neither moment in \( \theta \)-direction nor force in \( r \)-direction for joint 1 in Figure 2.1b. Likewise, for joint 2, the force in \( \theta \)-direction and moment in \( z \)-direction vanish. Due to symmetrical loading condition, same loading condition on all connected unit-cells, the magnitude of the force and moment at joint 1 should be exactly same as joint 3; this conclusion is valid for joints 2 and 4 as well (Figure 2.1b). Figure 2.1d describes the general free body diagram of a unit-cell.

We can determine the total force due to pressure on a stent strut by:
2.2 Lattice Mechanics of Stent

\[ F_s = \int_0^l P_s(s) t(ds) \quad (2.1) \]

Where \( F_s \) is the magnitude of the total force due to strut pressure, \( P_s(x) \) is the pressure distribution function on the strut, \( t \) and \( l \) are the thickness and length of the strut. In this equation, \( s \) represents the path on the strut (Figure 2.1c).

Joints 2 and 4 are between two unit-cells that have an identical pressure distribution (due to symmetric pressure distribution), which makes \( F_r \) (Radial shear force) at these joints equal to zero. The loading condition with respect to the \( z \)-axis is exactly same for joints 2 and 4. Thus the reaction moments at these joints must be in the same direction. All of the tangential forces have an identical distance from the \( z \)-axis, and all of the radial forces are crossing the \( z \)-axis. As we drive summation of moments in \( z \)-direction in equation (2.2), it can be concluded that \( M_z \) should be zero.

\[ \sum M_{z-axis} = F_0 r - F_0 r + M_z + M_z = 0 \quad (2.2) \]

In Figure 2.1e, we can determine \( \beta \) by the following equation in which \( n_c \) is number of unit-cells in circumference of the stent.

\[ \beta = \frac{\pi}{n_c} \quad (2.3) \]
2.2 Lattice Mechanics of Stent

It is clear that the pressure distribution is symmetric with respect to the central point of the unit cell and the line that connect the central point to the center of the coordinate system (Figure 2.1e). Consequently, the resultant force \( F_p \) due to pressure on all struts has an action point on the center of the unit-cell and has a direction along the r-axis (Figure 2.1e).

\[
F_p = 4F_s \cos(\beta)
\]  

(2.4)
2.2 Lattice Mechanics of Stent

Considering the force equilibrium in Figure 2.1e, we can get to:

\[ F_p = 2F_\theta \sin(\beta) \]  

(2.5)

Substituting equation (2.3) to equation (2.4), brings the following equation:

\[ F_s = \frac{1}{2} F_\theta \tan(\beta) \]  

(2.6)

For joints 2 and 4, the loading condition is reversed with respect to \( \theta \)-axis, which means that reaction moments at these sections are in the opposite direction. Equation (2.7) indicates that summation of moments in \( \theta \)-direction is satisfied. So, we get to the point that this problem is statically indeterminate. However, knowing that the deformation field is uniform on the left and right side of the unit-cell, will bring the conclusion that joints 2 and 4 must have same loading conditions. Thus, \( M_\theta \) -that has opposite direction on these joints- should be equal to zero.

\[ \sum M_{\theta-axis} = 2F_\theta \sin(\beta) l\cos(\frac{\alpha}{2}) - F_p l\cos(\frac{\alpha}{2}) + M_\theta - M_\theta = 0 \]  

(2.7)

\( \alpha \) is the angle between struts at each diameter (Figure 2.1e) and from equation (2.5) we know that the first two terms are identical.

As discussed in the introduction chapter (section 1.3), after fabrication process of self-expanding stents, they are compressed to the size that is compatible with the delivery system and then are expanded in the vessel (Figure 2.2). The loading and boundary conditions are symmetric with respect to circumferential and axial coordinates in a unit-cell. This fact indicates that the deformation characteristics of all struts in a single unit-cell should be symmetric as well. Consequently, we can define the total length (\( L \)) and the diameter (\( D \)) of
the stent by focusing on the deformation of a single strut in a unit-cell.

\[ L = n_a (l_0 - 2u) \quad (2.8) \]

\[ D = \frac{n_c (w_0 + 2v)}{2\pi} \quad (2.9) \]

Figure 2.2: Expansion of stent, unit-cell, and strut and the symmetric boundary conditions at both ends of the strut.
Where \( n_c \) is number of circumferential unit-cells, \( u \) and \( v \) are axial and circumferential displacements of the strut tip. \( l_0 \) and \( w_0 \) are respectively length and width of a unit-cell at the beginning of the expansion (Figure 2.2).

Since the main purpose of deploying a stent is to interact with the narrowed lumen, most of the literature focuses on the radial pressure that stent applies to the lumen or the balloon [26] [27]. For balloon-expandable stents the balloon pressure is an important factor; the pressure distribution for balloon and lumen is comparable (both are cylindrical structures that apply pressure on stent strut). It is clear that the lumen does not have any uniform internal pressure as well as the balloon. However, we can still calculate the average pressure that is applied by each unit-cell. The average pressure can be defined as:

\[
P = \frac{4F_s}{D\theta(l_0 - 2u)} \tag{2.10}
\]

Where the denominator is the circumferential area of a unit-cell, \( P \) is the lumen radial pressure and the numerator is the total applied pressure.

