

Open Stent Design

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Introduction

Why Open Stent Design?

This project is intended to bring the collaborative principles of open source to the typically closed and proprietary world of medical device development. NDC has a long history pioneering development of Nitinol stents and similar components, and has also been a leading publisher and educator in the field. Contributing to the open source and creative commons movements is a natural evolution of our commitment to Nitinol education. It is our hope that providing these tools and resources in an unlimited way to the community of medical device developers, as well as academic researchers, reviewers, and others, we will inspire a new generation of designers with ideas that will advance the state of the art, and the practice of medicine.

Thoughts on Intellectual Property

It is nearly impossible to separate commercial medical device development from intellectual property. Bringing a medical component to market, especially in the case of an implant, is an exceptionally expensive affair. The level of upfront investment is high, the road is long, the outcome is uncertain. If the constellations align, the rewards are great. Consequently, any investor (whether a venture capitalist, or the R&D department of a large corporation) considering funding a medical device development endeavour is very concerned about intellectual property (IP) ownership and rights. IP is a broad term that includes creative works that may be protected by trade secrets, copyrights, trade secrets, or patents. In the case of medical component design, the focus is typically on patents and the issue for an investor is simple: after I invest my capital in developing this design, will someone else be able to simply copy my work and unfairly reap the benefit of my investment? Without patent protection, the risks to the potential investor may be unacceptably high, and consequently the investment may not be made, and the invention may never come to fruition.

So in the medical device business, just about everything we do is covered by patents, patent applications, trade secrets, and/or confidentiality agreements. The objective of any design is to create something novel and differentiated that can be protected by patents and distinguished in the marketplace. Companies work hard to preserve these benefits by enforcing strict practices of secrecy. So the medical device industry is proprietary by nature; the natural incentives in the industry promote secrecy and discourage sharing. In this way, the theory goes, innovation is enabled by providing the economic rationale for investments in expensive projects with long development cycles.

The proprietary nature of the medical device industry creates some difficulties when those of us inside the industry are motivated to share design guidance, principles, and techniques: Every realistic example we know about is proprietary! This manuscript seeks to circumvent this problem by creating a realistic medical component, the “Open Stent” that is completely generic, and using it as an example to discuss useful techniques and procedures relating to design and analysis of similar components.

In the microelectronics, software, and entertainment industries, by contrast, the development cycle is much shorter, the regulatory barriers are much lower, and intellectual property flows much more freely. The speed of innovation in these industries is ferocious. This accelerated culture of collaboration is enabled by the principles of *open source* development. In this model, creative individuals contribute their effort to a project, in exchange for a promise: I will donate my efforts to the commons, and in exchange the community can build upon my work, and society will enjoy the benefits of our collective efforts. This approach works quite well in the case of software, where IP is neatly embodied in lines of code that can be easily exchanged.

In the medical device industry, there is no direct equivalent of “lines of code.” Instead, there is a constellation of resources, including sketches, drawings, specifications, protocols, procedures, processes, and so on. In practice, though, much of this gets reduced to “lines of code,” in a figurative and often literal sense. Design specifications are often created using computer aided (CAD) systems, detailed in spreadsheets, and analyzed using sophisticated computer simulations. All of these things share the character of software code: they neatly capture creative effort, they are readily portable, and are easily shared and extended.

So this brings us to the purpose of this manuscript. Stents have been around for quite some time, thousands of stent related patents have been granted, and many more have been applied for. In IP terms, this means that there is a significant amount of *prior art* in the field. Because of all the published patents and other works in the public domain, it is now exceedingly difficult to develop novel designs in this field. The stent design used throughout this manuscript, instead, takes the opposite approach: it is intended to be completely generic, and intentionally *not* novel.

While the stent design itself is quite general, the techniques and resources that are described

here are creative works that have not been previously published, and (we hope) are useful, practical, and can be extended, expanded upon, and applied to new, different, and novel designs. Our motivation for this is simple: we want the medical design community to have the best tools and resources available for designing Nitinol medical devices. In doing so, the community benefits, society benefits, and NDC benefits along the way.

Thoughts on Licensing

In the past few years, a variety of standardized licensing strategies have been developed to aid and encourage efforts such as these. Typically, the copyright for creative works such as this manuscript is typically held by the author. In the era of the printing press, an author assigned his or her copyrights to a publisher, because only publishers had the means to duplicate and distribute content to reach a large audience. In the modern internet era, any content can be made available instantaneously throughout the world, with minimal cost. The intent of this publication is to reach as wide an audience as possible, and to make it as easy as possible to apply and adapt the content for new purposes.

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Publication, Attribution and Feedback

The version of this manuscript that you are currently reading is an unfinished working draft. We intend to continue to add and edit content, and hope to incorporate thoughts and feedback from the community. We plan to publish this through formal channels at some point in the near future, simply because a bound volume is often more convenient than an electronic version, and further, it is helpful to have a more formal means to cite the work in other publications. The terms of the license require any copies or derivative works to include a reference to the title and author. Though not strictly required, the author is quite interested in your thoughts on this work, and any improvements or adaptations you may make. The online home for this work can be found at <http://nitinoluniversity.com>, and we encourage you to visit us there to provide your feedback, and check for updates or new revisions as they become available. There you will also find additional resources relating to this work, including links to the design files, spreadsheets, finite element analysis input files, and related items.

Now go forth, remix, reuse, recycle. Everybody wins.

Chapter 1

Basic Elements of Stent Design

The word *stent* is used to describe any artificial structure that is used to provide support or scaffolding to a lumen or cavity within the body. The term is often credited to Charles Stent, a nineteenth century English dentist [3], and came into common use in the medical field with the introduction of the Wallstent, co-invented by Hans I. Wallstén in the 1980's [6] [5]. Modern stents are used throughout the human body, most commonly in arteries of the heart, neck, and lower limbs. Many other stent applications exist throughout the cardiovascular, pulmonary, and gastrointestinal systems of the body. Stents are typically fabricated from metals like stainless steel, cobalt alloys, or nitinol, and some polymer based designs are also being investigated.

1.1 Introduction to Nitinol

Nitinol, a nearly equiatomic alloy of nickel and titanium, is one of many materials that is commonly used to fabricate cardiovascular implants such as stents. Unlike traditional engineering materials like stainless steel and cobalt alloys, Nitinol exhibits the unusual properties of *shape memory* and *superelasticity*. These properties are manifestations of a *phase change* that occurs in the material as it transitions between a higher temperature *austenite* phase and a lower temperature *martensite* phase. The mechanical properties of these phases are quite different, and the transition between the phases creates unusual properties that are useful for many medical applications.

The temperature at which the phase change occurs, the *transition temperature* is critically important to the mechanical properties of the finished component. More specifically, it is the *difference* between the transition temperature and the environmental temperature that dictates performance. This is one of the reasons that Nitinol works so well in medical

applications: the environmental temperature of the human body is very stable, therefore the mechanical properties of a Nitinol implant are also stable.

When the material is substantially below its transition temperature, it is fully martensitic, and has material characteristics much like soft lead. It is easily deformed, and will remain deformed, just like any ordinary material. The unusual properties of Nitinol are demonstrated when the material is heated above its transition temperature to return to its austenitic phase. Now, this same material will spontaneously recover to its original shape, as if it had never been deformed. This demonstrates the *shape memory* property of nitinol.

When the material is substantially above its transition temperature, it is fully austenitic, and has material properties more like steel than lead. It is very elastic, with much higher stiffness than it had in the marenritic phase, though lower stiffness than typical stainless steels or other conventional engineering materials. Unlike typical materials, though, austenitic Nitinol can be deformed to a very substantial degree, and still recover to its original shape. This is a demonstration of *superelasticity*, and it is enabled by the stress induced transformation from austenite to martensite in local regions of high stress.

For all of these reasons, the transition temperature of a Nitinol component is of critical importance. It is commonly measured using a *bend free recovery* technique, wherein the component is cooled until it is fully martensitic, deformed to a specific shae, then slowly warmed to higher temeperatures while measuring the recovery to its original shape. Results from a typical transition temperature test are shown in Figure 1.1. The test begins at position 1. When heated, the shape begins to recover at position 2, and completes its recover fully by position 3. Tangent lines are drawn as indicated to establish A_s , the *austenite start* temperature, and the more commonly used A_f , the *austenite finish* temperature.

Figure 1.2 below illustrates typical stress vs. strain response for superelastic Nitinol in a uniaxial tensile test, for material having a transition temperature of approximately 25 degrees C. From position 1 to 2, the material is in its austenite phase. From position 2 to 3, the material is undergoing a transition from austenite to martnesite; this region is typically described as the *upper plateau*. From position 3 to 4, the material is fully martensitic; note that the slope in the 3-4 region is less steep than that in the 1-2 region, demonstrating the relatively lower modulus of martensite compared with austenite. When material is unloaded, it follows a different stress-strain path from position 4 to 5, then transitions along the *lower plateau* to position 6, before full recovering to its original shape at position 1.

The Stent Calculator formulations described later can theoretically apply to any type of metallic stent, but are especially well suited to Nitinol designs. This has nothing to do with the unusual shape memory or superelastic properties of the material, but rather the unusually high strains that can be achieved in the *linear elastic* region of the austenite phase.

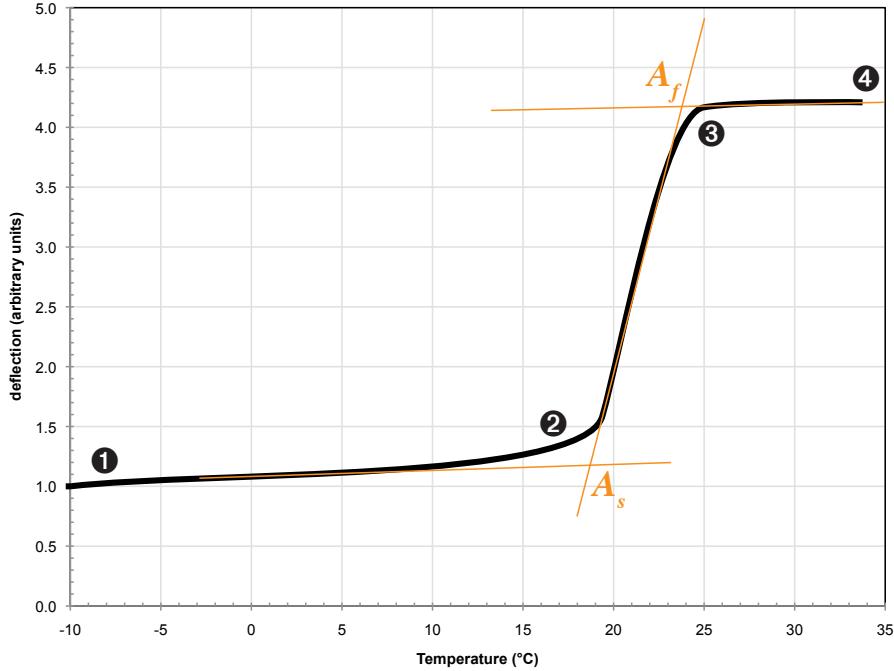


Figure 1.1: Typical transition temperature measurement results, using a bend free recover technique

The stress-strain curve between position 1 and 2 is substantially linear for strains of 1% to 2% in typical superelastic nitinol, which is an order of magnitude higher than the comparable level of fully recoverable strain in conventional engineering materials like stainless steel. Because of this, the stress vs. strain relationship for nitinol stents is approximately constant for relatively large, and often clinically relevant, range of deformations.

1.2 Stent Anatomy

Stents typically are comprised of an array of repeating structural elements commonly described as *struts*. These struts are generally oriented with their long dimension aligned with the axis of the cylindrical form of the stent. Struts are typically disposed around the circumference of a stent, and joined at alternating ends to form a series of “V” or “W” shapes. The union of adjacent struts is commonly described as a tip, elbow, or *apex*. A series of struts and apices that traverses one complete circumference is commonly described as a ring or *column*. Adjacent columns of struts are typically joined by *bridges* which connect some or all apices according to some regular pattern.

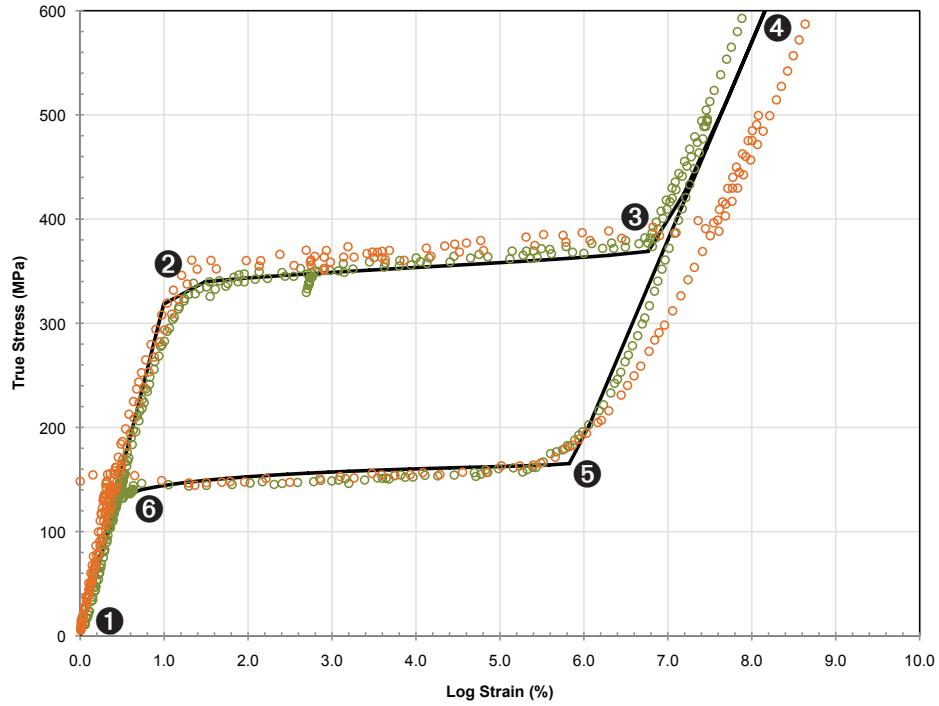


Figure 1.2: Typical uniaxial tensile test data for superelastic Nitinol

1.3 Transformations

Stents experience some important transformations during fabrication and service. Several of these are described in the following sections.

1.3.1 Diameter Transformation

A stent must be able to transform from a small diameter during insertion and delivery to a larger diameter at the implantation site, and in some cases repeat this cycle one or more times. If the stent is designed at or near its intended minimum diameter, the designer must craft features that can be fabricated at this small diameter, and expand to the intended maximum diameter, while providing the intended strength, scaffolding, flexibility and durability at a range of service diameters. Alternatively, if a stent is designed and fabricated at or near its maximum diameter, the designer must assure that the features

can crimp, fold, or otherwise pack efficiently allowing the structure to be constrained to the intended minimum diameter. In both cases, it is very easy to design structures that appear compelling in their fabricated state, but fail to transform to the opposite end of the expansion range. To avoid this unsatisfying end, the stent must be designed with both the *crimped* and *expanded* configuration in mind.

1.3.2 Material Removal

Another important transformation that occurs during manufacturing is *material removal*. Stents are commonly fabricated using a laser machining process that leaves a heat affected zone (HAZ) of some thickness adjacent to cut surfaces. Furthermore, the tubing from which stents are fabricated commonly have draw lines or other undesired features on their inner or outer surfaces. For these and other reasons, material is typically removed from the *raw*, or *as-cut* component by some combination of mechanical or chemical processes. Consequently, the stent must be designed to be fabricated according to one set of feature dimensions, then processed to remove a specified amount of material from each surface, such that the features achieve some desired *finished* dimensional targets. Here again, the stent must be designed with both the *raw* and *finished* configuration in mind.

1.3.3 Dimensionality and Coordinate Systems

One additional transformation is simply an engineering abstraction, albeit an important one. Stents are typically cylindrical structures that naturally exist in a cylindrical coordinate system. However, they are typically designed in planar form, using a cartesian coordinate system. Both are essential. The laser cut pattern for a stent must be developed in a two dimensional planar form, wherein the vertical height of the “unwrapped” stent is equivalent to the circumference of the tube on which it will be cut. The motion controller that reads the machine code will transform the vertical coordinates to *theta* coordinates, or rotational motions to fabricate the stent. While the two dimensional planar representation is essential for fabrication, a three dimensional cylindrical, or *wrapped*, representation is helpful for visualizing the actual component, and is essential for simulation and analysis.

1.3.4 Simultaneous Configurations and Constraints

Within a single instance of a single iteration of a single stent design, lie a multitude of embodiments, all of which must be considered simultaneously to achieve a successful design. The designer must consider:

- Crimped and expanded diameter configurations
- Raw and finished feature dimensions
- Planar and cylindrical representations
- And more...

Beyond these items, a design family may be comprised of a matrix of different stent lengths and expansion diameters, and may have multiple design features within a single stent. And it is likely that these features will be iterated many times during the design and development process to achieve optimal performance, reliability, and manufacturability. The combination of all of these simultaneous configurations and constraints creates an important opportunity to apply the tools of *computer aided design*, or *CAD*.

1.4 Computer Aided Design of a nitinol Stent

While Computer Aided Design, or CAD, has come to be associated with computerized drafting or solid modeling, in a more general sense the term applies to any computer based techniques that can be applied to the design or development process. This manuscript considers three interrelated elements of computer aided stent design. Each is driven by some essential design inputs, and provides some prediction of relevant performance outputs.

1. **Parametric Solid Modeling:** A three dimensional solid model is developed to programmatically create a stent design in any combination of crimped, expanded, raw, finished, planar or cylindrical forms.
2. **Stent Calculator:** A series of formulas is developed to predict the strength, strain, durability, and other performance features of a stent design on the basis of a finite set of input parameters.
3. **Finite Element Analysis:** The stent design is simulated using the techniques of finite element analysis to confirm the Stent Calculator results.

Each of these are described in the following chapters. The order of the first two is somewhat arbitrary, and does not imply dependency. Stent Calculator and the Parametric Solid Model both require the same input data, and neither require the results of the other. The tools of Stent Calculator are very easy to apply to many “what-if” design scenarios very quickly, making it a very useful screening tool. Consequently, it is best to explore many potential designs using Stent Calculator before investing energy into any Parametric Solid Modeling. In any event, Finite Element Analysis (FEA) is the most complex of the three, and is typically used sparingly. In this manuscript, the Parametric Solid Modeling

chapter is presented first with the intention of providing a visual and geometric basis for understanding the math and discussion in the later Stent Calculator chapter.

Chapter 2

Parametric Solid Model

It would be challenging to describe the design process for a stent without referring to an actual stent design. Since virtually every stent design in existence is proprietary, a new generic design was created for this exercise. The Open Source Stent (OSS) is designed for no particular purpose other than provide a realistic example for utilizing the tools of computer aided stent design.