By substituting equation (2.9), (2.6) and (2.3) to equation (2.10), we have:

\[
P = \frac{F_0\tan(\frac{\pi}{n_c})}{(\frac{w_0}{2} + v)(\frac{l_0}{2} - u)} \tag{2.11}
\]

To drive the foreshortening percentage (\( f \)) equation, we can substitute the equation (2.8) to (1.1):

\[
f = \frac{2u}{l_0} \times 100 \tag{2.12}
\]
Furthermore, by substituting equations (2.11) and (2.9) into equation (1.2), the definition of compliance will be:

\[ C = \frac{v_1 - v_2}{\tan(\frac{\pi}{n_c})(\frac{w_0}{2} + v_2)(\frac{I_0}{2} - u_2) - \frac{F_{\theta_1}}{F_{\theta_2}}} \]  

(2.13)

2.3 Analytical Approach to Study Expansion of Nitinol Stents

2.3.1 Analytical Solution Regarding Bending of Nitinol Stent

As described in the previous chapter, expansion of a stent is performed by the bending of its strut. According to equations (2.11) to (2.13), the stent mechanical parameters are a function of strut bending factors such as bending force, longitudinal and circumferential displacements. Consequently, clarifying the relationship between the bending parameters is the essential step in studying mechanics of the stent. Mirzaeifar et al. introduced a mathematical base model for the bending analysis of Nitinol beams [28]. They defined a series of functions to correlate the bending moment to the curvature of the deflection curve. They conducted a standard three-point bending test associated with an FE code to validate their model. Equation (2.14) correlate the curvature of a beam deflection curve to the applied bending moment. It should be noted that the neutral axis does not necessarily coincide with the center line due to asymmetry in compression and tension loading of Nitinol. After solving this equation for the curvature function \((k)\), we can find the deflection curve and the displacements of the tip of the beam \((u\) and \(v\) in Figure 2.2).
2.3 Analytical Approach to Study Expansion of Nitinol Stents

\[ M = -\frac{1}{3} E^A k w (y_{1c}^3 - y_{1t}^3) + \left( I(y_{2c}) - I(y_{1c}) \right) \]
\[ + E^M w \left[ \frac{1}{3} k \left( \frac{h_c^3}{8} - y_{2c}^3 \right) - H^c \left( \frac{h_c^2}{4} - y_{2c}^2 \right) \right] \]
\[ + \left( I(y_{2t}) - I(y_{1t}) \right) \]
\[ + E^M w \left[ \frac{1}{3} k \left( \frac{y_{2t}^3 - h_t^3}{8} \right) - H^c \left( \frac{y_{2t}^2 - h_t^2}{4} \right) \right] \]  \hspace{1cm} (2.14)

\[ I(y) = \int y \sigma(y) w dy \]  \hspace{1cm} (2.15)

Figure 2.3: Deflection curve of a Nitinol beam. a) stress distribution, blue (Meshed), yellow (Solid) and red (Dashed) are respectively, Austenite, Transition and Martensite Phases, b) Cross section stress distribution.

In Equation (2.14), \( y_{1c} \) and \( y_{2c} \) are respectively the distance from neutral axis to the boundaries of the transition, and martensite regions, which are under compression (Figure 2.3); the same terminology is considered for \( y_{1c} \) and \( y_{2c} \) which are representing the same variables for the tension portion. The \( H^c \) is a
2.3 Analytical Approach to Study Expansion of Nitinol Stents

mechanical property of Nitinol and function I can be calculated by equation (2.15). To calculate the equation (2.15), Mirzaeefar et al introduced four different functions for different loading conditions, which are out of scope of this thesis to be discussed here. In this thesis, we are using the function that was defined for the bending due to transverse force (the closest loading condition for a stent strut) [28].

The thermo-mechanical properties of Nitinol -extracted from literature [29]- is presented in Table 2.1.

Table 2.1: Thermo-mechanical Properties of Nitinol

<table>
<thead>
<tr>
<th></th>
<th>$A^o$</th>
<th>$A^{os}$</th>
<th>$M^{os}$</th>
<th>$M^{of}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>303K</td>
<td>286K</td>
<td>248K</td>
<td>276K</td>
<td></td>
</tr>
<tr>
<td>$E^A$</td>
<td>$E^M$</td>
<td>Poisson ratio</td>
<td>$H^c$</td>
<td></td>
</tr>
<tr>
<td>72Mpa</td>
<td>30Mpa</td>
<td>0.42</td>
<td>-0.035</td>
<td></td>
</tr>
</tbody>
</table>

The foreshortening is the only characteristic of the stent that can be addressed through kinematic method. Douglas et al. introduced a model to predict the foreshortening through kinematic analysis [10]. They assumed that the struts and the joints of the unit-cell are acting as a pin-joint structure. The unit-cell geometry of the Cook Vena is similar to one of the stents in their work (chevron A stent). Their method also has been employed in this work to predict the foreshortening of Luminexx stents as well. The geometry of Luminexx unit-cell is close enough to the diamond stent, and the kinematic approach for the analysis of foreshortening can be used here [10].
2.3 Analytical Approach to Study Expansion of Nitinol Stents

2.3.2 Nitinol Strut Bending (Cook Vena & Luminexx)

Figures 2.4 and 2.5 illustrate the geometry, and forces of the Luminexx and Cook Vena struts. We can define the function of bending moment for both stents according to the strut geometry and loading condition. Cook Vena is made of two curved parts and a straight link at the middle of them. The bending moment function of the curve parts and the link are presented in equations (2.16) and (2.17). It should be noted that both curve parts have an identical bending moment due to symmetrical boundary and loading conditions. Unlike the multiple part geometry of the Cook Vena, Luminexx is formed by a single straight link. Equation (2.18) represents the function of bending moment over the length of Luminexx strut.

\[ M_c = \frac{1}{2} Fl \cos(\alpha) - Fr(1 - \cos(\theta)) \quad (2.16) \]

\[ M_l = \frac{1}{2} Fl \cos(\alpha) - F \cos(\alpha) x + Fr \quad (2.17) \]

\[ M_{Luminexx} = \frac{1}{2} Fl \cos(\alpha) - F \cos(\alpha) \quad (2.18) \]
2.3 Analytical Approach to Study Expansion of Nitinol Stents

Figure 2.4: Cook Vena unit-cell and strut free body diagram. a) Unit-cell geometry, b) Strut loading condition, c) Bending moment in the curved section, d) Bending moment in the straight section

Figure 2.5: The Luminexx unit-cell and strut free body diagram. a) Unit-cell geometry, b) Strut loading condition
2.4 Analytical Approach to Study Expansion of Steel Stents

The self-expanding steel stent is capable of tolerating a large displacement during the manufacturing process without experiencing any plastic deformation. Consequently, the residual elastic stresses perform stent expansion. The mechanical properties of stainless steel -specifically designed for Self-expanding stents- are listed in table 2.2 [30]. Unlike the complex method needed to study the bending mechanics of Nitinol struts, investigating the struts bending of the steel stents is straightforward through Euler-Bernoulli beam bending analysis.

Table 2.2: Mechanical Properties for steel

<table>
<thead>
<tr>
<th>Elastic Modules</th>
<th>193 GPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poisson Ratio</td>
<td>0.3</td>
</tr>
<tr>
<td>Plastic yield</td>
<td>260 MPA</td>
</tr>
</tbody>
</table>

2.4.1 Cook Z Strut Bending

Two sets of steel links and a coil that connect these links are the elements that shape the Cook Z unit-cell (Figure 2.6). The displacement in a single strut is a combination of the coil torsion angel and the link bending deflection. Torsional stiffness of the coil and the torsion angle can be calculated through equations (2.19) and (2.20), where \( k_t \), E, d, D, n and \( \theta \) are torsional stiffness, young modules, wire diameter, diameter of the coil, number of coil body turns and the torsion angle [31]. Equations (2.21) and (2.22) present the contribution of the torsion angle in the longitudinal and circumferential displacements. The contribution of bending deflection in longitudinal displacement has been
neglected (the longitudinal deflection of the link is negligible with respect to longitudinal displacement due to coil torsion), but equation (2.23) represents its contribution in circumferential displacement.

\[ k_t = \frac{E d^4}{10.8 D n} \]  
\[ \theta = k_t F(l + 2d) \]  
\[ u_t = l(1 - \cos(\theta)) \]  
\[ v_t = l\sin(\theta) \]  
\[ v = \frac{Fl^3}{3EI} - \frac{Ml^2}{2EI} \]

2.4.2 Wallstent Expansion

Unlike the previous types of stents in the above sections, the assumptions in section 2.2 are not valid for Wallstent. At the first look, it seems that Wallstent has a diamond shape unit-cells, but referring to the definition in section 2.2 we cannot actually call the diamond shape as a unit-cell. Wallstent is fabricated by
braiding. The same number of clockwise and counter-clockwise helical wires form the entire structure of the Wallstent. During expansion, these wires slide over each other, the pitch of these helical wires decreases and the diameter of the helix increases. Consequently, not only the angle between struts changes but also the geometry of the diamond cells changes. In other words, we cannot define a particular unit-cell geometry in this case. Wang et al. investigated the expansion of Wallstent to derive the equation that can correlate the pressure to the diameter of a single helical wire. Then they generalized the equation to the entire structure [32] [33]. They also developed a kinematic model (equations (2.27) and (2.28)) to investigate the axial and radial deformations of Wallstent.

\[
P = \frac{nc\cos^2(\alpha)}{2\pi r^2 \sin^2(\alpha)} \left[ \frac{E \sin(\alpha)}{r} \left( \frac{\cos^2(\alpha)}{r} - \frac{\cos^2(\alpha_0)}{r_0} \right) \right]
\]

\[
- \frac{Gl_p \cos(\alpha)}{r} \left( \frac{\cos(\alpha) \sin(\alpha)}{r} - \frac{\cos(\alpha_0) \sin(\alpha_0)}{r_0} \right)
\] (2.26)

\[
\lambda_1^2 + \pi^2 D_1^2 = \lambda_2^2 + \pi^2 D_2^2
\] (2.27)

\[
L = n. \lambda
\] (2.28)

In equation (2.26), \( n, E, G, l_p \) and \( r \) are respectively number of wires, young’s modules, shear modules and the area moment of inertia. In equations (2.27) and 2.28, \( \lambda, D, n \) and \( L \) are helix pitch, stent diameter, number of helix turns and the total length of the stent.
2.5 Results and Discussion

This chapter developed the analytical method to study the mechanical properties of the self-expanding stents. This method is specially designed for each stent geometry. The results of this method will be presented in the next two chapters to be evaluated. However, we present the results of foreshortening performance of the candidate stents through the proposed method in this section and the pin-joint approach. It should be noted that since the Wallstent does not have any geometrical unit-cell, its foreshortening cannot be studied by the pin-joint method. Figure 2.7 shows the foreshortening parameter of each stent at different radial strains. The common characteristic between the foreshortening performance of Cook Vena, Cook Z, and Luminexx is the fact that pin-joint predicted a larger value. This arises from the nature of the pin-joint method. This method assumes that the entire length of the strut is contributing to the expansion and deformation, the analytical method, however, consider the effective length of the strut which is always shorter than the total length. According to the Figure 2.7, both Cook stents show a more desirable characteristic regarding foreshortening. On the other hand, Luminexx and Wallstent significantly foreshorten and have an undesirable performance in terms of longitudinal deformation.
Figure 2.7: Foreshortening characteristic of four candidate stents versus the radial strain during expansion

2.6 Conclusions

We studied the contribution of unit-cell forces and kinematics in the deformation characteristics (foreshortening, radial pressure, etc.) of the stent. Afterwards, the mechanics of a unit-cell has been defined in terms of bending of its struts. By breaking down the mechanical properties of the stent into its strut mechanics, we can define the deformation characteristics of a stent in terms of the loading-deflection relationship of a strut. The bending moment has been defined along the length of the strut for Cook Vena, Cook Z and Luminexx. Cook Z is made of steel; the Euler–Bernoulli bending analysis can be used for deflection determination. For Luminexx and Cook Vena, the Nitinol Stents, the equation (2.14) has been employed to define the deformations of strut [28]. The analytical method to address the foreshortening, radial pressure and compliance of the Wallstent is available through the work of Wang et al. [32, 33].
Chapter 3

Unit-cell Study: Finite Element Analysis of Expansion of Self-Expanding Stents

3.1 Introduction

The FEA it the most popular approach to study the mechanics of the self-expanding stents. The accuracy of the FEA is highly related to the size and number of simulation elements. However, there is a penalty for increasing the number of elements (decreasing the size of the elements), which is excessive computing time. To address this issue, FE user can benefit from the geometrical features such as symmetry to reduce the number of elements in the simulation. For lattice structures, the best option is to model the problem based on a unit-cell, which can significantly reduce the number of elements. Reduction in the total number of elements allows using smaller element size in the simulation and obtain more accurate results.