The Open Source Stent described here was designed with SolidWorks Professional 2010 (Dassault Systèmes SolidWorks Corporation, Concord, MA). SolidWorks is a widely used commercial CAD software package that is commonly used in the medical device industry. The source part file that is provided under the same terms as this manuscript can be edited and manipulated with SolidWorks 2010 or higher, and can be viewed using the eDrawings Viewer application available from <http://edrawingsviewer.com>.

As noted in the previous chapter, the stent must be designed with a number of simultaneous constraints in mind. This SolidWorks part is *parameter* driven, allowing the user to easily select the raw or finished state, crimped or expanded state, and planar or wrapped configuration. The following sections provide step by step details describing exactly how the stent geometry is built, and how the model can be transformed between states. With the detail provided, a moderately experienced user of Solidworks, or other solid CAD packages (Pro/Engineer, Autodesk Inventor, or others) should be able to recreate the design, and more importantly extend or customize the design to be suitable for various applications. In the spirit of the Creative Commons, the community is encouraged to create “translated” versions of this design, and share them with the same licensing terms.

Table 2.1: Global variables defined using SolidWorks equations

title name of the table

Global Variable	Comment
"finishing"=1	A logic flag to define whether the design is in a raw/as-cut state (0) or finished state (1).
"expanded"=1	A logic flag to define whether the design is in a crimped state (0) or expanded state (1).
"N_col"=10	Numer of columns of struts along the length of the stent.
"N_struts"=42	Number of struts around the circumference of the stent.
"D_tube"=1.915	Outer diameter of the tubing from which the stent is cut.
"D_set"=8	Expanded diameter of the stent.
"t_raw"=0.17	Wall thickness of the tubing from which the stent is cut.
"L_strut_inner"=1.2	Length of the strut.
"w_apex_raw"=0.13	Width of an apex in the raw state.
"X_bridge"=.15	Axial gap between adjacent columns of struts
"Y_bridge"=0	Circumferential offset for each bridge.
"w_bridge_raw"=0.125	Width of a bridge in the raw state.
"N_bridges"=7	Number of bridges around the circumference
"w_kerf"=0.025	Minimum circumferential gap between struts in the crimped state.
"m_width"=0.036	Amount of material removal from feature widths.
"m_thickness"=0.059	Amount of material removal from wall thickness.

2.1 Input Parameters and Equations

The variables and equations described by Tables 2.1 and 2.2 can all be defined before beginning any geometry creation. In SolidWorks, the equations are entered by accessing

Table 2.2: Equations to define global variables linked to feature dimensions

Equation	Comment
<code>"D_model"=</code> <code>"D_tube"+"expanded"*("D_set"- "D_tube")</code>	Diameter of the model, considering the state of the <code>expanded</code> logic flag.
<code>"Y_strut"=</code> <code>"D_model" *pi / "N_struts"</code>	Circumferential distance occupied by a single strut at the analysis diameter.
<code>"w_strut"=</code> <code>(("D_tube" *pi) / "N_struts")</code> <code>- "w_kerf"- "m_width" * "finishing"</code>	Width of a strut, considering the state of the <code>finishing</code> logic flag.
<code>"w_bridge"=</code> <code>"w_bridge_raw"- "m_width" * "finishing"</code>	Width of a bridge, considering the state of the <code>finishing</code> logic flag.
<code>"w_apex"=</code> <code>"w_apex_raw"- "m_width" * "finishing"</code>	Width of an apex, considering the state of the <code>finishing</code> logic flag.
<code>"t"=</code> <code>"t_raw"- "m_thickness" * "finishing"</code>	Wall thickness, considering the state of the <code>finishing</code> logic flag.
<code>"inner_radius"=</code> <code>("w_kerf" + "m_width" * "finishing") / 2</code>	Inner radius of an apex
<code>"outer_radius"=</code> <code>"inner_radius" + "w_strut"</code>	Outer radius of an apex
<code>"L_strut_rectangle"=</code> <code>"L_strut_inner"- "inner_radius" * 2</code>	Length of the perfectly rectangular section of a strut between apices
<code>"D_inner"=</code> <code>"D_model"- ("t" * 2)</code>	Inner diameter of the stent

Tools > Equations... from the menu. When defining dimensions in sketches and features, the driving value can be linked to these global variables as shown in Figures 2.1 and 2.2. The completed global variables and equations appear as shown in Figure 2.3.

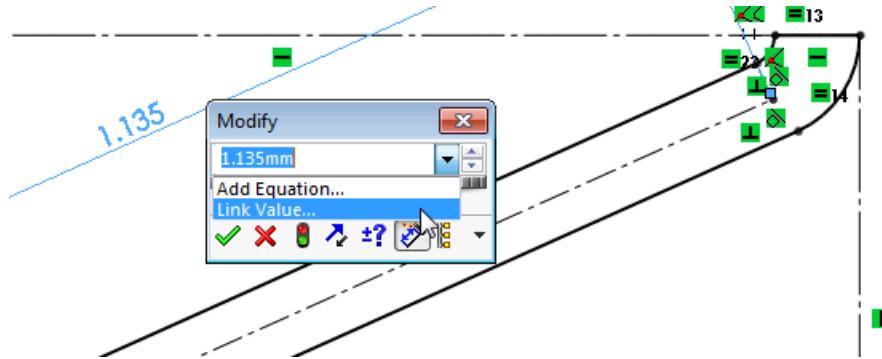


Figure 2.1: Define dimension by selecting “Link values...”

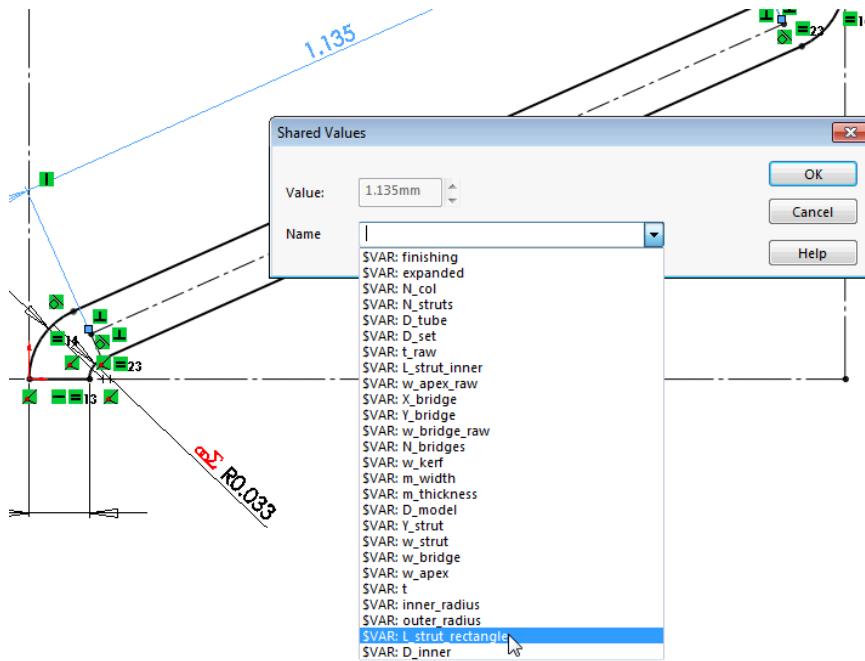


Figure 2.2: Select desired global variables to link to feature dimension.

2.2 Master Strut Sketch

The first sketch in the stent part is the *Master Strut Sketch*. This sketch is carefully constructed such that all of its feature dimensions are driven by global variables, and it can reliably transform from the crimped to expanded state, and raw to finished state, without “breaking”. The sketch is fully constrained without being overconstrained, which

Active	Equation	Evaluates To	Comment
✓	1 "finishing"=1	✓ 1	
✓	2 "expanded"=0	✓ 0	
✓	3 "N_col"=10	✓ 10	
✓	4 "N_struts"=42	✓ 42	
✓	5 "D_tube"=1.915	✓ 1.915	
✓	6 "D_set"=8	✓ 8	
✓	7 "t_raw"=0.17	✓ 0.17	
✓	8 "L_strut_inner"=1.2	✓ 1.2	
✓	9 "w_apex_raw"=0.13	✓ 0.13	
✓	10 "X_bridge"=.15	✓ 0.15	
✓	11 "Y_bridge"=0	✓ 0	
✓	12 "w_bridge_raw"=0.125	✓ 0.125	
✓	13 "N_bridges"=7	✓ 7	
✓	14 "w_kerf"=0.025	✓ 0.025	
✓	15 "m_width"=0.040	✓ 0.04	
✓	16 "m_thickness"=0.06	✓ 0.06	
✓	17 "D_model"="D_tube"+"expanded"*(D_set"-D_tube")	✓ 1.915	
✓	18 "Y_strut"="D_model"*\pi/N_struts"	✓ 0.143242	
✓	19 "w_strut"=(D_tube*\pi)/N_struts"-w_kerf"-m_width"*finishing"	✓ 0.0782417	
✓	20 "w_bridge"="w_bridge_raw"-m_width"*finishing"	✓ 0.085	
✓	21 "w_apex"="w_apex_raw"-m_width"*finishing"	✓ 0.09	
✓	22 "t"="t_raw"-m_thickness"*finishing"	✓ 0.11	
✓	23 "inner_radius"="w_kerf"+m_width"*finishing"/2	✓ 0.0325	
✓	24 "outer_radius"="inner_radius"+w_strut"	✓ 0.110742	
✓	25 "L_strut_rectangle"="L_strut_inner"-inner_radius"**2	✓ 1.135	
✓	26 "D_inner"="D_model"-("t"**2)	✓ 1.695	

Figure 2.3: SolidWorks global variables and equations driving design features

is a balance that can be challenging to achieve with stent models in SolidWorks.

The sketch is created on the front plane, and the first geometry features placed in the sketch form a rectangle comprised of *construction lines*. The bottom horizontal line is anchored at one end to the origin, and the top horizontal line is placed at a distance of *Y_strut* above the bottom line. These two lines define the bounds of the strut in the vertical or circumferential direction, and the spacing between them will vary depending upon the crimped or expanded diameter of the stent. Vertical lines are then placed at the left and right, forming a construction rectangle that will bound the strut at all times. Figure 2.4 shows the master strut sketch in the crimped state, and Figure 2.5 shows the same master strut sketch in the expanded state. Note that the horizontal length of the construction rectangle is not defined, but rather it is dependent upon the defined length of

the strut, and the angle at which the strut is expanded. It should also be noted that the expanded configuration assumes that the strut will be perfectly straight, while in reality an expanded strut bend with a curvature that is too complex to represent in this simple model. Consequently, the expanded configuration constructed in this CAD model should be considered a visual approximation only.

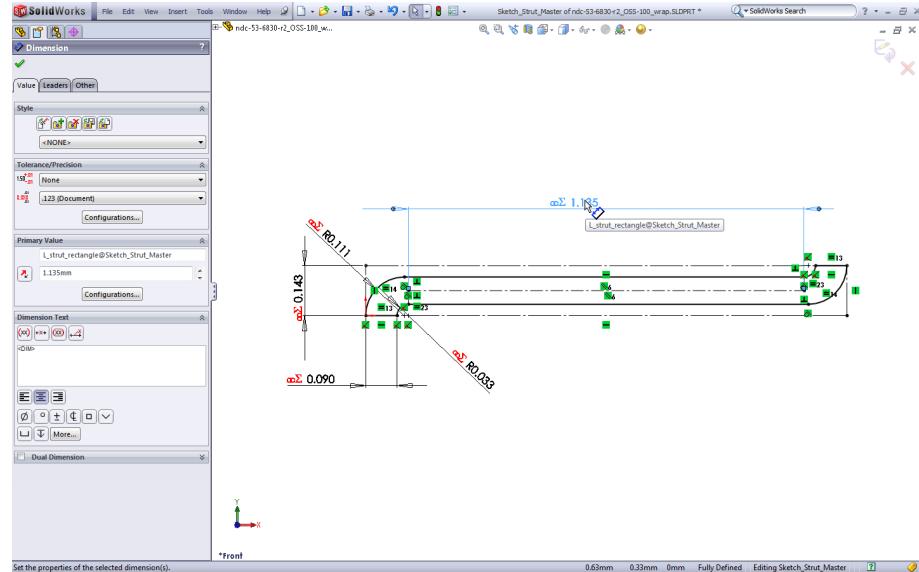


Figure 2.4: Master strut sketch, with the model in the crimped state

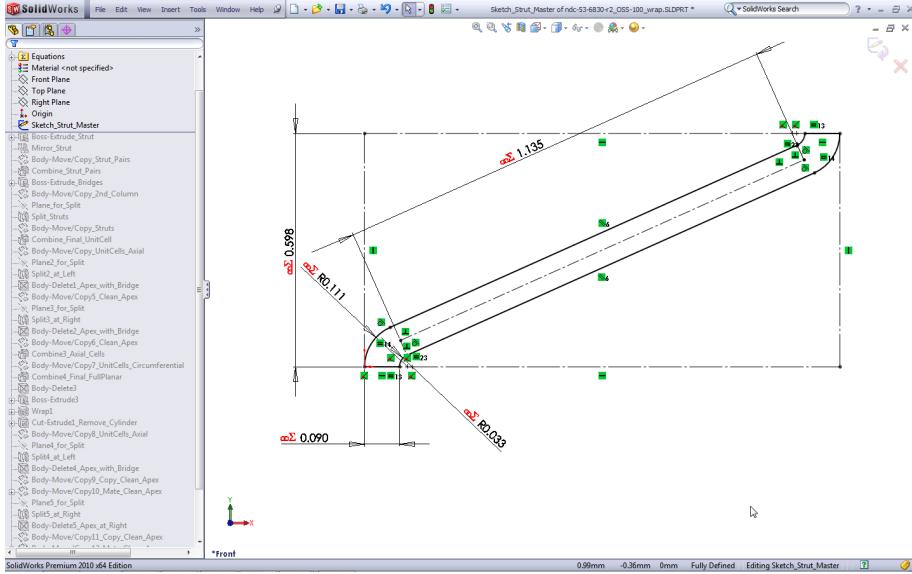


Figure 2.5: Master strut sketch, with the model in the expanded state

2.3 Creating a Planar Unit Cell

The first sketch is preserved as a “master”, leaving it available for future use if necessary. To achieve this, a new sketch is created for the first extrude feature, and the “convert entities” function in the sketch module is used to create new entities that are linked to those in the master sketch. With this technique, no new dimensions are defined in the extrude feature, other than the thickness of the extrusion itself (which is linked to the global variable t). The first strut is shown in Figure 2.6. After creating this first strut, it is mirrored to form a strut pair. In the next step, the strut pair is copied twice. The number of “copies” to define in this step depends on the pattern of bridge connections in the desired design. In this 42-strut case, there are seven bridges around the circumference, or one for every three strut pairs; therefore, two copies are required for this design. The mirrored, copied, and combined strut are shown in Figure 2.7.

Once the first set of struts has been created, the bridge features are added to each end, as shown in Figure 2.8. The combined structure now represents half of the *unit cell*, or smallest repeating geometry unit in the stent. This structure is next copied in the axial direction, forming the first elements of the second column of the design, as seen in Figure 2.9. The struts are now in an inconvenient arrangement, so a split and move features are created to form the final combined planar unit cell geometry as shown in Figure 2.10

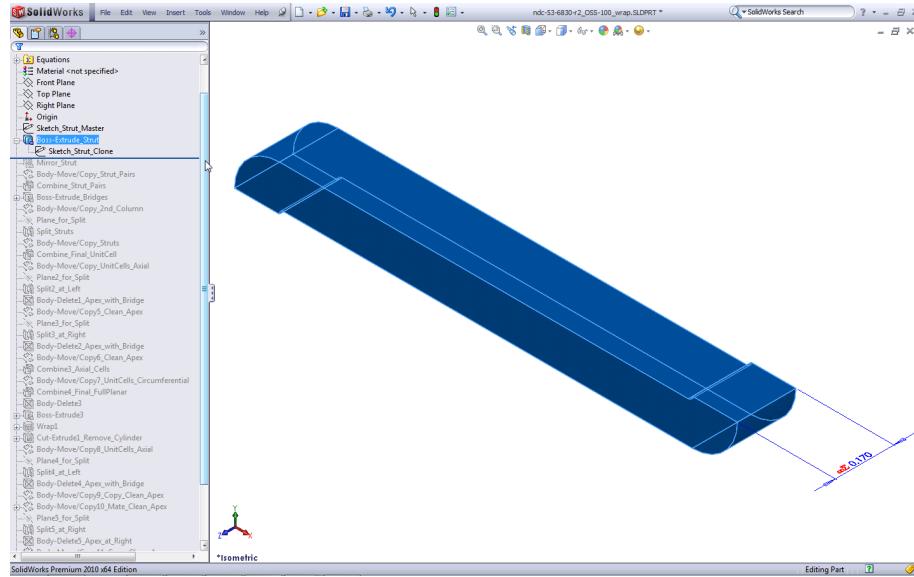


Figure 2.6: The first strut is extruded into solid form.

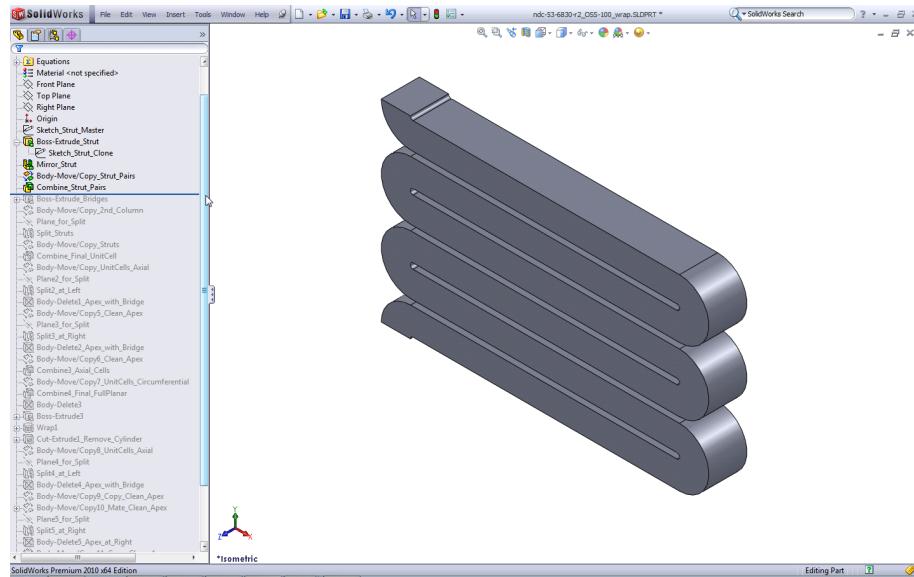


Figure 2.7: The strut is mirrored, copied, and combined.