3.2 Simulation Parameters

According to section 1.4, we can divide the stent material into two different categories, Steel and Nitinol. The material properties for each category were given in Tables 2.1 and 2.2. The material model of Nitinol is not available in most of the FE commercial software. In this work, the simulation has been performed in ABAQUS/Standard commercial code linked with a user material subroutine (UMAT). UMAT is a framework for ABAQUS user to write a material subroutine model. The foundation of the UMAT code is the thermo-mechanical constitutive model of Nitinol in a continuum mechanics basis [20] [21] [34].
To include the loading history and manufacturing process, the simulation runs in three steps: 1. compressing to delivery size (Diameter=1.8 mm) at 280K, 2. heating up to 310k at the delivery size, 3. Expansion at 310k (280k and 310k are respectively forming temperature and human body temperature). All of the three steps are boundary value problems, which means the displacement will be applied on the unit-cell and the load is measured based on reaction forces and moments (Figure 3.1).

![Fixed Boundary Conditions](image)

Figure 3.1: FE Unit-cell Boundary Condition

One of the essential factors in computational mechanics of Nitinol stents is the element type and size. According to literature, the best element type for stent finite element analysis is full-integrated solid linear hexahedron (ABAQUS library name: C3D20), which provides a good balance between accuracy and efficiency [33]. The C3D20 element, however, is not the best choice for the large curvature geometries and can be replaced by tetrahedron element (C3D10) for coil part in Cook Z and wires of Wallstent. The global size for the meshing alternates from 0.075mm to 0.05 based on the mesh sensitivity test (Table 3.1).
### 3.3 FE Results and Comparison to Analytical Results

Table 3.1 Number of finite elements in a unit-cell (or wire for Wallstent)

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Cook Vena</th>
<th>Cook Z</th>
<th>Luminexx</th>
<th>Wallstent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of elements</td>
<td>2196</td>
<td>2928</td>
<td>2472</td>
<td>3066</td>
</tr>
</tbody>
</table>

### 3.3 FE Results and Comparison to Analytical Results

The most important mechanical parameters, which should be evaluated for FE and analytical methods, are unit-cell force-deflection performance and stent radial pressure. The other mechanical performances are related to the radial pressure and unit-cell bending deflection. For instance, the compliance is simply related to radial pressure by a specific differentiation method (equation (1.2)); the foreshortening is a function of circumferential and longitudinal displacements which also contribute to radial pressure performance. Consequently, evaluating the stent radial pressure and the strut bending performance is sufficient for investigating the efficiency of the analytical method.

Although we didn’t include any experiments in this research, for further investigation (experiment-wise), the dimensions of the unit-cell for force-deflection figure have been modeled ten times bigger (in order of 50 mm). Therefore, it is possible to perform experiments on the unit-cells in this size. The size of the actual unit-cells is in order of 5mm which is not practical for conducting experiments.
3.3 FE Results and Comparison to Analytical Results

3.3.1 Cook Vena

Figure 3.2 depicts the stress contour for a unit-cell of Cook Vena. The regions having Von Mises stress less than 190 MPa include pure austenite phase and between 190 MPa to 260 MPa are in the transition phase. If Mises stress is more than 260 MPa, the region has a pure martensite phase. A core of pure austenite always exists for the Cook Vena joint. The symmetric stress contour can confirm the unit-cell study symmetrical assumptions. Furthermore, it is clear that the stress distribution matches with a pure bending as stress magnitude increases form middle surface towards outer surfaces. Thus, it is valid to neglect the shear stress effect in the analytical approach.

Figure 3.2: Cook Vena Stress contour (Mises Stress (MPa)), Diameter: 2mm
3.3 FE Results and Comparison to Analytical Results

Figure 3.3: Comparison of Bending Characteristic for Cook Vena expansion

Figure 3.3 compares the force-displacement relationship during bending of a Cook Vena unit-cell. The variation in the curves trend (slope) reflects the phase transition. The FE simulation starts its phase transition in smaller deflections, and this is because of the shear stresses, which have been ignored in the analytical model [28]. The FE solution here is stiffer, which indicates the fact that for an equivalent displacement it predicts a larger value for force. This fact is clear in Figure 3.4 as well. The maximum deviation between FE and Analytical solution here is 9.77%. It should be noted that smaller displacements indicate the larger radius and vice versa.
To determine the radial pressure, equation (2.11) has been employed here. The Cook Vena loses a significant amount of radial pressure at a very beginning of its expansion (Figure 3.4). The radial pressure reduction is 70% in the first 6.7% of the expansion progress. The maximum deviation between FE and analytical results in terms of radial pressure is 10.16% at the beginning of expansion; the deviation gradually vanishes through expansion. The maximum pressures are 19.729 KPa and 21.702 KPa respectively for Analytical and FE method. Same as Figure 3.3, we can observe and realize the start of phase transition when curve changes its trend.