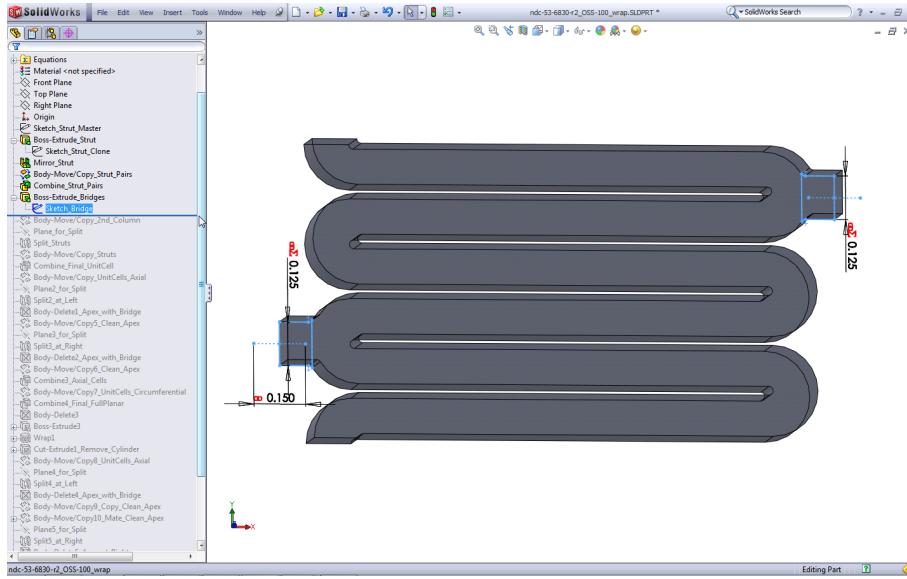


Figure 2.8: The bridge geometry is sketched and extruded.

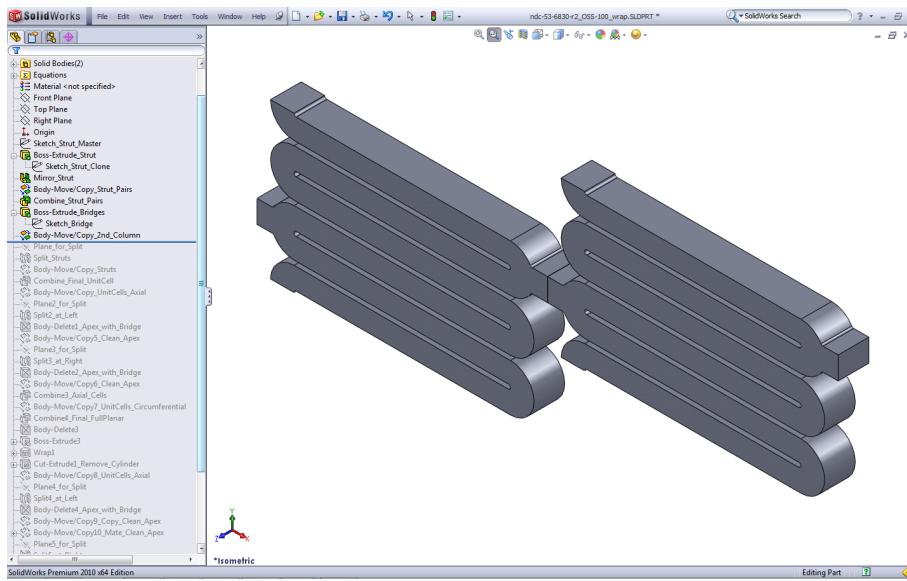


Figure 2.9: The first partial column of struts is copied to form the second partial column.

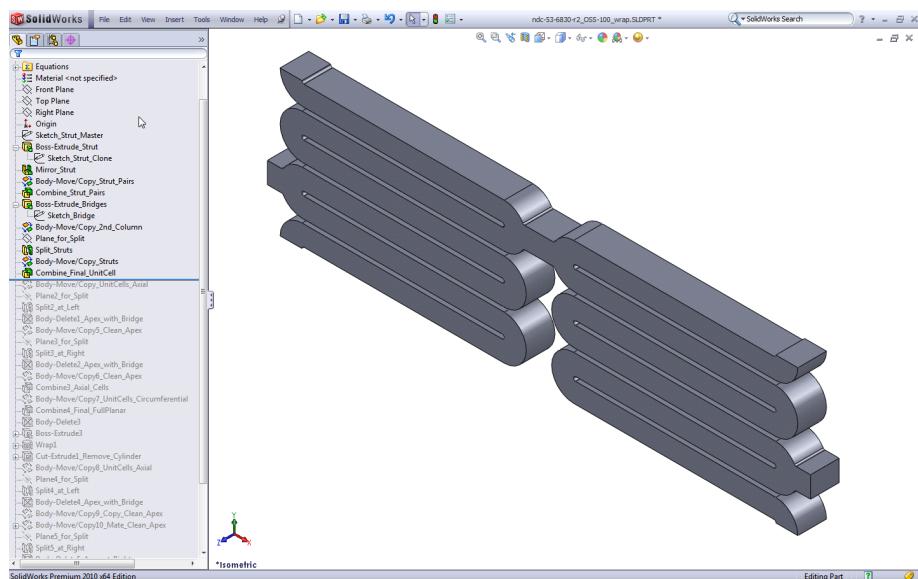


Figure 2.10: The struts are realigned to form the final unit cell.

2.4 Creating a Full Planar Stent Model

The unit cell geometry developed in the previous section is the repeating unit that forms the basis for the full stent geometry. However, the ends of a stent typically have some unique geometry features that require special treatment. At very least, the bridges should not be present at the ends of the stent, so they need to be removed. The approach, then, is to copy the unit cell in the axial direction as many times as necessary, then modify the end features before copying the full axial unit around the circumference. These steps are created in the same SolidWorks part file, but using a new *configuration*. With this approach, the full model can build from the unit cell model, and when both are completed, the user can easily switch between them.

Figure 2.11 shows the first axial copying step,¹ in this case creating four copies of the first pair of columns, for a total of ten columns in the finished design. To correct the geometry at each end, the strut pairs are *split* in such a way that the apex with the bridge can be deleted with a *Delete Body*, and the apex without the bridge can be copied in its place with a *Body Move/Copy* feature. These steps are shown in Figures 2.12 and 2.13. Finally, the geometry is patterned around the circumference using copy and combine features, with the final result shown in Figure 2.14.

¹Using a *Linear Pattern* feature may be more obvious and intuitive, but this feature does not allow the offset distance to be derived directly from existing geometry. With the *Body Move/Copy* feature, corresponding points at the right and left bridges are used to define the translation for each copy. Now, as the geometry is modified, these points move automatically, and the copy feature always uses the correct translation.

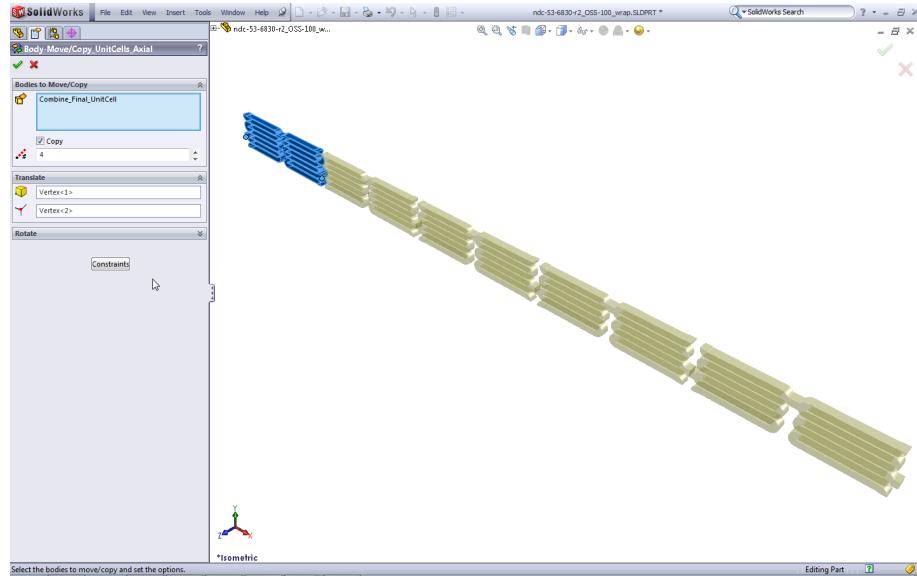


Figure 2.11: Master strut sketch, with the model in the crimped state.

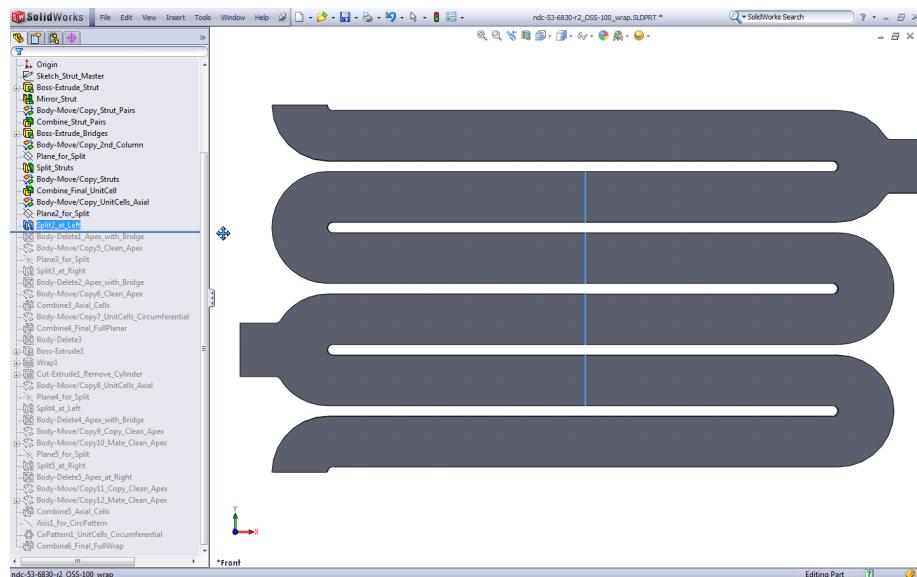


Figure 2.12: Defining the split feature. Prior to this step, a reference plane was created by selecting the midpoints of the struts shown. Now, the split feature is always positioned at the correct location on the strut.

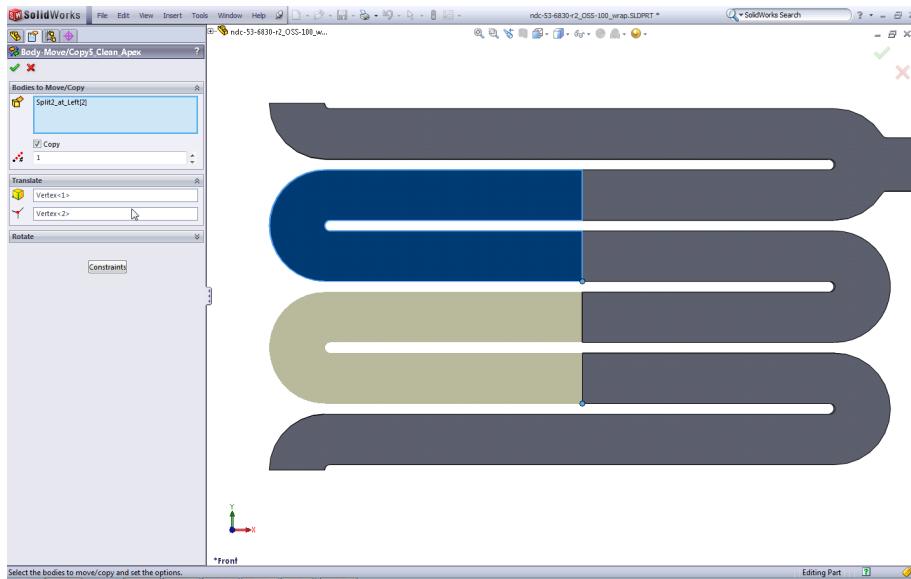


Figure 2.13: After deleting the apex with the unwanted bridge, the clean apex is copied into place.

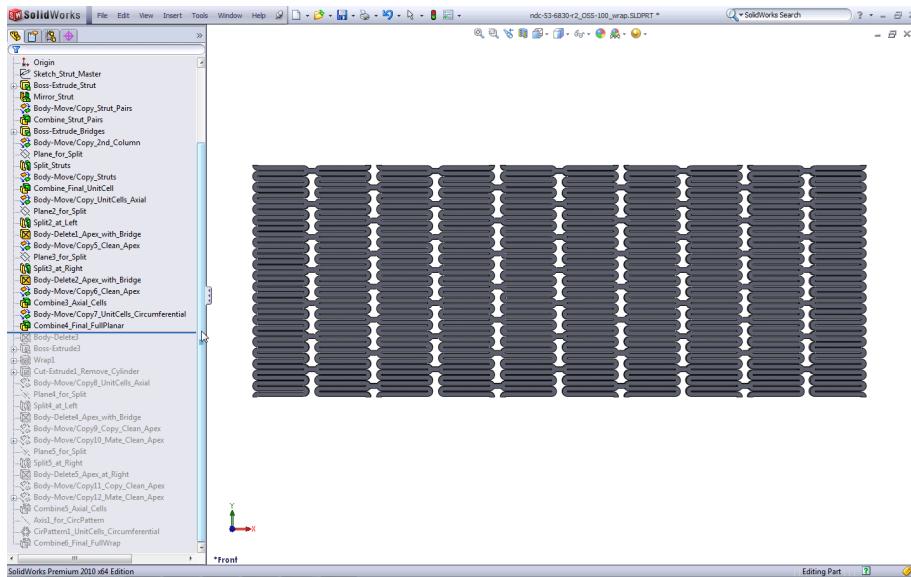


Figure 2.14: The full planar stent geometry, ready to create a two dimensional CAD file for laser coding.

2.5 Creating a Wrapped Unit Cell Model

As described in the previous section, the wrapped unit cell model is created as a new configuration that builds upon the planar unit cell shown above in Figure 2.10. The first step in building this configuration is to actually delete the planar unit cell using the *Delete Body* feature, as seen in Figure 2.15. Next, in Figure 2.16, a cylinder is created, onto which the unit cell geometry will be projected and embossed. A *Wrap* feature is created, along with a new sketch on the front plane. While in this sketch, the deleted final planar unit cell geometry is selected from the model tree. One face is selected, the *Convert Entities* function in the sketch module traces the unit cell, and creates new cloned geometry for the wrap feature that is linked back to the original planar unit cell, shown in Figure 2.17. When the wrap feature is completed, the unit cell geometry becomes embossed on the inner surface of the cylinder, as shown in Figure 2.18. Next, in Figure 2.19, the cylinder is cut away, leaving behind the finished wrapped unit cell, as shown in Figure 2.20.

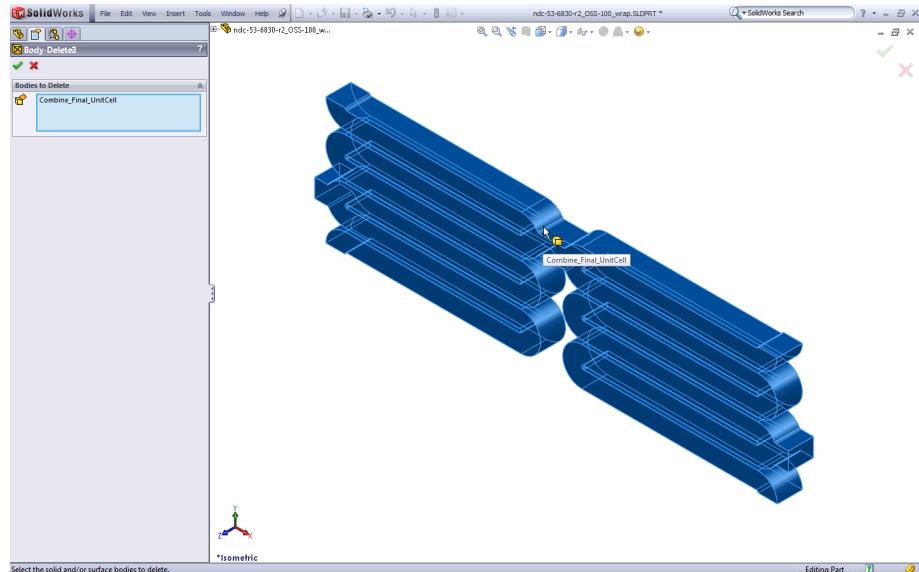


Figure 2.15: The planar unit cell is deleted from the model, but can still be used later to define the wrapping geometry.

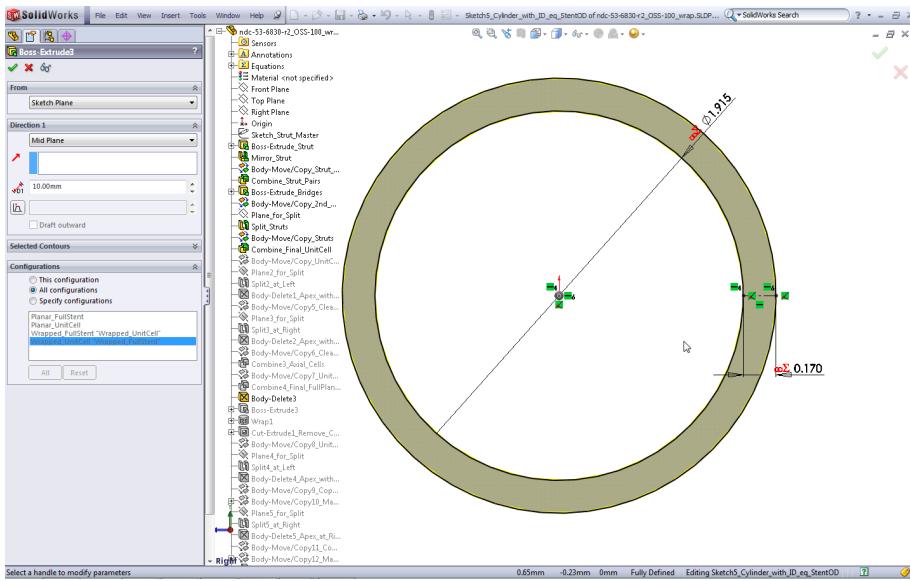


Figure 2.16: A cylinder with its inner diameter equal to the desired outer diameter of the wrapped stent. The thickness of this cylinder is arbitrary.

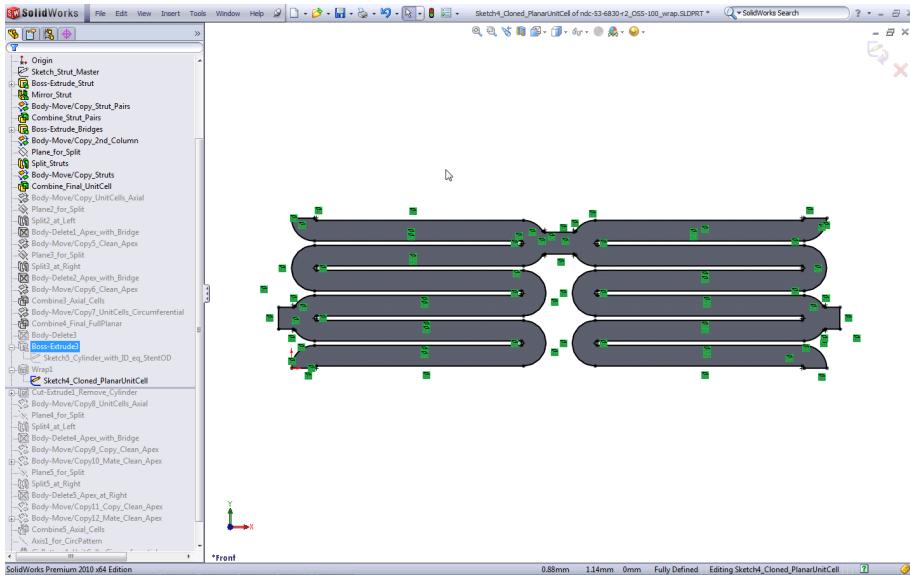


Figure 2.17: A clone of the unit cell is created by linking features in a new sketch back to the planar unit cell created above.