### 3.3.2 Luminexx

The phase of different regions can be determined in Figure 3.5 in a similar manner as Figure 3.3 (pure austenite <190 MPa, 190 MPa<transition< 260 MPa, 260 MPa<pure martensite). The symmetric stress distribution confirms the assumptions for the unit-cell study of Luminexx. It should be pointed out that the stress distribution doesn’t follow the routine pure bending stress contour. We can conclude this fact by considering the joint stress. The inner regions have martensite phase and larger stress than those outer regions, which is in absolute
contrast to bending stress distribution that must be larger in outer regions. We can justify this observation by considering the shear stress distribution that is larger in the middle surface in comparison to the outer surface. The shear component of the force is larger for Luminexx in comparison to Cook Vena, which makes the shear effect more significant (Figure 3.6).

Figure 3.5: Luminexx Stress contour (Mises Stress (MPa)), Diameter: 2mm

Figure 3.6: Shear angle in Luminexx

This angle is close to 90 degrees in Luminexx causes larger shear component.
3.3 FE Results and Comparison to Analytical Results

As mentioned before, the trend of the curve changes due to the phase transition. According to figure 3.7, the irregular feature is that FEA and Analytical curves cross each other. Comparable to Cook Vena, the phase transition is observed for a small value of displacement in the FEA curve. However, it affects the FE curve more significantly that make it more compliant to be even less than the Analytical curve in the figure. This is because of the fact that shear stress (which cannot be neglected here) plays a significant role in phase transition scenario. It is worth mentioning that the maximum deviation here is 4.49%.

Examination of figure 3.8 indicates that Luminexx can preserve its radial pressure much longer than Cook vena. The 70% reduction in radial pressure occurs when stent expands to 51.44% of the maximum diameter. The maximum pressure here is 15.66 and 14.86 KPa respectively for Analytical and FE analyses. Furthermore, the maximum deviation here is 6.93%.
3.3 FE Results and Comparison to Analytical Results

3.3.3 Cook Z

As shown in Figure 3.9, the coil of the Cook Z unit-cell almost has a constant stress all over its structure. For analytical approach for expansion of Cook Z, the number of coil revolutions is assumed to be 1.5 which seems to match the FE analysis results. The FE solution here is stiffer as well as Cook Vena. The maximum deviation for figures 3.10 and 3.11 (deflection and radial pressure figures) are respectively 5.18% and 6.12%. The maximum radial pressure for Cook z is 33.79 KPa which is 56.43% and 55.69% respectively larger than Luminexx and Cook Vena. Although the maximum radial pressure of Cook Z is significantly larger, at 4.7% of the expansion process, this stent loses 70% of its radial pressure, which is not a desirable performance.
3.3 FE Results and Comparison to Analytical Results

Figure 3.9: Cook Z Stress contour (Mises Stress (MPa))

Figure 3.10: Comparison of Bending Characteristic for Cook Z expansion, Diameter: 2mm
3.3 FE Results and Comparison to Analytical Results

3.3.4 Wallstent

As we stated in Chapter 2, the wall stent analytical approach focuses on a single wire rather than a geometrical unit-cell. Consequently, the total pressure is a multiple of a wire pressure by the factor of the number of wires. Figure 3.12 shows the stress contour for a single wire of the Wallstent. According to the figure, maximum stress is less than the yield stress, and it indicates that the wire is still at elastic region and can automatically expand. The maximum deviation here is 6.45%, the maximum pressures for analytical and FE methods are respectively 28.97 and 27.11 kPa. At 41% of expansion, Wallstent loses 70% of its radial pressure.
3.3 FE Results and Comparison to Analytical Results

Figure 3.12: Wallstent Stress contour (Mises Stress (MPa)), Diameter: 2mm

Figure 3.13: Radial Pressure for Wallstent
3.4 Discussions

The assessment of Analytical method through an evaluation with FE simulation reveals the acceptable accuracy of this method. The computation time for the analytical method is less than five minutes on a system with 2.5 GHz CPU and 4GB RAM. The FE simulation, however, takes at least twenty minutes on the same system. The FE simulation predicted higher pressure for Cook Vena and Cook Z, while, it predicted less pressure for Luminexx and Wallstent for most of the expansion process. The FE result’s deviation has roots in a number of factors. We can classify these factors for the Analytical simulation in two categories: pure bending assumption and geometrical simplification. Except for Wallstent that is assumed to deals with both torsion and bending, we assume that just bending is responsible for the deformation in case of the other stents. The role of shear in the deflection of the strut brings some portion of error (significantly for Luminexx). The curve part of Cook Vena structure is connected to the straight strut by another fillet curve. Since the curvature of this fillet part has been neglected in the Analytical simulation, the results deviate from the FE simulation which is based on the real shape. This conclusion is also valid for the fillet that connects the coil and straight part of Cook Z. Furthermore, the FE simulation is not always accurate, and some restrictions such as the number of elements leads to computational errors.

The radial pressure is a function of bending force in each unit-cell, which is itself, is a function of cross-section area, length of the strut and the material of the stent. There is a contrast if we compare the radial pressure-radius and force-displacement curves. For instance, Cook Z radial pressure drops significantly, while it has a larger force in comparison with Cook Vena and Luminexx. By substituting equation (2.12) into equation (2.11), we can have
3.4 Discussions

\[ P = \frac{F_{\theta} \cdot \tan \frac{\pi}{n_c}}{\left( l \cdot \sin \frac{\alpha}{2} - v \right) \cdot l \cdot \cos \frac{\alpha}{2} \cdot (1 + 0.01 \cdot \text{foreshortening})} \]  

The new equation indicates that while a large value of foreshortening is undesirable regarding precise deployment, it can provide a larger radial pressure.

The bending force, longitudinal and circumferential displacements of a unit-cell are the essential variables that are contributing in other parameters such as radial pressure and foreshortening. Albeit it may seem that the examination of longitudinal displacement has been overlooked, the investigation of radial pressure and longitudinal displacement circuitously covers the longitudinal displacement. According to equation (2.11), the radial pressure is a function of bending force, longitudinal and circumferential displacement; consequently, the acceptable agreement between FE and Analytical results (radial pressure and circumferential displacement) can indeed claim the agreement in the longitudinal displacement. Furthermore, it contradicts to the nature and physics of the problem to have a significant discrepancy in the results of the longitudinal displacement, while there is an acceptable agreement for circumferential displacement results of both FE and analytical simulations. Overall, we can compare the final values of foreshortening by Figure 3.14, which indicates an adequate deviation between longitudinal displacement results.
According to Figure 3.15, Cook Z has the largest radial pressure at the beginning of the expansion. However, it ends with the smallest value in comparison to the other stents. In absolute contrast to Cook Z, Luminexx starts its expansion with smallest radial pressure and has the largest at the final stages of expansion. The desirable feature of Luminexx is its gradual radial pressure
3.4 Discussions

reduction. Although the reduction in radial pressure is inevitable during expansion, we can avoid a rapid drop in radial pressure to keep larger pressure values during expansion. Wallstent also has a satisfactory radial pressure performance. This stent applies a larger pressure than Luminexx in most of the expansion process, but Luminexx pressure outweighs at the end of the expansion which is the diameter that stents are usually designed to work. In spite of initial radial pressure value, Cook Vena approximately follows the Cook Z. Both Cook Z and Vena have a more appropriate performance in terms of foreshortening, but small foreshortening can impair the radial pressure performance according to equation (3.1).

In most of the endovascular surgeries after stent deployment, the diameter of the vessel is not sufficient. A large radial pressure is favourable because the stent always can expand to the desired diameter; however, a stent that failed to enlarge the vessel lumen enough is not necessarily failed. To address this problem, surgeon employs a balloon to force the stent to expand up to the anticipated diameter. The more important characteristic that stents should have is to be adequately stiff enough to embrace the desirable diameter. Accordingly, the radial compliance is a more important factor in stent clinical long-term performance. A larger Compliance indicates that the stent is more likely to recoil and fail to retain the anticipated diameter. Figure 3.16 represents compliance for all of the stents, which was calculated by equation (2.13). The compliance follows almost a similar trend for Cook Z and Wallstent that are made of stainless steel. Wallstent is significantly more compliant at the beginning of the expansion and slightly stiffer at the end. Both Cook Vena and Luminexx have a singularity in their compliance curves which represents the phase transition in Nitinol. The phase transition occurs sooner in the expansion of Cook Vena rather than Luminexx. For each stent, the maximum compliance is exactly before phase transition singular point.
3.5 Conclusions

This chapter presented the FE and Analytical results to evaluate the presented analytical method in chapter 2. The method can predict the foreshortening, compliance and radial pressure with an acceptable computational error and deviation. Among all of the mechanical parameters (radial pressure, foreshortening, compliance, and collapse), only the collapse cannot be investigated through unit-cell study. The reason is the fact that unit-cell study relies on the assumption that loading and deformation are same for the entire stent structure, which contradicts with the nature of collapse mechanism.
Chapter 4

Axisymmetric Finite Element Analysis of Stent Expansion

4.1 Introduction

The unit-cell study, which was examined in Chapter 3, relies on the correlation between the mechanics of the unit-cell and stent. In this chapter, instead of FE analysis of a single unit-cell, we study the entire structure of the stent to investigate the efficiency of the presented analytical method. The other fact is that the radial pressure has been calculated through equation (2.11) based on the other variables such as bending force and deformation in a single unit-cell. But, we can determine the radial pressure directly from the FE simulation of an entire structure of the stent in this section. As discussed in the first chapter, the collapse is another challenge that stents experience. The analytical unit-cell study is not capable of investigating the stent collapse. However, the mechanics of collapse will be examined through FE simulation for all the four candidate stents in this chapter. The main objective of this chapter is to investigate if it is possible to predict the collapse of each stent by investigating other parameters such as radial pressure and compliance. Accordingly, we can indirectly investigate the collapse phenomenon through analytical unit-cell study. Therefore, we have a method that is efficient for multiple computational problems (design problems) and is suitable to study all mechanical parameters that contribute to the stent clinical performance.
4.2 Method

The FE simulation procedure is same as chapter 3, in which the displacement is applied to the boundaries and the reaction forces are measured to calculate the radial pressure. Since all of the stents have an axisymmetric structure, we can model only a quarter of each stent to reduce the computation time (Figure 4.1). The same mechanical properties and user material subroutine (Umat) has been employed here. The finite element size is larger here to avoid an excessive number of elements and reduce the computation time (Table 4.1).

![Axisymmetric Boundary Conditions](image)

Figure 4.1: Axisymmetric FE simulation Boundary Conditions

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Cook Vena</th>
<th>Cook Z</th>
<th>Luminexx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of elements</td>
<td>4392</td>
<td>4692</td>
<td>4644</td>
</tr>
</tbody>
</table>

Table 4.1: Number of elements for axisymmetric FE simulation

To capture the stiffness of the stents against collapse deformation, a contact problem has been simulated as shown in Figure 4.2. The solid surface on top has been modeled as a solid analytical surface in ABAQUS. The contact between the solid surface and the stent was defined as a general mechanical contact with a
normal behaviour, and the tangential behaviour (friction) was neglected. In Figure 4.2, \( Z \) is the collapse displacement, and \( R \) is the radius of the stent; the contact forces represent the collapse force that is measured during the FE simulation.