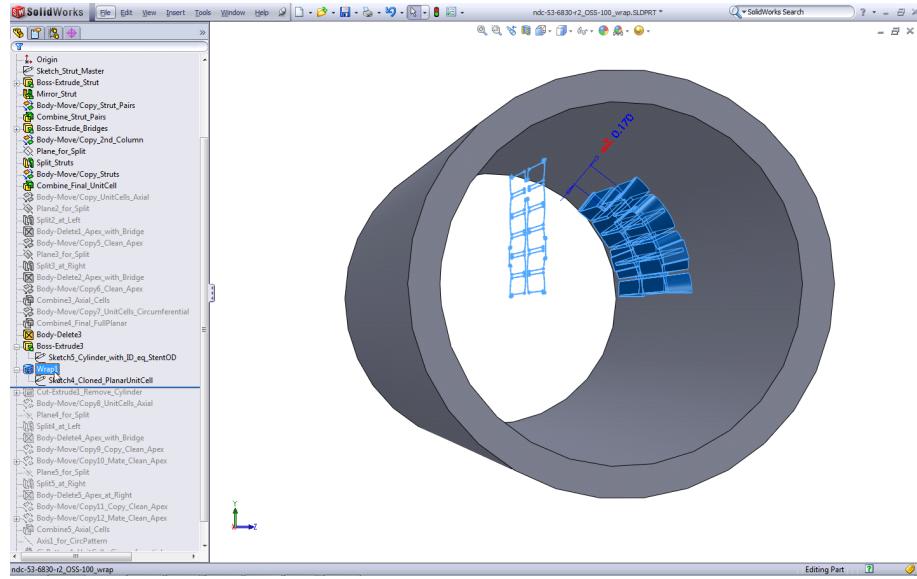


Figure 2.18: The unit cell is projected onto the inner surface of the cylinder and embossed to create a wrapped unit cell.

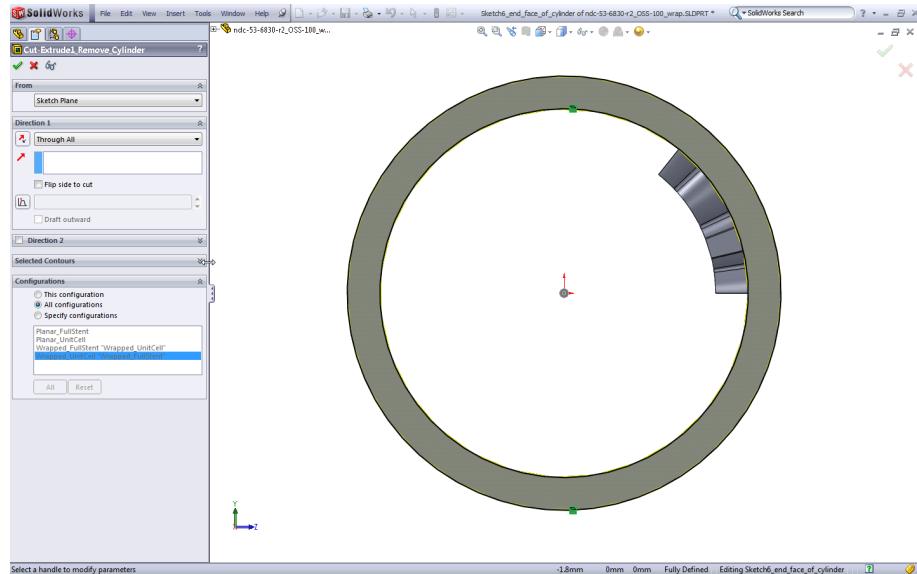


Figure 2.19: The cylinder is stripped away from the unit cell using a cut feature.

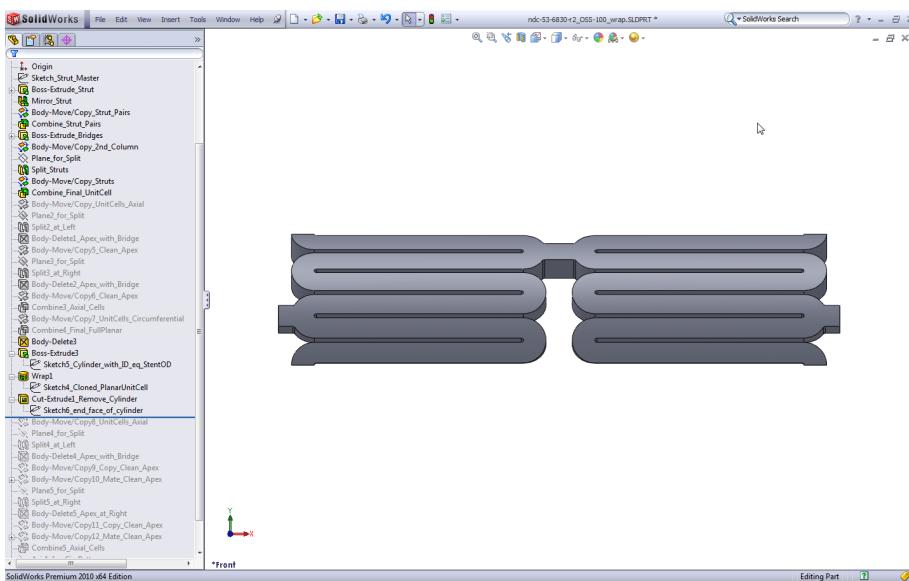


Figure 2.20: The final wrapped unit cell.

2.6 Creating a Full Wrapped Model

The fourth and final configuration to create is a full wrapped stent model. The process for creating this model is similar to that used to extend the planar unit cell model to a full planar model above. First, in Figure 2.21, the wrapped unit cell is patterned in the axial direction using *Body Move/Copy* as before. Next, in Figure 2.22, the struts are split, and the unwanted apex is deleted. For the next step, the new apex can not be simply translated to the empty place as before; rather, it must be translated *and rotated* to align properly. To accomplish this, the apex is first copied to an area away from the stent, as shown in Figure 2.23. This detached apex is next moved into place using *mating* functionality of *Body Move/Copy*². As shown in Figure 2.24 two pairs of coincident points are selected on the detached apex and the stent itself. This provides adequate constraints to position the new apex properly. This is repeated on both ends of the stent. In Figure 2.25, an axis is created at the intersection of the top and front planes to define the central axis of the stent. Finally, in Figure 2.26, the *Circular Pattern* feature is used to complete the wrapped stent geometry. After a final *combine* feature, the full wrapped stent geometry can be seen in Figure 2.27.

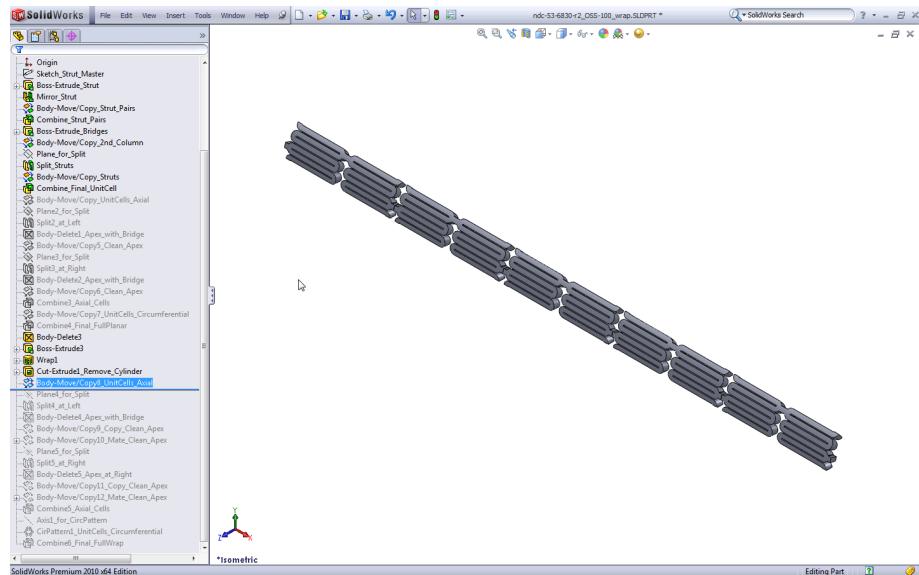


Figure 2.21: The wrapped unit cell is copied in the axial direction.

²Unfortunately, SolidWorks does not allow mating alignments when *copying* bodies – this only works when *moving* bodies. It is for this reason that the intermediate step of creating a detached apex is required.

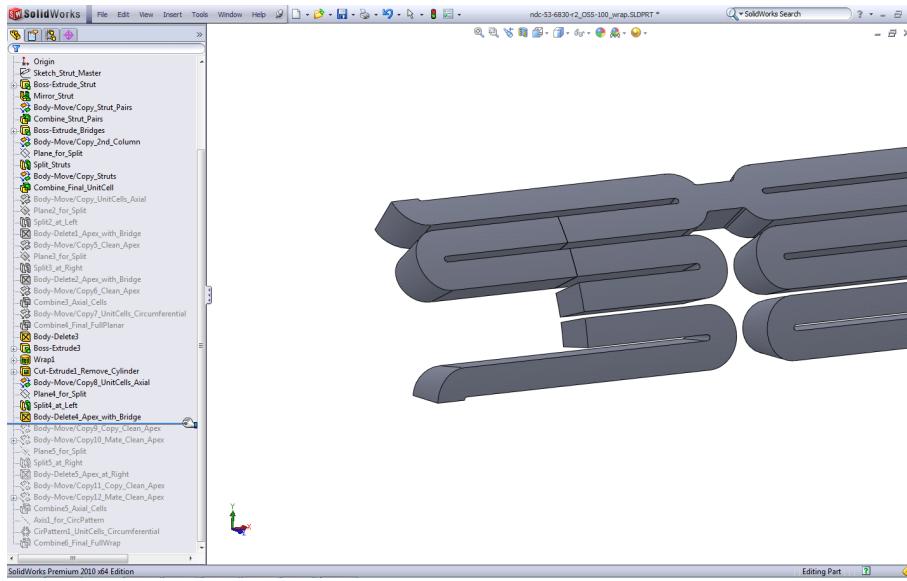


Figure 2.22: After splitting the struts, the unwanted apex is deleted.

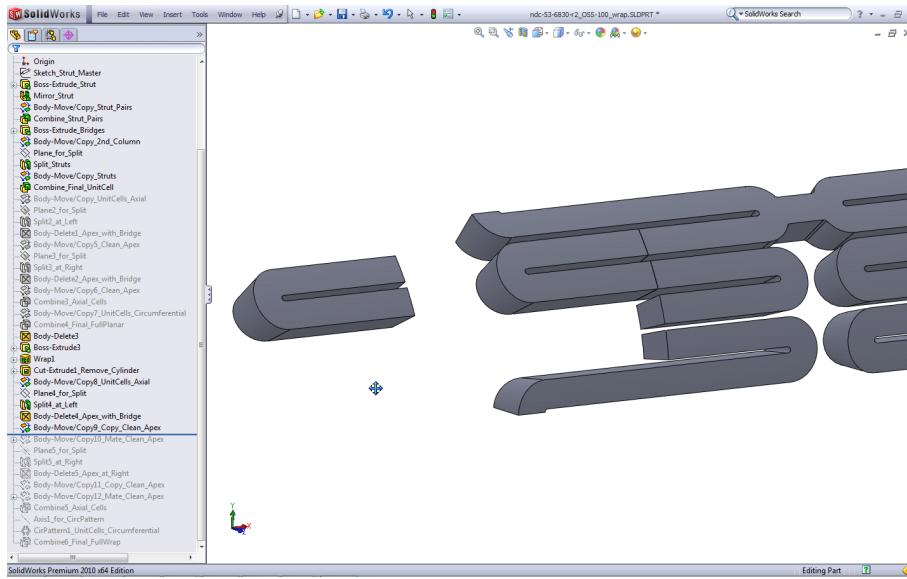


Figure 2.23: The new apex is copied away from the stent temporarily.

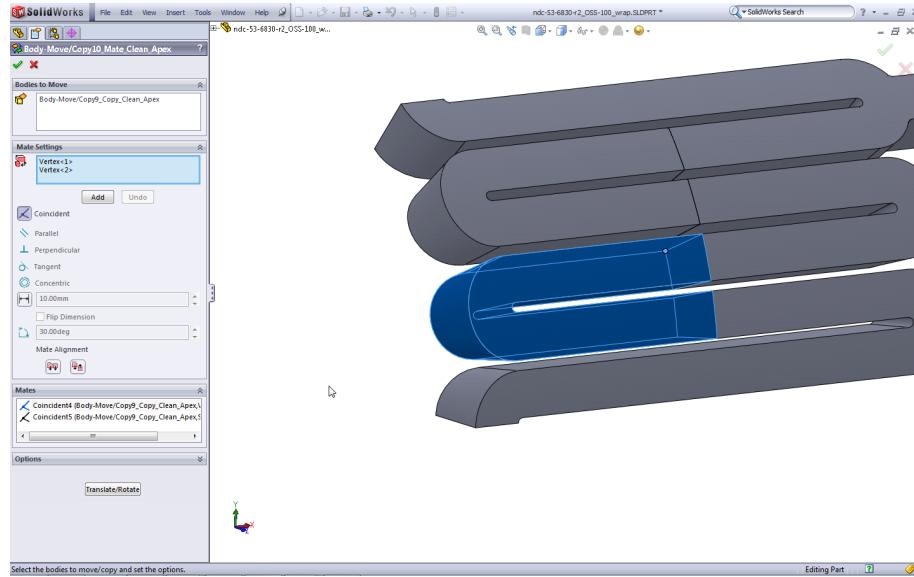


Figure 2.24: The detached apex is moved into place using coincident point pairs.

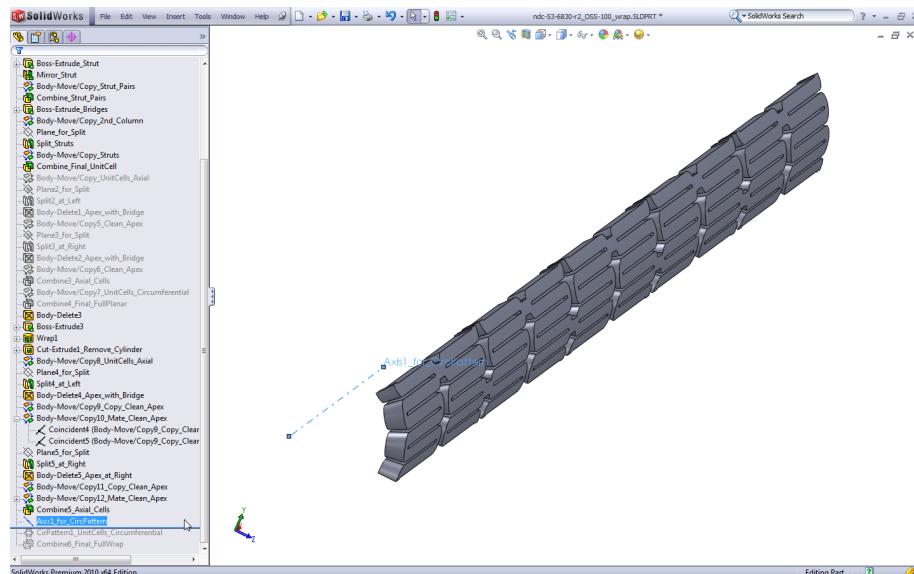


Figure 2.25: An axis is placed at the center of the stent.

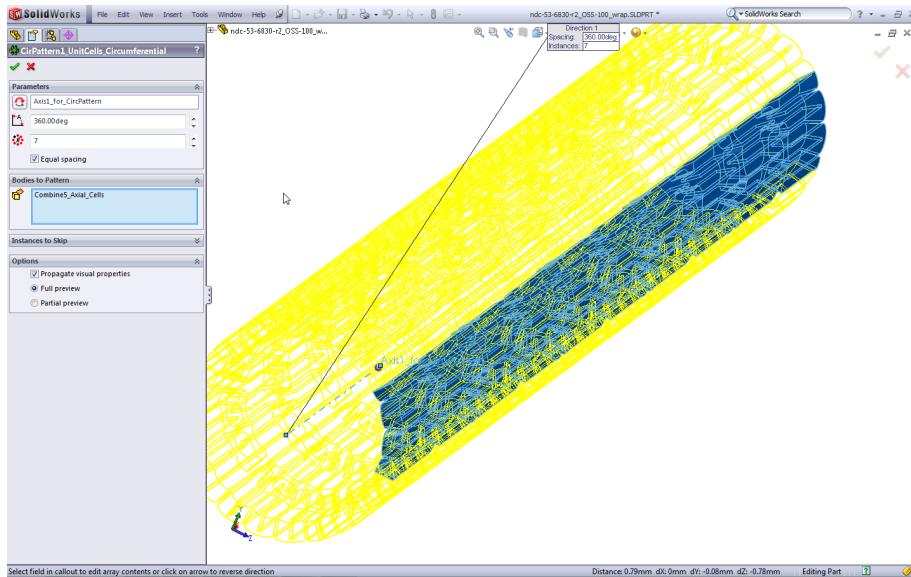


Figure 2.26: A circular pattern feature completes the circumferential patterning.

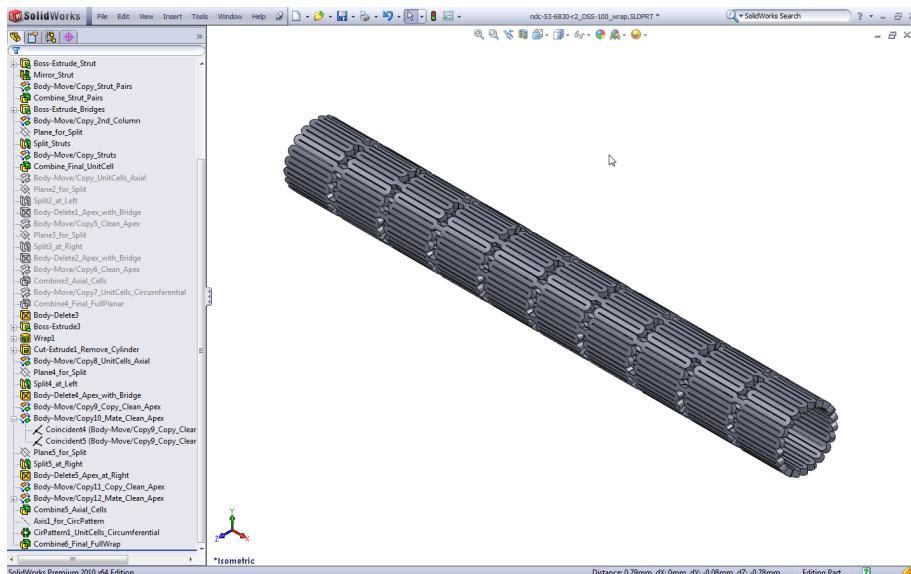


Figure 2.27: The final fully wrapped stent.

2.7 Transforming the State of the Model

The completed solid part can now be easily transformed into alternate configurations. To change from the raw to the finished state, change the `finishing` global variable from 0 to 1, as shown in Figure 2.28. After making the change, the user must manually trigger a rebuild of the model by clicking the appropriate icon, or pressing `Ctrl+B`. The transformed finished part is shown in Figure 2.29. To change from the crimped to expanded state, change the `expanded` global variable from 0 to 1, as shown in Figure 2.30. After rebuilding the model, the result is shown in Figure 2.31.

The wrapped and planar state, as well as the unit cell and full states for each, are controlled by SolidWorks *Configurations*.³ Figure 2.32 shows the configuration selection for the wrapped unit cell case, and Figure 2.33 shows the configuration selection for the planar unit cell case. Figure 2.34 depicts four possible unit cell configurations in the crimped state. The bottom right case, a wrapped unit cell with finished dimensions, is one that might be used for finite element analysis simulation. Figure 2.35 is a planar full stent, in the crimped configuration, with raw dimensions – this is a configuration that might be used to generate a laser cutting program. Finally, Figure 2.36 depicts the full stent in its finished state – this configuration might be used to support a finished specification for the component.

³Ideally, the crimped or expanded state, and raw or finished state would also be controlled by *Configurations*. Unfortunately, this is not possible because of a limitation that prevents global variables from being controlled in a configuration design table. Reference SolidWorks Knowledge Base issue S-04428: “Can a design table establish global variables which are used in SolidWorks equations?”

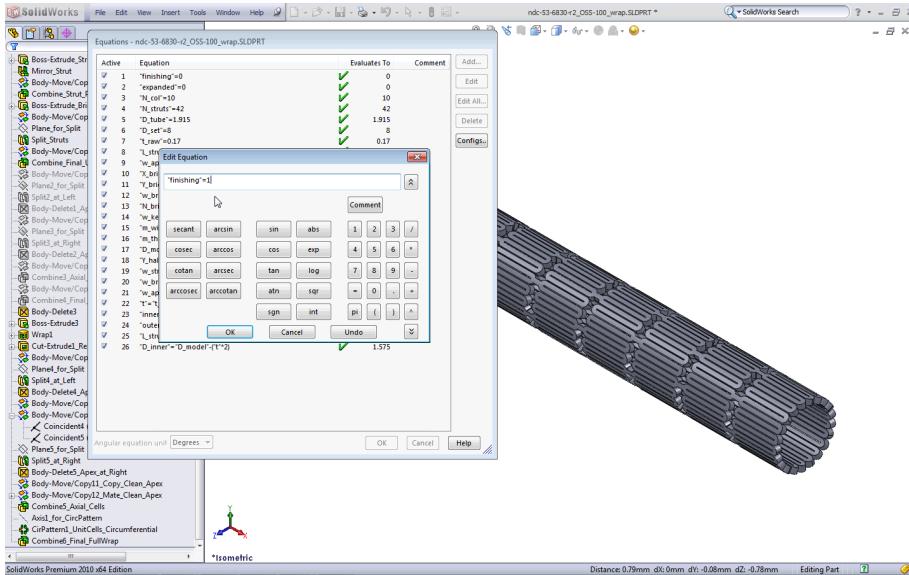


Figure 2.28: Change from the raw to finished state by editing the “finishing” global variable.

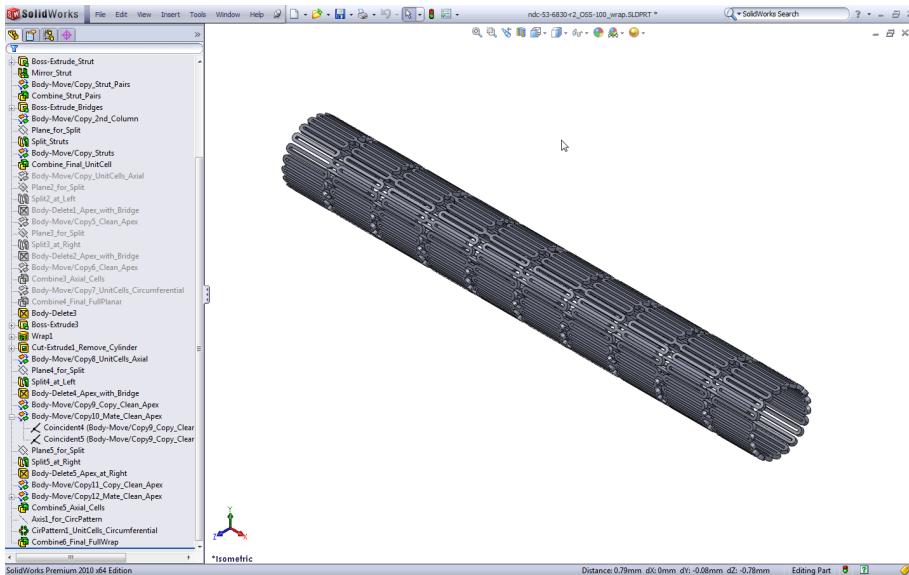


Figure 2.29: Transformation to the finished state.

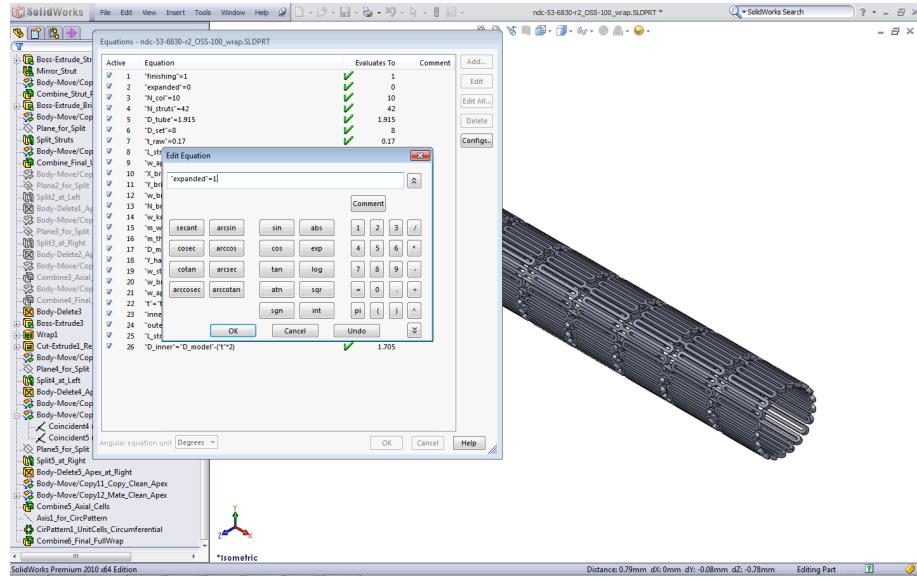


Figure 2.30: Change from the crimped to expanded state by editing the “expanded” global variable.

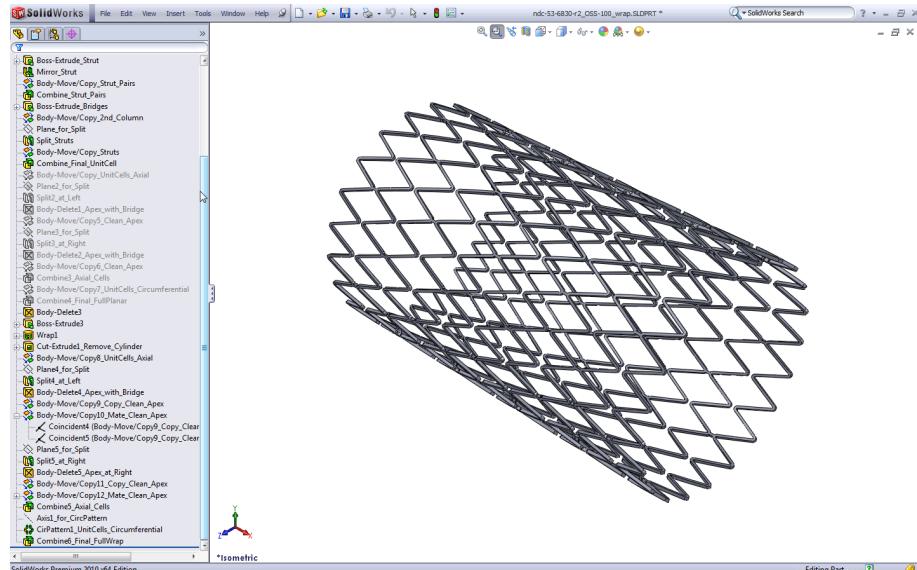


Figure 2.31: Transformation to the expanded state.

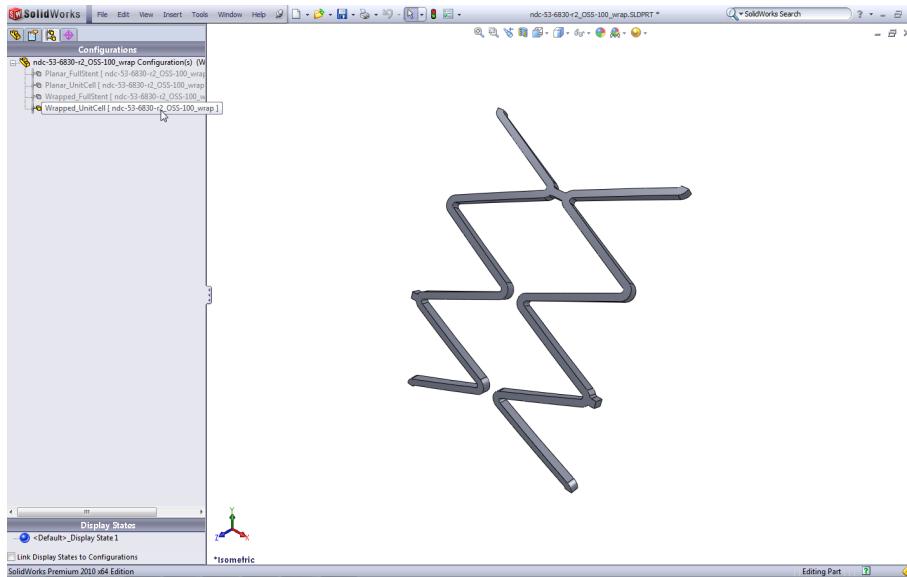


Figure 2.32: Change to the wrapped unit cell state using the SolidWorks configuration manager.

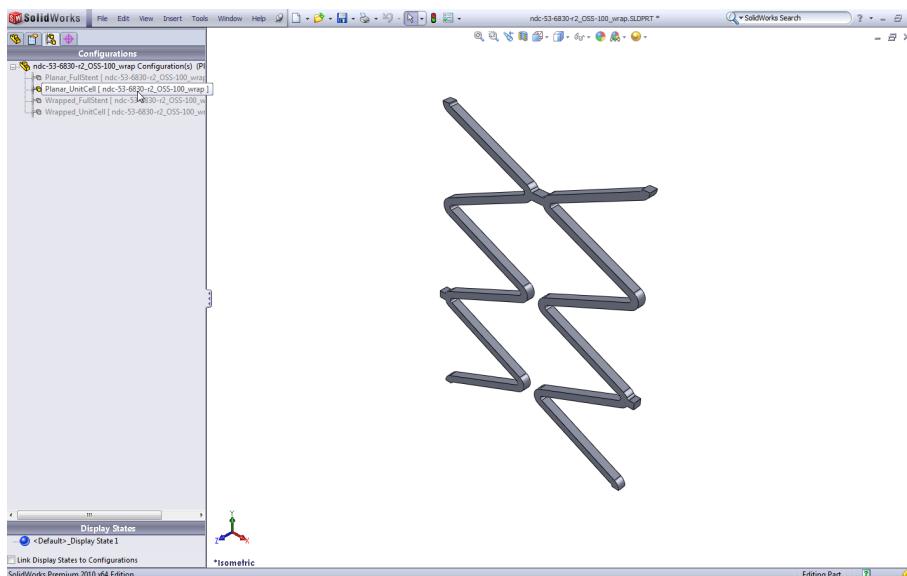


Figure 2.33: Change to the planar unit cell state using the SolidWorks configuration manager.

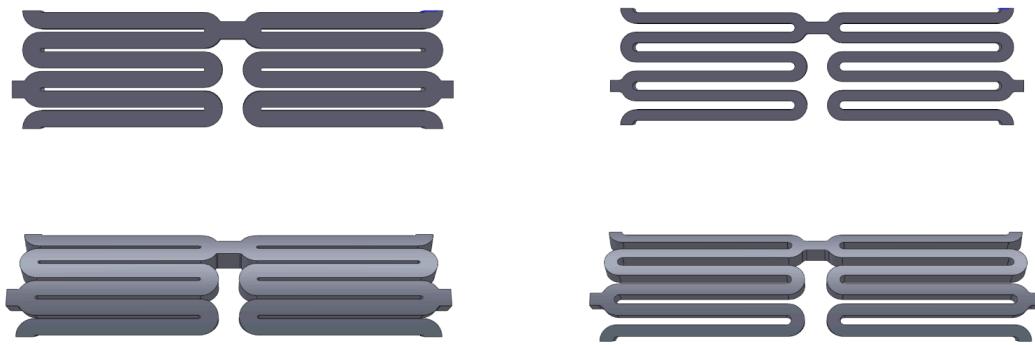


Figure 2.34: Crimped unit cell configurations. Top: Planar. Bottom: Cylindrical. Left: Raw. Right: Finished.

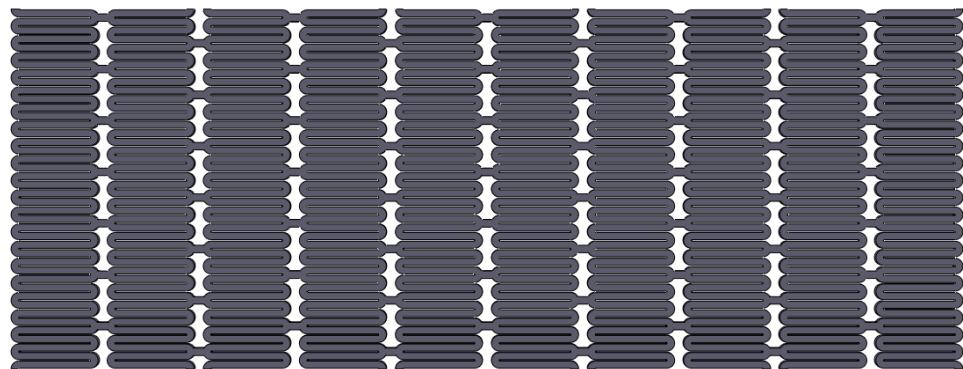


Figure 2.35: Planar full stent, in the raw state. This geometry is suitable for laser cutting.

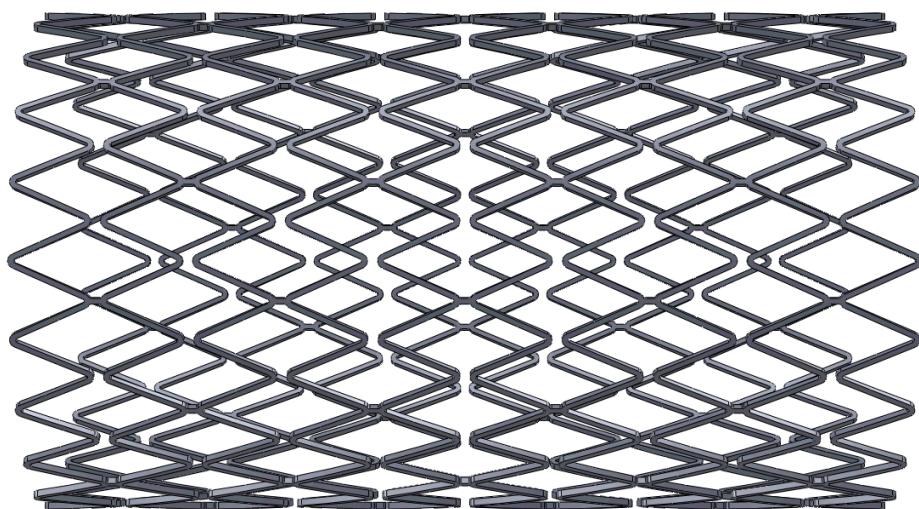


Figure 2.36: Cylindrical full stent, in the finished state. This geometry is suitable for supporting a final component specification.

Chapter 3

Stent Calculator Formulas

This chapter details the variables and formulas used in the Stent Calculator application. Each section focuses on a specific aspect of design or performance, and generally the results from each section are used for further calculations in later sections. Throughout this text, example values are provided based on the Open Source Stent design described in the previous section. Where applicable, the example values are provided with corresponding SI units of measure.

3.1 Stent Design Inputs

The variables below define the key aspects of stent geometry. These inputs are typically drawn from an engineering drawing or related specification.