![Figure 4.2: Schematic of collapse FE simulation](image)

### 4.3 Results

In the following figures, the dashed line represents the axisymmetric FE simulation results, and the solid line is the results of the analytical method. In this chapter, the only mechanical parameter that we look into is the radial pressure. As explained in chapter 3, if two different methods agree on the value of the radial pressure, the other parameters such as foreshortening should be almost in the same range of accuracy. Since the analytical method regarding Wallstent already considers the actual stent shape and does not rely on the unit-cell study, there is no logic to conduct the axisymmetric FE simulation on this stent. According to the figures and results, the maximum deviation between FE axisymmetric simulation and the analytical solution is 35\% for the maximum pressure of Cook Z. However, the deviation decreases during expansion and the average value is 13.37\%. For Cook Vena and Luminexx, the deviation from axisymmetric FE simulation results is maximum at the beginning of the
expansion. But the average deviation is 7.62% and 8.85% respectively for Luminexx and Cook Vena.

Figure 4.3: Cook Z Radial Pressure vs. Diameter

Figure 4.4: Cook Vena Radial Pressure vs. Diameter
Figure 4.5: Luminexx Radial Pressure vs. Diameter

Figure 4.6 reflects the performance of each stent against collapse. This figure depicts the collapse force versus the collapse displacement ratio that is the ratio of collapse displacement to the radius of the stent (Z/R). Since the collapse simulation deals with a contact problem, it brings larger values of error due to the nature of the contact computational simulations and the curves are not smoothly continuous. For small displacement ratio, the stiffest stent against collapse is Wallstent followed by Cook Z, Cook Vena, and Luminexx. However, for deformation ratio over 14.8%, Wallstent loses its stiffness significantly to 6.37% of its initial value. Overall, Cook Z has the larger value for collapse stiffness followed by Wallstent, Cook Vena, and Luminexx.
4.3 Results

Figure 4.6: Force versus collapse displacement ratio

Figure 4.7: FE Simulation for Cook Vena Collapse
4.3 Results

Figure 4.8: FE Simulation for Luminexx Collapse

Figure 4.9: FE Simulation for Wallstent Collapse
4.4 Discussions

Figures 4.7 to 4.10 present the stress distribution contour of the collapse FE simulation for each stent. The top right part of each figure shows the von Mises stress values in MPa; the bottom left depicts a closer view of the stent under collapse loading. As shown in the figures, the maximum stress is on the joint that is on each side of the stent and far from the collapse loading spot. This fact claims that the collapse deformation is more similar to a bending deformation. These figures also declare that the collapse stress distribution is not same for all of the unit-cells; as mentioned before, the unit-cell study cannot approach investigating stent collapse directly.

4.4 Discussions

This section focuses on two objectives, the first one is to investigate the unit-cell study efficiency and the second one is to study the collapse performance through other parameters such as radial pressure and compliance. Although there is no numerical simulation that can replicate all the aspects of an actual problem, the first objective of this chapter at least can endorse the results of the previous
chapter. The error between the results of analytical method and axisymmetric FE simulation is maximum at the beginning of the expansion and minimum at the final stages. As discussed before, the expansion is actually the second step in FE simulation, which follows the first step that is compressing stent to the required diameter (the first step accounts for the real manufacturing process). In the analytical method for Nitinol stents, which is based on Mirzaeifar et al. work, the effect of the previous loading has been included in their solution [28]. Consequently, the analytical method and FE simulation do not settle on the same radial pressure value at the beginning of the expansion. We can draw this analogy for all of the three candidate stents that were examined through unit-cell study. The results, however, follow a same path and trend and the error is decreasing during expansion. This indicates that the results of the analytical method are acceptable and promising.

By comparing Figure 4.6 and 3.16, the first obvious conclusion is that a less compliant stent is less susceptible to collapse. The most compliant stent is Luminexx followed by Cook Vena, Cook Z and Wallstent and sorting stents from low to high stiffness leads to the same order. As a preliminary outcome, we can point out that stainless steel stents are more reliable than Nitinol stents in terms of collapse. Aside from the initial performance of the stents regarding collapse deformation, we can point out Cook Z as best performance against collapse. In spite of the initial performance, Wallstent illustrates that it has a potential instability that doesn’t make it the best choice to deal with the collapse problem. The instability can be concluded from the collapse curve that is almost flat for forces larger than 1.169 N. Therefore, in addition to the material and the compliance of the stent, structural features contribute to the performance of the stent against collapse as well.
The results in Chapter 3 and 4 evaluate four different venous stent designs (Cook Vena, Cook Z, Luminexx, and Wallstent) based on their collapse, foreshortening, radial pressure, and compliance. Table 4.2 ranks the designs in terms of their suitable characteristics to be deployed within body venous system. Cook Z has the best performance against collapse deformation and it is more reliable regarding treatment of dense and localized blood clots, which apply concentrated forces. Since the Nitinol stents are more compliant, they can follow the joint movements. Accordingly, they are more suitable for deployment close to body joints. Luminexx and Wallstent apply larger radial pressure and are the most reasonable choices for vital vein branches (renal vein) to guarantee a successful enlargement. Stents have a number of anchors at their both tips, which attach them to the vessel wall to avoid migration. If the location of the stent tips is critical to be predicted (e.g., deployment close to branch orifice), Cook Z can be the best choice. Because of the small foreshortening of Cook Z in comparison to other designs, we can predict the final location of the tips. Figure 4.11 illustrates the recommended design for different types of thrombosis in various locations.

Table 4.2: Stents ranking, most suitable (1) to least suitable (4)

<table>
<thead>
<tr>
<th></th>
<th>Cook Vena</th>
<th>Luminexx</th>
<th>Cook Z</th>
<th>Wallstent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial Pressure</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Foreshortening</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Compliance</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Collapse</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
4.5 Conclusions

This chapter was concerned with demonstrating the accuracy of the analytical method that is presented in chapter 2 and connecting the collapse incidence to the parameters, which can be investigated through analytical unit-cell study. The axisymmetric FE simulation confirmed the previous results with an acceptable error. It was found that the stiffness of the stent against collapse deformation is highly dependent on the compliance at the end of the expansion. However, the geometrical parameters and structure of the stent strongly affect the performance against collapse. Accordingly, considering compliance to study the collapse of the stent is necessary, but it is insufficient.