N_{col} is the number of columns of struts along the length of the stent.

$$N_{col} = 10 \quad (3.1)$$

N_{struts} is the number of columns of struts around the circumference of the stent.

$$N_{struts} = 42 \quad (3.2)$$

D_{tube} is the outer diameter of the tube from which the stent is fabricated, in millimeters.

$$D_{tube} = 1.915 \text{ mm} \quad (3.3)$$

t_{raw} is the wall thickness of the tube from which the stent is fabricated, in millimeters.

$$t_{raw} = 0.17 \text{ mm} \quad (3.4)$$

L_{strut_inner} is the length of a strut, as measured between the quadrants of the inner arcs of opposite apices, in millimeters.

$$L_{strut_inner} = 1.200 \text{ mm} \quad (3.5)$$

w_{apex_raw} is the width of an apex in the raw, or as-cut, state. This width may be equal to the strut width, but it does not necessarily need to be. It is often designed to be some multiple of a strut width (*i.e.* 1.0x, 1.1x, 1.2x, etc.).

$$w_{apex_raw} = 0.130 \text{ mm} \quad (3.6)$$

X_{bridge} is the axial gap between adjacent columns of struts, as measured by the axial distance between the closest points on the outer arc of adjacent apices.

$$X_{bridge} = 0.125 \text{ mm} \quad (3.7)$$

Y_{bridge} is the circumferential distance traversed by a single bridge, or the offset in the circumferential direction between like points of corresponding adjacent apices.

$$Y_{bridge} = 0.000 \text{ mm} \quad (3.8)$$

w_{bridge_raw} is the width of a bridge element in the raw, or as-cut, state.

$$w_{bridge_raw} = 0.125 \text{ mm} \quad (3.9)$$

$N_{bridges}$ is the number of bridges around the circumference of the stent. Typically, this value must be a factor of $\frac{N_{struts}}{2}$. In the case of this example, with 42 struts, $N_{bridges}=21$ would imply that every internal apex is connected to an adjacent apex. $N_{bridges}=7$ would imply that every third internal apex is connected to a corresponding adjacent apex. The only other option, $N_{bridges}=3$ suggests that every seventh internal apex is connected.

$$N_{bridges} = 7 \quad (3.10)$$

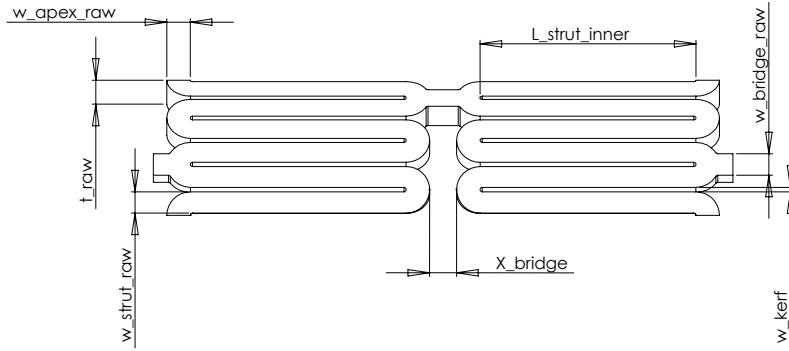


Figure 3.1: Unit cell stent geometry in the raw, or as-cut, state

3.2 Stent Process Inputs

The variables below relate to various assumptions regarding the manufacturing processes used to fabricate the stent.

w_{kerf} is the effective kerf width between struts when fabricated (or in the crimped state). In the typical case of laser micromachining of stent from tubing, this is the effective width of the laser beam.

$$w_{kerf} = 0.025 \text{ mm} \quad (3.11)$$

m_{width} is the total amount of material removal from feature widths during finishing operations, i.e. after laser cutting is complete. Typically, the raw feature widths are planned

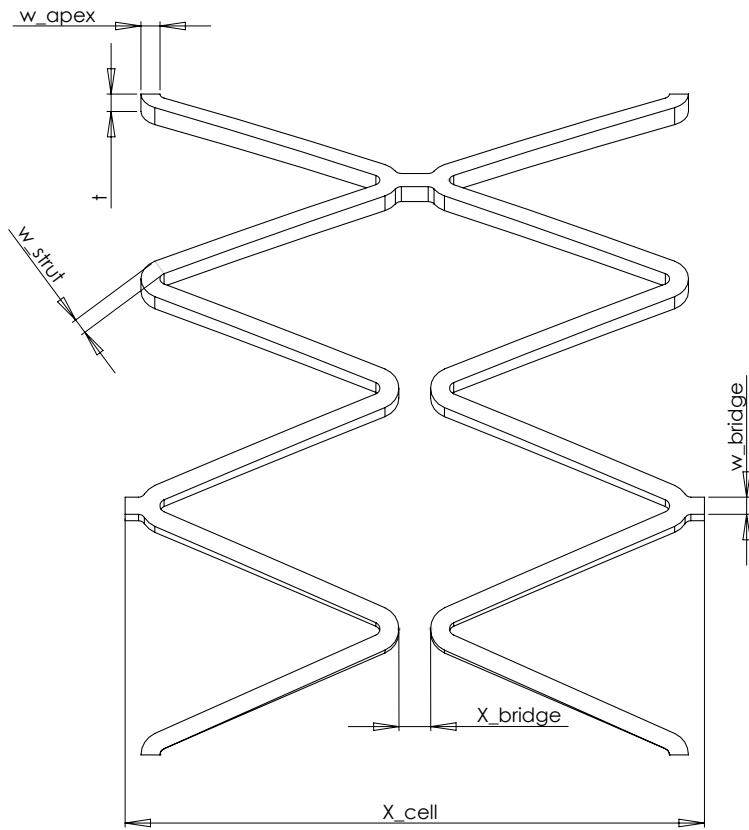


Figure 3.2: Unit cell stent geometry in the expanded and finished state

to be larger than finished feature widths to allow for effective removal of the *heat affected zone*, or HAZ, of material that may be embrittled by the cutting operation. m_{width} is selected to allow for HAZ removal, as well as provide for sufficient surface smoothing and edge rounding as required by the design.

$$m_{width} = 0.036 \text{ mm} \quad (3.12)$$

$m_{thickness}$ is the total amount of material removal from the wall thickness during finishing operations, i.e. after laser cutting is complete. This is commonly greater than m_{width} because it often desirable to remove additional material from the inner surface of the stent to eliminate tubing draw lines or other unwanted surface features from the inner and/or outer surfaces of the stent.

$$m_{thickness} = 0.059 \text{ mm} \quad (3.13)$$

A_f is the austenite finish temperature of the finished component. This is the temperature at which the transformation from martensite to austenite is complete, as measure by bend free recovery techniques.

$$A_f = 27^\circ\text{C} \quad (3.14)$$

3.3 Material Property Inputs

The Stent Calculator application is particularly well suited to analyze nitinol designs because of the unique linear elastic behavior of the material with strains of 1-2%. In this regime, the material is dominated by the properties of the austenite phase. The elastic modulus of this material in this phase varies with the transformation temperature. With A_f temperatures progressively lower than body temperature, the stiffness of the material at body temperature increases (See Figure 3.3). Understanding this relationship, Stent Calculator can adjust the elastic modulus of the material as a function of specified A_f temperatures using the curves fit to data as shown in Figure 3.3.

$E_{Af,low}$ is the elastic modulus of the austenite phase having an A_f temperature of Af_{low} .

$$E_{Af,low} = 94,000 \text{ MPa} \quad (3.15)$$

Af_{low} is the first A_f temperature at which the austenite elastic modulus is defined.

$$Af_{low} = -5^\circ\text{C} \quad (3.16)$$

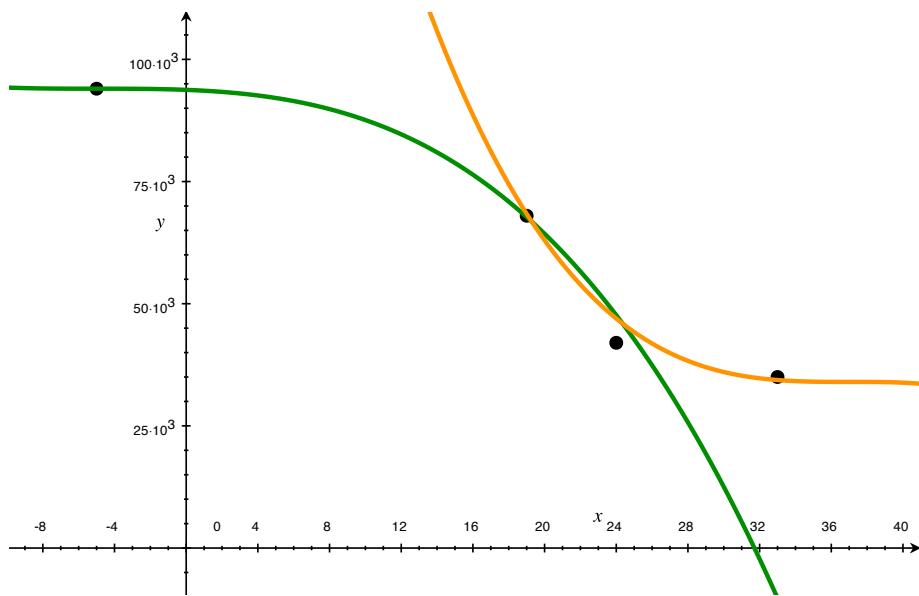


Figure 3.3: Relationship between initial (austenite) modulus and A_f temperature for superelastic nitinol at an environmental temperature of 37°C . The points shown were obtained experimentally from nitinol tubing heat treated to achieve desired A_f temperatures. The green and orange curves were developed manually to fit the data, and reasonably reflect the expected performance of the material. The green curve applies for A_f temperatures less than 19°C , and the orange curve applies for A_f temperatures greater than 19°C .

$E_{Af,high}$ is the elastic modulus of the austenite phase having an A_f temperature of Af_{high} .

$$E_{Af,high} = 34,000 \text{ MPa} \quad (3.17)$$

Af_{high} is the second A_f temperature at which the austenite elastic modulus is defined.

$$Af_{high} = 37^\circ\text{C} \quad (3.18)$$

$Af_{inflection}$ is the temperature at which the A_f vs E relationship transitions from the low temperature curve to the high temperature curve, as shown in Figure 3.3.

$$Af_{inflection} = 19^\circ\text{C} \quad (3.19)$$

The calculated value of E , the austenite elastic modulus for a material having the specified A_f , depends on the A_f temperature. For A_f less than Af_{low} :

$$E_{case1} = E_{Af,low} \quad (3.20)$$

For A_f between Af_{low} and $Af_{inflection}$, the green curve of Figure 3.3 applies:

$$E_{case2} = E_{Af,low} - 1.9 \cdot (A_f - Af_{low})^3 \quad (3.21)$$

For A_f between $Af_{inflection}$ and Af_{high} , the orange curve of Figure 3.3 applies:

$$E_{case3} = E_{Af,high} + 5.9 \cdot (Af_{high} - A_f)^3 \quad (3.22)$$

For A_f equal to or above Af_{high} :

$$E_{case4} = E_{Af,high} \quad (3.23)$$

In this example, with $A_f = 27$, E_{case3} applies.

$$\begin{aligned} E &= E_{case3} \text{ for } A_f = 27^\circ\text{C} \\ E &= 34059 \text{ MPa} \end{aligned} \quad (3.24)$$

ρ is the mass density of nitinol, used later to estimate the mass of the stent on the basis of its estimated volume.

$$\begin{aligned}\rho &= 6.7 \text{g/cm}^3 \\ \rho &= 6.7 \text{mg/mm}^3\end{aligned}\tag{3.25}$$

ϵ_{fsl} is the fatigue strain limit of the material. For mean strains less than 4%, Pelton *et al.* report a strain amplitude fatigue strain limit of 0.4% for nitinol test samples fabricated and processed using techniques representative of those used for stents.[2]

$$\epsilon_{fsl} = 0.4\%\tag{3.26}$$

3.4 Service Parameters

This section defines the diameter to which the stent is expanded, and the diameter of the vessel into which the stent is placed. The Analysis Diameter is also defined here, typically equal to the vessel diameter. Various properties of the stent, including strength and strain, are calculated at this diameter.

This section also defines the mechanical properties of the vessel into which the stent is placed. Commonly, the compliance of a vessel is reported in terms of a percentage change in diameter related to a specific applied pressure range. This compliance is typically defined based on arterial, venous, or other data derived experimentally or drawn from literature. The systolic and diastolic pressures considered in the fatigue analysis are also defined in this section.

D_{set} is the expanded, or thermal shape set, diameter of the stent. This is the maximum diameter to which the stent is expanded for any given usage case.

$$D_{set} = 8.0 \text{ mm}\tag{3.27}$$

D_{ves} is the diameter of the vessel into which the stent is placed. This is typically smaller than D_{set} , the fully expanded diameter of the vessel. In this example, the stent is *oversized* by 1.5mm.

$$D_{ves} = 6.5 \text{ mm}\tag{3.28}$$

D is the diameter at which strains are calculated.

$$D = D_{ves} = 6.5 \text{ mm} \quad (3.29)$$

$C_{percent}$ is part of the definition for vessel compliance. This is the percent change in effective diameter for a defined change in pressure, $C_{pressure}$. In the literature, this is often reported as $\Delta D/D$. The compliance in this example is arbitrary, but similar to values commonly used in the arterial system.

$$C_{percent} = 6\% \quad (3.30)$$

$C_{pressure}$ is part of the definition for vessel compliance. This is the change in pressure¹ that is related to a $\Delta D/D = C_{percent}$.

$$C_{pressure} = 100 \text{ mmHg} \quad (3.31)$$

$P_{systolic}$ is the systolic pressure experienced at the site of stent implantation.

$$P_{systolic} = 150 \text{ mmHg} \quad (3.32)$$

$P_{diastolic}$ is the diastolic pressure experienced at the site of stent implantation.

$$P_{diastolic} = 50 \text{ mmHg} \quad (3.33)$$

P_{mean} is the mean pressure experienced at the site of stent implantation, assuming a simple sinusoidal pressure wave.

$$\begin{aligned} P_{mean} &= \frac{P_{systolic} + P_{disatolic}}{2} \\ P_{mean} &= 100 \text{ mmHg} \end{aligned} \quad (3.34)$$

¹This is an arbitrary value, not necessarily related to a physiologic pressure. Rather, it is simply the pressure half of the definition for compliance, as reported in literature or by experiment

3.5 Stent Dimension Calculations

This section explains the calculations of a number of derived stent characteristics and dimensions.

N_{cells} is the number of “crowns,” “tips,” or “*cells*” around the circumference of the stent. This is equal to half the number of struts around the circumference.

$$\begin{aligned} N_{cells} &= \frac{N_{struts}}{2} \\ N_{cells} &= 21 \end{aligned} \tag{3.35}$$

D_{crimp} is the fully constrained outer diameter of the stent within its delivery sheath.

$$\begin{aligned} D_{crimp} &= D_{tube} \\ D_{crimp} &= 1.915 \text{ mm} \end{aligned} \tag{3.36}$$

L_{strut} is the effective length of the strut, as measured between the centerlines of opposite apices. This measurement is not easily measured or defined, so it is derived here based on the inner strut length and the width of the apices in the raw state.

$$\begin{aligned} L_{strut} &= L_{strut_inner} + 2 \cdot \frac{w_{apex_raw}}{2} \\ L_{strut} &= 1.330 \text{ mm} \end{aligned} \tag{3.37}$$

w_{strut_raw} is the width of each strut in the as-cut, or raw, state. This value is derived based on the tubing diameter, number of struts around the circumference, and the kerf width.

$$\begin{aligned} w_{strut_raw} &= \frac{D_{tube} \cdot \pi}{N_{struts}} - w_{kerf} \\ w_{strut_raw} &= 0.118 \text{ mm} \end{aligned} \tag{3.38}$$

w_{strut} is the width of each strut in the finished state.

$$\begin{aligned} w_{strut} &= w_{strut_raw} - m_{width} \\ w_{strut} &= 0.082 \text{ mm} \end{aligned} \quad (3.39)$$

w_{bridge} is the width of each bridge in the finished state.

$$\begin{aligned} w_{bridge} &= w_{bridge_raw} - m_{width} \\ w_{bridge} &= 0.089 \text{ mm} \end{aligned} \quad (3.40)$$

w_{apex} is the width of each apex in the finished state.

$$\begin{aligned} w_{apex} &= w_{apex_raw} - m_{width} \\ w_{apex} &= 0.094 \text{ mm} \end{aligned} \quad (3.41)$$

t is the wall thickness of the stent in the finished state.

$$\begin{aligned} t &= t_{raw} - m_{thickness} \\ t &= 0.111 \text{ mm} \end{aligned} \quad (3.42)$$

3.6 Strut Angle and Deflection Calculations

This section calculates a variety of derived strut angle and deflection calculations. Angles and deflections are calculated here for the vessel diameter, and for a diameter 1mm less than the fully expanded diameter.

θ_{set} is the angle a single strut is deflected between the crimped state and the fully expanded (thermal shape set) state.

$$\begin{aligned} \theta_{set} &= \left(\frac{180}{\pi} \right) \sin \left[\frac{D_{set} \cdot \pi - D_{crimp} \cdot \pi}{\frac{N_{struts}}{L_{strut}}} \right] \\ \theta_{set} &= 20.0 \text{ degrees} \end{aligned} \quad (3.43)$$

θ_d is the angle a single strut is deflected between the crimped state and the analysis diameter.

$$\theta_d = \left(\frac{180}{\pi} \right) \sin \left[\frac{\frac{D \cdot \pi - D_{crimp} \cdot \pi}{N_{struts}}}{L_{strut}} \right] \quad (3.44)$$

$$\theta_d = 14.9 \text{ degrees}$$

$\Delta\theta_d$ is the change in angle of a single strut between the fully expanded diameter and the analysis diameter.

$$\begin{aligned} \Delta\theta_d &= \theta_{set} - \theta_d \\ \Delta\theta_d &= 5.1 \text{ degrees} \end{aligned} \quad (3.45)$$

2θ is the maximum included angle, or the angle between a pair of circumferentially adjacent struts in the expanded state.

$$\begin{aligned} 2\theta &= 2 \cdot \theta_{set} \\ 2\theta &= 40.0 \text{ degrees} \end{aligned} \quad (3.46)$$

δ_d is the deflection of a single strut between the expanded state and the analysis diameter.

$$\begin{aligned} \delta_d &= 2 \cdot L_{strut} \cdot \sin \left(\frac{\Delta\theta_d}{2} \right) \\ \delta_d &= 0.118 \text{ mm} \end{aligned} \quad (3.47)$$

θ_{1mm} is the deflection of a single strut between the expanded state and one millimeter less than the expanded diameter.

$$\begin{aligned} \theta_{1mm} &= \left(\frac{180}{\pi} \right) \sin \left[\frac{\frac{(D_{set} - 1) \cdot \pi - D_{crimp} \cdot \pi}{N_{struts}}}{L_{strut}} \right] \\ \theta_{1mm} &= 16.6 \text{ deg} \end{aligned} \quad (3.48)$$

$\Delta\theta_{1mm}$ is the change in angle of a single strut between the fully expanded diameter and one millimeter less than the expanded diameter.

$$\begin{aligned}\Delta\theta_{1mm} &= \theta_{set} - \theta_{1mm} \\ \Delta\theta_{1mm} &= 3.4 \text{ degrees}\end{aligned}\tag{3.49}$$

δ_{1mm} is the deflection of a single strut between the expanded state and one millimeter less than the expanded diameter.

$$\begin{aligned}\delta_{1mm} &= 2 \cdot L_{strut} \cdot \sin\left(\frac{\Delta\theta_{1mm}}{2}\right) \\ \delta_{1mm} &= 0.079 \text{ mm}\end{aligned}\tag{3.50}$$

3.7 Stent Length Calculations

X_{cell_crimp} is the axial length of a repeating unit cell (a full strut plus half a bridge on each end) in the constrained state.

$$\begin{aligned}X_{cell_crimp} &= L_{strut_inner} + 2 \cdot \left(w_{apex_raw} + \frac{X_{bridge}}{2} \right) \\ X_{cell_crimp} &= 1.610 \text{ mm}\end{aligned}\tag{3.51}$$

X_{total_crimp} is the axial length of the full stent in the constrained state.

$$\begin{aligned}X_{total_crimp} &= X_{cell_crimp} \cdot N_{col} - \left(\frac{X_{bridge}}{2} \right) \cdot 2 \\ X_{total_crimp} &= 15.950 \text{ mm}\end{aligned}\tag{3.52}$$