![Recommended venous stents for different locations.](image)
Chapter 5

Conclusions and Closing Remarks

5.1 Conclusions of Present Work

This thesis reports three different methods to study the mechanical parameters that contribute to the clinical performance of the venous stents. The literature lacks an analytical method that particularly addresses the expansion of self-expanding venous stents. Introducing a method that can study stent mechanics is the primary motivation of this thesis. An analytical method is desirable for the design procedures that required multiple computational analysis. A preliminary literature review reveals that unit-cell study, which is efficient in investigating mechanics of lattice materials, can be advantageous to simplify analytical approach toward stent expansion and reduce the computation time of FE simulation. Radial Pressure, Compliance (Radial Strength), Foreshortening, and Collapse are the mechanical characteristics that are important in designing the self-expanding venous stents. The presented method in Chapter 2 defines the Radial Pressure, Compliance, and Foreshortening based on the mechanical parameters in the bending of a single strut. The collapse, however, is not a uniform deformation and the unit-cell study is not an efficient approach to study the collapse deformation. The presented analytical method in Chapter 2, is a more efficient method than FE simulation to study the above mechanical properties. The accuracy of this method was investigated in Chapters 3 and 4, which was satisfactory. Although the deviation from FE simulation results is large at the beginning of the expansion, the results at the final stages of expansion (the required diameter in the vessel) were found acceptable. The analytical method is a more suitable alternative for FE simulation due to a number of reasons. First, it can be coded in most of the programming software (Matlab, C, Python, etc.).
However, a FE simulation software is not available for any user. To capture the effect of changing a design parameter (e.g., the thickness of the strut) on a mechanical property (e.g., radial pressure), we only need to change a variable in the analytical method equations rather than setting up a new FE simulation. Writing a program for Nitinol material behaviour is another obstacle for FE simulation of Nitinol stents (Cook Vena and Luminexx). Usually, writing material subroutines is a time-consuming process and requires advanced computer coding skill. Furthermore, the computation time is much less for the analytical method than FE simulation.

As mentioned earlier, the collapse is the only deformation characteristic that can be addressed through unit-cell study. It was discovered that the collapse could be predicted based on compliance performance, while the structural features also have a significant effect on the stent performance against collapse. Generally, a less compliant stent has a more favourable performance against collapse deformation.

Four different venous stent designs (Cook Vena, Cook Z, Luminexx, and Wallstent) was evaluated based on their collapse, foreshortening, radial pressure, and compliance. Steel stents (Cook Z and Wallstent) are less compliant than Nitinol stents (Luminexx and Wallstent) and are more reliable regarding concentrated forces, which are applied by dense and localized blood clots. Since the Nitinol stents are more compliant, they can follow the joint movements. Accordingly, they are more suitable for deployment close to body joints. Luminexx and Wallstent apply larger radial pressure and are the most reasonable choices for vital veins to guarantee a successful enlargement. If the final length of the stent is critical (e.g., deployment close to branch orifice), Cook Z can be the best choice because of its small foreshortening in comparison to other designs.
The major contributions of the thesis can be summarized as follows:

1. Established a framework for analytical unit-cell study of the mechanics of self-expanding stent
2. Introduced a suitable stent design for different locations and types of thrombosed (blocked) veins.
3. Studied collapse of self-expanding stents through compliant of the stent at the final stage of expansion

Furthermore, the objectives of the thesis were satisfied as follows:

1. The introduced analytical method is accurately capable of predicting the mechanical performance of the stent and be efficient enough to be employed for multiple computational analyses.
2. The candidate stents were compared in terms of mechanical performances such as radial pressure, foreshortening compliance, and collapse.

5.2 Limitations and Future Work

The lack of experimental results is the most vital limitation of this work. Analytical simulations are not capable of replicating the mechanics of a physical system. Thus, it is necessary to design a suitable experiment to evaluate the results of analytical and FE simulations. Another limitation is the number of stents which were investigated. We studied four stent designs which may not be enough to generalize the conclusions. The effect of shear forces has been neglected in developing the analytical method that can be investigated in the future work. To establish the unit-cell study framework, we assumed the radial pressure as the average pressure that each stent applies on the vessel. This assumption should be examined in further. In addition, the pressure distribution on the strut, which is applied by the vessel, was assumed to be uniform on the entire length of the stent, this can be modified in the later studies. The pressure distribution also depends on the mechanical interaction between the vein and the
stent. Studying the pressure distribution effect on the expansion is another area for future work.

The mechanics of venous stents was studied regardless of the anatomy and geometry of the vein. For instance, the expansion was assumed to be uniform on the entire structure of the stent, however, in the actual case, the stent expands to the geometry of the vessel lumen. The interaction between the vessel and the stent can affect the radial pressure, compliance and the performance against collapse. The collapse load is simply modeled as a contact problem. However, the actual mechanism is more complex. It appears that the mechanics of the vessel is another factor that affects the collapse. However, this factor has not been considered in this research.

5.3 Potential Applications

The analytical method presented here is suitable for design purposes and the optimization problems that required multiple computational analyses. The average process time on the same system for the analytical method, unit-cell study FE simulation and axisymmetric FE simulation was respectively few minutes, less than an hour and more than 2 hours. Although the precision of the presented method is not absolutely perfect, it can nominate some new models through designing processes. The nominated designs can be examined through different experiments for recognizing the most efficient stent.

The introduced method is useful for comparative studies. In addition to the candidate designs that have been examined, the mechanical performances of the other stent designs can also be evaluated through this model. Furthermore, by some modifications, we can investigate the mechanics of the other devices, which includes a lattice structure that is made of Nitinol.
References


27. Morlacchi S, Migliavacca F. Modeling Stented Coronary Arteries: Where We are, Where to Go. Annals of Biomedical Engineering. 2013. 41(7):1428-44.