X_{cell} is the axial length of a repeating unit cell (a full strut plus half a bridge on each end) at the analysis diameter. This differs from X_{cell_crimp} by estimating the change in cell length, or *foreshortening*, that occurs as the cell is expanded in diameter.

$$\begin{aligned}X_{cell} &= L_{strut_inner} \cdot \cos(\theta_d) + 2 \cdot \left(w_{apex_raw} + \frac{X_{bridge}}{2} \right) \\ X_{cell} &= 1.569 \text{ mm}\end{aligned}\tag{3.53}$$

X_{total} is the axial length of the full stent at the expanded diameter. Here again, this formulation accounts for estimated foreshortening.

$$X_{total} = X_{cell} \cdot N_{col} - \left(\frac{X_{bridge}}{2} \right) \cdot 2 \quad (3.54)$$

$$X_{total} = 15.544 \text{ mm}$$

FS is the foreshortening of the stent, or percentage reduction in length as the stent expands from the constrained state to the analysis diameter. This tends to underestimate the actual amount of foreshortening experienced in a real stent, because this model assumes that the struts act as perfectly straight beams with perfect hinges. This formulation is useful for comparing relative foreshortening between different designs.

$$FS = X_{cell} \cdot N_{col} - \left(\frac{X_{bridge}}{2} \right) \cdot 2 \quad (3.55)$$

$$FS = 2.54 \%$$

3.8 Surface Areas, Volume, and Mass Estimation

A_{strut} is the outer surface area of a single strut, as measured in the rectangular area between apices.

$$A_{strut} = (L_{strut_inner} - w_{kerf}) \cdot w_{strut} \quad (3.56)$$

$$A_{strut} = 0.092 \text{ mm}^2$$

R_{apex} is the outer radius of an apex.

$$R_{apex} = w_{strut} + \frac{w_{kerf}}{2} + \frac{m_{width}}{2} \quad (3.57)$$

$$R_{apex} = 0.113 \text{ mm}$$

A_{apex} is the outer surface area of a single apex.

$$A_{apex} = \frac{1}{2} \cdot \left(\pi [R_{apex}]^2 \right) - \pi \left[\frac{w_{kerf}}{2} + \frac{m_{width}}{2} \right]^2 + 2 \cdot R_{apex} \cdot (w_{apex} - w_{strut}) \quad (3.58)$$

$$A_{apex} = 0.021 \text{ mm}^2$$

A_{bridge} is the outer surface area of a single bridge.

$$A_{bridge} = \sqrt{(X_{bridge}) + (Y_{bridge})^2} \cdot w_{bridge} \quad (3.59)$$

$$A_{bridge} = 0.013 \text{ mm}^2$$

$A_{contact}$ is an estimate of the total outer surface area of the stent, which is also the total area in contact with the vessel. Note that for each strut in the stent, there is half an apex at one end of the strut, and half an apex at the opposite end of the strut; therefore, the total number of struts is equal to the total number of apices in the model.

$$A_{contact} = (A_{strut} + A_{apex}) \cdot N_{struts} \cdot N_{col} + A_{bridge} \cdot N_{bridges} \cdot (N_{col} - 1) \quad (3.60)$$

$$A_{contact} = 50.3 \text{ mm}^2$$

$A_{cylinder}$ is the cylindrical area of the vessel occupied by the stent, at a length corresponding to the analysis diameter.

$$A_{cylinder} = \pi \cdot D \cdot X_{total} \quad (3.61)$$

$$A_{cylinder} = 317.4 \text{ mm}^2$$

PCA is the *percent coverage area*, also known as percent metal area. This is the proportion of the cylindrical vessel area occupied by the stent that is actually in contact with the stent. This is reported at the analysis diameter.

$$PCA = \frac{A_{contact}}{A_{cylinder}} \quad (3.62)$$

$$PCA = 15.9 \%$$

POA is the *percent open area*, or the proportion of the cylindrical vessel area that is not in contact with the stent. This is reported at the analysis diameter.

$$\begin{aligned} POA &= 1 - PMA \\ POA &= 84.1 \% \end{aligned} \quad (3.63)$$

A typical strut has a wedge shaped cross-section, wherein the width at the outer surface is larger than the width at the inner surface. w_{strut_id} is the width of a strut at the inner surface.

$$\begin{aligned} w_{strut_id} &= \left[\frac{\pi \cdot (D_{tube} - 2t)}{N_{struts}} \right] - w_{kerf} - m_{width} \\ w_{strut_id} &= 0.066 \text{ mm} \end{aligned} \quad (3.64)$$

In the next series of formulas, A_{strut_id} , A_{apex_id} , and A_{bridge_id} estimate the surface area of the inner surface of each of these features. The inner surface area is estimated by multiplying the outer surface areas, calculated above, with the ratio of w_{strut_id} with w_{strut_od} .

$$\begin{aligned} A_{strut_id} &= A_{strut} \cdot \frac{w_{strut_id}}{w_{strut_od}} \\ A_{strut_id} &= 0.077 \text{ mm}^2 \end{aligned} \quad (3.65)$$

$$\begin{aligned} A_{apex_id} &= A_{apex} \cdot \frac{w_{strut_id}}{w_{strut_od}} \\ A_{apex_id} &= 0.017 \text{ mm}^2 \end{aligned} \quad (3.66)$$

$$\begin{aligned} A_{bridge_id} &= A_{bridge} \cdot \frac{w_{strut_id}}{w_{strut_od}} \\ A_{bridge_id} &= 0.011 \text{ mm}^2 \end{aligned} \quad (3.67)$$

Now, knowing the surface area at the outer surface and inner surfaces of each feature, the volume of each feature can be estimated by multiplying the average of these by the wall thickness.

$$\begin{aligned} V_{strut} &= t \cdot \left(\frac{A_{strut} + A_{strut_id}}{2} \right) \\ V_{strut} &= 0.010 \text{ mm}^3 \end{aligned} \quad (3.68)$$

$$\begin{aligned} V_{apex} &= t \cdot \left(\frac{A_{apex} + A_{strut_id}}{2} \right) \\ V_{apex} &= 0.002 \text{ mm}^3 \end{aligned} \quad (3.69)$$

$$\begin{aligned} V_{bridge} &= t \cdot \left(\frac{A_{apex} + A_{strut_id}}{2} \right) \\ V_{bridge} &= 0.001 \text{ mm}^3 \end{aligned} \quad (3.70)$$

With the volumes of each feature known, the total volume of the stent can be calculated using a formulation similar to that for A_{total} above.

$$\begin{aligned} V_{total} &= (V_{strut} + V_{apex}) \cdot N_{struts} \cdot N_{col} \\ &\quad + V_{bridge} \cdot N_{bridges} \cdot (N_{col} - 1) \\ V_{total} &= 5.021 \text{ mm}^3 \end{aligned} \quad (3.71)$$

$mass$ is the estimated mass of the stent based on V_{total} and density ρ .

$$\begin{aligned} mass &= \rho \cdot V_{total} \\ mass &= 33.640 \text{ mg} \end{aligned} \quad (3.72)$$

3.9 Moment of Inertia Calculations

The cross section of a typical stent strut can be approximated as rectangular, but can be more accurately modeled as a sector of a hollow circle. The formulation for the moment of inertia for such a section is detailed below in Figure 3.4, and the following formulas.

R , as defined in Figure 3.4 above, is the outer radius of the tubing from which the stent is cut.

<p>21. Sector of hollow circle</p> <p>(Note: If t/R is small, α can exceed π to form an overlapped annulus)</p>	$A = at(2R - t)$ $y_{c1} = R \left[1 - \frac{2\sin\alpha}{3\alpha} \left(1 - \frac{t}{R} + \frac{1}{2-t/R} \right) \right]$ $y_{c2} = R \left[\frac{2\sin\alpha}{3\alpha(2-t/R)} + \left(1 - \frac{t}{R} \right) \frac{2\sin\alpha - 3\cos\alpha}{3\alpha} \right]$ $x_c = R \sin\alpha$	$I_x = R^3 t \left[\left(1 - \frac{3t}{2R} + \frac{t^2}{R^2} - \frac{t^3}{4R^3} \right) \times \left(\alpha + \sin\alpha \cos\alpha - \frac{2\sin^2\alpha}{\alpha} \right) + \frac{t^2 \sin^2\alpha}{3R^2 \alpha (2-t/R)} \left(1 - \frac{t}{R} + \frac{t^2}{6R^2} \right) \right]$ $I_y = R^3 t \left(1 - \frac{3t}{2R} + \frac{t^2}{R^2} - \frac{t^3}{4R^3} \right) (\alpha - \sin\alpha \cos\alpha)$ $r_x = \sqrt{\frac{I_x}{A}}, \quad r_y = \sqrt{\frac{I_y}{A}}$
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Figure 3.4: Moment of Inertia for a typical strut cross section. [4]

$$R = \frac{D_{tube}}{2}$$

$$R = 0.958 \text{ mm}$$
(3.73)

t , as defined in Figure 3.4 above, is the finished wall thickness of the stent.

$$t = 0.111 \text{ mm}$$
(3.74)

w_{strut} is the finished width of each strut, which is required to derive the α parameter.

$$w_{strut} = 0.082 \text{ mm}$$
(3.75)

α is the angle occupied by half the strut cross section, as defined in Figure 3.4 above.

$$\alpha = \frac{1}{2} \cdot \left(\frac{w_{strut}}{D_{tube} \cdot \pi} \right) \cdot 2\pi$$

$$\alpha = 0.043 \text{ radians}$$
(3.76)

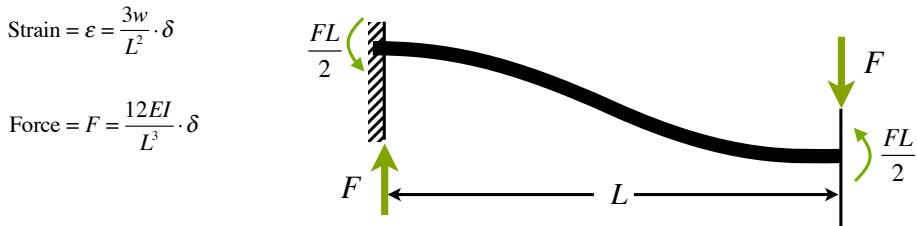
I is the moment of inertia for a strut having a cross section described by a sector of a hollow circle. I is calculated for bending about the y axis depicted in Figure 3.4.

$$I = R^3 t \cdot \left(1 - \frac{3t}{2R} + \frac{t^2}{R^2} - \frac{t^3}{4R^3} \right) \cdot (\alpha - \sin(\alpha) \cos(\alpha))$$

$$I = 4.32 \cdot 10^{-6} \text{ mm}^4$$
(3.77)

3.10 Force and Strain Calculations

The relationships between stress, load, deflection, and strain have been thoroughly documented for a variety of beam loading conditions. Force and strain related to a specified strut deflection are based on the formulation for a beam fixed at one end, and free but guided at the other as documented in *Machinery's Handbook* [1].



E = modulus of elasticity

I = moment of inertia, beam cross section

w = strut width

L = strut length

Figure 3.5: Beam fixed at one end, and free but guided at the other.

F_{hoop} is the hoop component of the force exerted by a single strut when the stent is constrained from the fully expanded state to the analysis diameter. This is equal to F in Figure 3.5 by the definition of the “free but guided” beam as described in *Machinery's Handbook* [1].

$$F_{hoop} = \frac{12 \cdot E \cdot I}{(L_{strut})^3} \cdot \delta_d \quad (3.78)$$

$$F_{hoop} = 1.03 \cdot 10^{-1} \text{ N}$$

F_{hoop_1mm} is the hoop component of the force exerted by a single strut when the stent is constrained from the fully expanded state to a diameter one millimeter less than the analysis diameter. This allows for later calculation of stent forces normalized per millimeter diameter constraint.

$$F_{hoop_1mm} = \frac{12 \cdot E \cdot I}{(L_{strut})^3} \cdot \delta_{1mm} \quad (3.79)$$

$$F_{hoop_1mm} = 6.92 \cdot 10^{-2} \text{ N}$$

ϵ_d is the maximum strain experienced within the strut when the stent is constrained from the fully expanded state to the analysis diameter. This is equal to ϵ in Figure 3.5 by the definition of the “free but guided” beam as described in *Machinery’s Handbook* [1].

$$\begin{aligned}\epsilon_d &= \frac{3w_{strut}}{(L_{strut})^2} \cdot \delta_d \\ \epsilon_d &= 1.64 \%\end{aligned}\quad (3.80)$$

ϵ_{1mm} is the maximum strain experienced within the strut when the stent is constrained from the fully expanded state to one millimeter less than the analysis diameter.

$$\begin{aligned}\epsilon_{1mm} &= \frac{3w_{strut}}{(L_{strut})^2} \cdot \delta_{1mm} \\ \epsilon_{1mm} &= 1.10 \%\end{aligned}\quad (3.81)$$

3.11 Pressure and Stiffness Calculations

In this section, the forces and other calculations derived above are used to estimate radial resistive force in terms that are common for bench testing.

RF_{hoop} is the hoop component of the force exerted when the stent is constrained from the fully expanded state to 1mm less than the expansion diameter, normalized by length in centimeters. This value is consistent with radial resistive force type measurement (RRF) generated from a collar type fixture. By convention, it is expressed in terms of Newtons per centimeter length, and is thus normalized by length.

$$\begin{aligned}RF_{hoop} &= \frac{F_{hoop_1mm}}{X_{cell}} \cdot \left[10 \cdot \frac{\text{mm}}{\text{cm}} \right] \\ RF_{hoop} &= 0.44 \text{ N/cm}\end{aligned}\quad (3.82)$$

RF_{trf} is the true radial component of the force exerted when the stent is constrained from the fully expanded state to 1mm less than the expanded diameter, normalized by length in centimeters. This value is consistent with radial resistive force type measurement (RRF) generated from a Blockwise or MSI type testing fixture. This is also expressed in terms of newtons per centimeter length, and is thus also normalized by length, and evaluated for a 1mm diameter constraint.

$$\begin{aligned} RF_{trf} &= 2\pi \cdot RF_{hoop} \\ RF_{trf} &= 2.77 \text{ N/cm} \end{aligned} \quad (3.83)$$

P_{eq} estimates the amount of outward pressure that could replace the effect of the stent, when the stent is constrained from its maximum diameter to the analysis diameter. This *equivalent pressure* is derived from the formulation for hoop stress in a thin walled cylinder: $\sigma_{hoop} = P \cdot r/t$, in combination with the formulation relating hoop force with hoop stress: $F_{hoop} = \sigma_{hoop} \cdot t \cdot L$. P_{eq} is derived by combining and rearranging these formulas to solve for pressure P in terms of a known force F_{hoop} , radius $r = (D/2)$, and length $L = X_{cell}$. It is expressed in clinically familiar pressure units of millimeters of mercury, or *mmHg*, also known as *torr*.

$$\begin{aligned} P_{eq} &= \frac{F_{hoop}}{X_{cell} \cdot \left(\frac{D}{2}\right)} \cdot \left[75,600.6 \frac{\text{mmHg}}{\text{MPa}} \right] \\ P_{eq} &= 151.9 \text{ mmHg} \end{aligned} \quad (3.84)$$

$P_{contact}$ estimates the contact pressure at the interface between the outer surface of the stent and the surrounding vessel. This value is derived by dividing the total radial outward force of the stent by the outer surface area of the stent. This estimates the pressure experienced by individual endothelial cells in contact with the struts of the stent, and is expressed in units of kilopascals.

$$\begin{aligned} P_{contact} &= \frac{2\pi \cdot F_{hoop} \cdot N_{col}}{A_{contact}} \\ P_{contact} &= 129.0 \text{ kPa} \end{aligned} \quad (3.85)$$

k_{stent} is another normalized expression of the stiffness of the stent, in terms of a "spring constant" describing the hoop force exerted per millimeter diameter constraint.

$$\begin{aligned} k_{stent} &= \frac{F_{hoop}}{X_{cell} \cdot \left(\frac{D}{2}\right)} \cdot \left[75,600.6 \frac{\text{mmHg}}{\text{MPa}} \right] \\ k_{stent} &= 0.069 \text{ N/mm} \end{aligned} \quad (3.86)$$

3.12 Calculating the Stiffness of the Vessel

This section considers the cyclic change in diameter expected within the vessel as a result of pulsatile nature of blood flow, where the maximum pressure occurs at systole and minimum pressure occurs at diastole. The actual compliance of the unstented vessel depends upon the defined pressure differential between systolic and diastolic pressures, combined with the compliance definition provided in the definition of $C_{percent}$ (Equation 3.30) and $C_{pressure}$ (Equation 3.31).

$CV_{pressure}$ is the vessel compliance pressure defined above, here converted to megapascal units.

$$CV_{pressure} = C_{pressure} \cdot \frac{1}{7500.6} \left[\frac{\text{MPa}}{\text{mmHg}} \right] \quad (3.87)$$

$$CV_{pressure} = 0.013 \text{ MPa}$$

Vessel compliance was defined by stating a percent change in vessel diameter associated with a change in pressure. DV_{low} is the diameter related to the low (or zero) pressure state. This is assumed to be equal to the nominal vessel diameter.

$$DV_{low} = D_{ves} \quad (3.88)$$

$$DV_{low} = 6.50 \text{ mm}$$

Vessel compliance was defined by stating a percent change in vessel diameter associated with a change in pressure. DV_{high} is the diameter related to the high pressure state.

$$DV_{high} = D_{ves} \cdot (1 + C_{percent}) \quad (3.89)$$

$$DV_{high} = 6.89 \text{ mm}$$

Next, the hoop force in the vessel wall, FV_{hoop} is calculated using the thin walled cylinder equation as in Equation 3.84. The hoop force is calculated for a length of vessel that is equal to the length of a single cell so it can be directly compared with stent hoop forces for a single cell.

$$FV_{hoop} = CV_{pressure} \cdot \frac{DV_{high}}{2} \cdot X_{cell} \quad (3.90)$$

$$FV_{hoop} = 0.72 \text{ mm}$$

Now, the change in hoop force related to a change in diameter can be expressed in terms of a “spring constant” k_{vessel} that is comparable to k_{stent} calculated above. In this example, the vessel is more than twice as stiff as the stent.

$$\begin{aligned} k_{vessel} &= \frac{FV_{hoop}}{DV_{high} - DV_{low}} \\ k_{vessel} &= 0.185 \text{ N/mm} \end{aligned} \quad (3.91)$$

3.13 Balanced Diameters of the Stented Vessel

The nominal vessel diameter is specified above as D_{ves} , and the diastolic and systolic pressures are specified above as well. The analysis assumes that the nominal vessel diameter relates to the *mean* pressure, and is defined below as $D_{v,mean}$

$$\begin{aligned} D_{v,mean} &= D_{ves} \\ D_{v,mean} &= 6.5 \text{ mm} \end{aligned} \quad (3.92)$$

$D_{v,diastolic}$, the diameter of the native vessel at diastolic pressure, is calculated based on the compliance definitions given above.

$$\begin{aligned} D_{v,diastolic} &= D_{v,mean} - D_{v,mean} \left(C_{percent} \cdot \frac{P_{mean} - P_{diastolic}}{C_{pressure}} \right) \\ D_{v,diastolic} &= 6.31 \text{ mm} \end{aligned} \quad (3.93)$$

$D_{v,systolic}$, the diameter of the native vessel at systolic pressure, is calculated similarly.

$$\begin{aligned} D_{v,systolic} &= D_{v,mean} + D_{v,mean} \left(C_{percent} \cdot \frac{P_{systolic} - P_{mean}}{C_{pressure}} \right) \\ D_{v,systolic} &= 6.70 \text{ mm} \end{aligned} \quad (3.94)$$

Now, these diameters can be recalculated considering the effects of an implanted stent. $D_{b,mean}$ is the balanced diameter of the stented vessel at mean pressure by relating the stiffness of the stent and vessel.

$$D_{b,mean} = \frac{(k_{stent} \cdot D_{set}) + (k_{vessel} \cdot D_{v,mean})}{k_{stent} + k_{vessel}} \quad (3.95)$$

$D_{b,mean} = 6.91 \text{ mm}$

$D_{b,diastolic}$ repeats this calculation to derive the balanced diameter of the stented vessel at diastolic pressure.

$$D_{b,diastolic} = \frac{(k_{stent} \cdot D_{set}) + (k_{vessel} \cdot D_{v,diastolic})}{k_{stent} + k_{vessel}} \quad (3.96)$$

$D_{b,diastolic} = 6.77 \text{ mm}$

And $D_{b,systolic}$ repeats this calculation to derive the balanced diameter of the stented vessel at systolic pressure.

$$D_{b,systolic} = \frac{(k_{stent} \cdot D_{set}) + (k_{vessel} \cdot D_{v,systolic})}{k_{stent} + k_{vessel}} \quad (3.97)$$

$D_{b,systolic} = 7.05 \text{ mm}$

3.14 Strut Deflections at Balanced Diameters

Next, having calculated the balanced diameter for diastolic, mean, and systolic pressures, the change in strut angle and strut deflection are calculated for each case as they were in Equation 3.44 for θ_d , Equation 3.45 for $\Delta\theta_d$, and Equation 3.47 for δ_d .

First, at the *mean* diameter, strut angle is calculated, followed by the change in strut angle between the set diameter and mean diameter, and finally the strut deflection.

$$\theta_{mean} = \left(\frac{180}{\pi} \right) \sin \left[\frac{\frac{D_{b,mean} \cdot \pi - D_{crimp} \cdot \pi}{N_{struts}}}{L_{strut}} \right] \quad (3.98)$$

$\theta_{mean} = 16.306 \text{ degrees}$

$$\begin{aligned} \Delta\theta_{mean} &= \theta_{set} - \theta_{mean} \\ \Delta\theta_{mean} &= 3.706 \text{ degrees} \end{aligned} \quad (3.99)$$

$$\delta_{mean} = 2 \cdot L_{strut} \cdot \sin \left(\frac{\Delta\theta_{mean}}{2} \right) \quad (3.100)$$

$$\delta_{mean} = 0.086 \text{ mm}$$

Next, these calculations are repeated for the balanced diameter of the stented vessel at *diastolic* pressure.

$$\theta_{diastolic} = \left(\frac{180}{\pi} \right) \sin \left[\frac{\frac{D_{b,diastolic} \cdot \pi - D_{crimp} \cdot \pi}{N_{struts}}}{L_{strut}} \right] \quad (3.101)$$

$$\theta_{diastolic} = 15.830 \text{ degrees}$$

$$\begin{aligned} \Delta\theta_{diastolic} &= \theta_{set} - \theta_{diastolic} \\ \Delta\theta_{diastolic} &= 4.183 \text{ degrees} \end{aligned} \quad (3.102)$$

$$\delta_{diastolic} = 2 \cdot L_{strut} \cdot \sin \left(\frac{\Delta\theta_{diastolic}}{2} \right) \quad (3.103)$$

$$\delta_{diastolic} = 0.097 \text{ mm}$$

Finally, these calculations are repeated for the balanced diameter of the stented vessel at *systolic* pressure.

$$\theta_{systolic} = \left(\frac{180}{\pi} \right) \sin \left[\frac{\frac{D_{b,systolic} \cdot \pi - D_{crimp} \cdot \pi}{N_{struts}}}{L_{strut}} \right] \quad (3.104)$$

$$\theta_{systolic} = 16.784 \text{ degrees}$$

$$\begin{aligned} \Delta\theta_{systolic} &= \theta_{set} - \theta_{systolic} \\ \Delta\theta_{systolic} &= 3.229 \text{ degrees} \end{aligned} \quad (3.105)$$

$$\delta_{systolic} = 2 \cdot L_{strut} \cdot \sin \left(\frac{\Delta\theta_{systolic}}{2} \right) \quad (3.106)$$

$$\delta_{systolic} = 0.075 \text{ mm}$$

3.15 Strain Values

Knowing the strut deflections relating to the balanced mean, diastolic, and systolic pressure cases, the maximum strain can be calculated for each of these cases according to the formulation described in Figure 3.5.

First, the strain is calculated at the nominal diameter of the vessel. This is somewhat arbitrary, because the stent will cause the vessel to increase in diameter, so it will not be expected experience this strain during service.

$$\epsilon_{vessel} = \frac{3 \cdot w_{strut}}{L_{strut}^2} \cdot \delta_d \quad (3.107)$$

$$\epsilon_{vessel} = 1.64 \%$$

Next, the strain is calculated at the diameter of the stented vessel at mean pressure.

$$\epsilon_{P,mean} = \frac{3 \cdot w_{strut}}{L_{strut}^2} \cdot \delta_{mean} \quad (3.108)$$

$$\epsilon_{P,mean} = 1.20 \%$$

Next, the strain is calculated at the diameter of the stented vessel at diastolic pressure. This is the maximum strain experienced during the pulsatile cycle; at the minimum pressure, the vessel is at its minimum diameter, and the stent is therefore smallest relative to its fully expanded diameter.

$$\epsilon_{P,diastolic} = \frac{3 \cdot w_{strut}}{L_{strut}^2} \cdot \delta_{diastolic} \quad (3.109)$$

$$\epsilon_{P,diastolic} = 1.35 \%$$

Finally, the strain is calculated at the diameter of the stented vessel at systolic pressure. This represents the minimum strain experienced by the stent during the pulsatile cycle; at maximum pressure, the vessel is at its maximum diameter, and the stent is therefore closest to its fully expanded diameter.

$$\epsilon_{P,systolic} = \frac{3 \cdot w_{strut}}{L_{strut}^2} \cdot \delta_{systolic} \quad (3.110)$$

$$\epsilon_{P,systolic} = 1.05 \%$$

3.16 Safety Factor Calculations

As described above, the pulsatile cycling of pressure within the vessel creates a cyclic change in vessel diameter. The stent contributes some outward force to the vessel, thus increasing its mean diameter from D_{ves} to $D_{b,mean}$. The stent also contributes some damping to the pulsatile cycle, because the stented vessel has a stiffness that is greater than the native vessel alone. Consequently, the pulsatile range of the native vessel, ($D_{v,systolic} - D_{v,diastolic}$), will be reduced to a smaller range in the balanced stented vessel, ($D_{b,systolic} - D_{b,diastolic}$).

The durability performance of a nitinol component is determined as a function of the *mean strain* and *strain amplitude* related to the cycling of the structure between $D_{b,systolic}$ and $D_{b,diastolic}$, as illustrated in Figure 3.6 below.

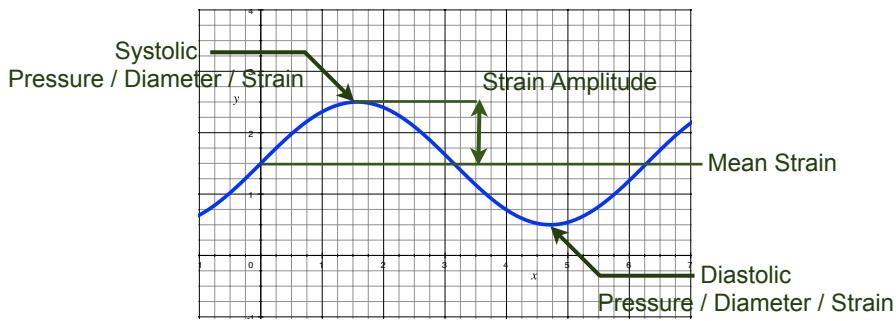


Figure 3.6: Mean strain and strain amplitude, as related to cyclic pressure and diameter

The mean strain, ϵ_{mean} , is calculated by averaging the strain at the systolic and diastolic balanced diameters.

$$\begin{aligned}\epsilon_{mean} &= \frac{\epsilon_{P,diastolic} + \epsilon_{P,systolic}}{2} \\ \epsilon_{mean} &= 1.20 \%\end{aligned}\tag{3.111}$$

Now, the strain amplitude $\epsilon_{amplitude}$ can be calculated as half the difference between the strain at systolic and diastolic pressures.

$$\begin{aligned}\epsilon_{amplitude} &= \frac{\epsilon_{P,diastolic} - \epsilon_{P,systolic}}{2} \\ \epsilon_{amplitude} &= 0.15 \%\end{aligned}\tag{3.112}$$

Finally, a fatigue safety factor N_{sf} can be estimated by comparing the strain amplitude with the fatigue strain limit defined above in Equation 3.26.

$$N_{sf} = \frac{\epsilon_{fsl}}{\epsilon_{amplitude}}$$
$$N_{sf} = 2.59 \quad (3.113)$$

Chapter 4

Stent Calculator Applications

The formulas described in the previous chapter have been implemented in the form of a spreadsheet model, and Python code. Each will be explained in the next section.

4.1 Stent Calculator Spreadsheet

Each of the formulas detailed above has been transcribed into a Stent Calculator Spreadsheet application. In the spreadsheet format, each calculation is contained within a row, and therefore each column can represent a unique combination of design input parameters and corresponding performance predictions. The Stent Calculator Spreadsheet is therefore a useful tool for conducting design explorations, “what if” analysis, and understanding design tradeoffs. It can also be a useful tool for documenting design history and rationale. The format of the Spreadsheet can be seen in Figure 4.1.

The Stent Calculator Spreadsheet is also useful for understanding design sensitivity and trends, and the cause/effect relationship between input parameters and performance measures of interest. For example, one might explore the impact of changing a single design input variable while holding all others constant, as illustrated for Strut Length in Figure 4.2. The following sections demonstrate this capability by exploring the performance trends associated with changing the target vessel diameter, wall thickness, and strut length.

Stent Design Inputs		Units	Value
4.1 N_col	number of columns	#	10
4.2 N_struts	struts around circumference	#	42
4.3 D_tube	outer diameter of tubing	mm	1.915
4.4 t_raw	wall thickness of raw tubing	mm	0.170
4.5 L_strut_inner	strut length to inner tangents	mm	1.200
4.6 w_apex_raw	apex width, as-cut	mm	0.130
4.7 X_bridge	axial gap between outer tangents	mm	0.150
4.8 Y_bridge	circumferential span of bridge	mm	0.000
4.9 w_bridge_raw	width of bridge	mm	0.125
4.10 N_bridges	number of bridges around circ.	#	7
Process Parameters			
4.11 w_kerf	minimum effective kerf width	mm	0.025
4.12 m_width	width removal in finishing	mm	0.036
4.13 m_thickness	wall thickness removal	mm	0.059
4.14 Af	Af of finished component	degC	27
Material Properties			
4.15 E_Af_low	modulus of elasticity at Low Af	Mpa	94000
4.16 Af_low	Low Af for defining E	degC	-5
4.17 E_Af_high	modulus of elasticity at Af High	Mpa	34000
4.18 Af_high	High Af for defining E	degC	37
4.19 Af_inflection	Inflection point in E vs Af	degC	19
4.20 E_case1	E for Af < Af_low	MPa	94000
4.21 E_case2	E for Af_low < Af < Af_inflection	MPa	31741
4.22 E_case3	E for Af_inflection < Af < Af_high	MPa	34059
4.23 E_case1	E for Af > Af_high	MPa	34000
4.24 E	modulus of elasticity at spec'ed Af	MPa	34059
4.25 density_niti	density of Nitinol	mg/mm^3	6.7
4.26 strain_endurance	endurance limit	%	0.40%
Service Parameters			
4.27 D_set	expanded inner diameter of stent	mm	8.00
4.28 D_ves	diameter of vessel	mm	6.50
4.29 D	analysis diameter	mm	6.50
4.30 C_percent	compliance: % change in diameter	%	6%
4.31 C_pressure	compliance: pressure for % change	mmHg	100
4.32 P_systolic	systolic pressure at implant site	mmHg	150
4.33 P_diastolic	diastolic pressure at implant site	mmHg	50
4.34 P_mean	mean pressure at implant site	mmHg	100

Figure 4.1: The first several rows of the Stent Calculator Spreadsheet define the input parameters for the design.

Stent Design Inputs		Units	Value												
4.1 N_col		number of columns	#	10	10	10	10	10	10	10	10	10	10	10	10
4.2 N_struts		struts around circumference	#	42	42	42	42	42	42	42	42	42	42	42	42
4.3 D_tube		outer diameter of tubing	mm	1.915	1.915	1.915	1.915	1.915	1.915	1.915	1.915	1.915	1.915	1.915	1.915
4.4 t_raw		wall thickness of raw tubing	mm	0.170	0.170	0.170	0.170	0.170	0.170	0.170	0.170	0.170	0.170	0.170	0.170
4.5 L_strut_inner		strut length to inner tangents	mm	0.700	0.800	0.900	1.000	1.100	1.200	1.300	1.400	1.500	1.600	1.700	1.700
4.6 w_apex_raw		apex width, as-cut	mm	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130
4.7 X_bridge		axial gap between outer tangents	mm	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150
4.8 Y_bridge		circumferential span of bridge	mm	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
4.9 w_bridge_raw		width of bridge	mm	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125
4.10 N_bridges		number of bridges around circ.	#	7	7	7	7	7	7	7	7	7	7	7	7
Process Parameters															
4.11 w_kerf		minimum effective kerf width	mm	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025
4.12 m_width		width removal in finishing	mm	0.036	0.036	0.036	0.036	0.036	0.036	0.036	0.036	0.036	0.036	0.036	0.036
4.13 m_thickness		wall thickness removal	mm	0.059	0.059	0.059	0.059	0.059	0.059	0.059	0.059	0.059	0.059	0.059	0.059
4.14 Af		Af of finished component	degC	27	27	27	27	27	27	27	27	27	27	27	27
Material Properties															
4.15 E_Af_low		modulus of elasticity at Low Af	Mpa	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000
4.16 Af_low		Low Af for defining E	degC	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5	-5
4.17 E_Af_high		modulus of elasticity at Af High	Mpa	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000
4.18 Af_high		High Af for defining E	degC	37	37	37	37	37	37	37	37	37	37	37	37
4.19 Af_inflection		Inflection point in E vs Af	degC	19	19	19	19	19	19	19	19	19	19	19	19
4.20 E_case1		E for Af < Af_low	MPa	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000	94000
4.21 E_case2		E for Af_low < Af < Af_inflection	MPa	31741	31741	31741	31741	31741	31741	31741	31741	31741	31741	31741	31741
4.22 E_case3		E for Af_inflection < Af < Af_high	MPa	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059
4.23 E_case1		E for Af > Af_high	MPa	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000	34000
4.24 E		modulus of elasticity at spec'ed Af	MPa	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059	34059
4.25 density_niti		density of Nitinol	mg/mm^3	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7
4.26 strain_endurance		endurance limit	%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%	0.40%

Figure 4.2: In this example, a separate tab has been created to study the impact of varying strut length while holding all other input parameters constant.

4.1.1 Trend Analysis: Vessel Diameter

The Open Stent design described above assumes placement in a vessel having a nominal diameter of 6.5mm. This section applies the Stent Calculator Spreadsheet to consider the impact of placing the stent in a vessel ranging from 6.0mm to 7.0mm. This is a typical scenario for nitinol stents, which are commonly indicated for use in vessels having a specified range of nominal diameters.

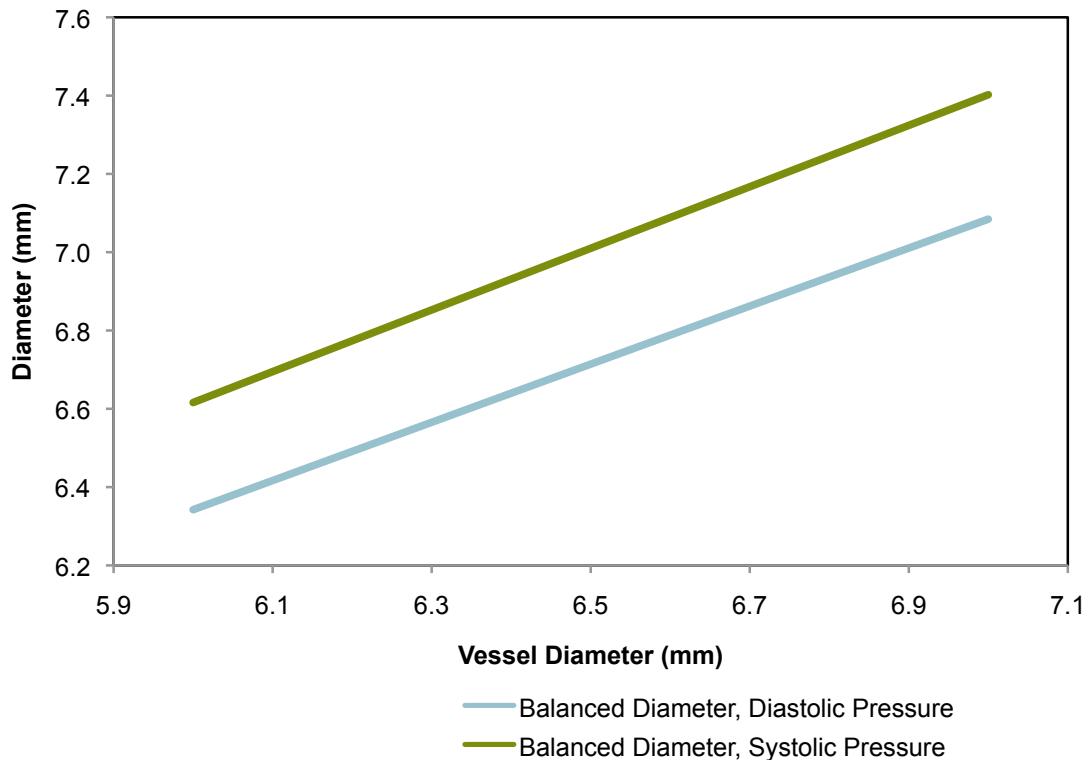


Figure 4.3: Balanced Diameters sensitivity to Vessel Diameter. The relationship here is substantially linear, as expected.

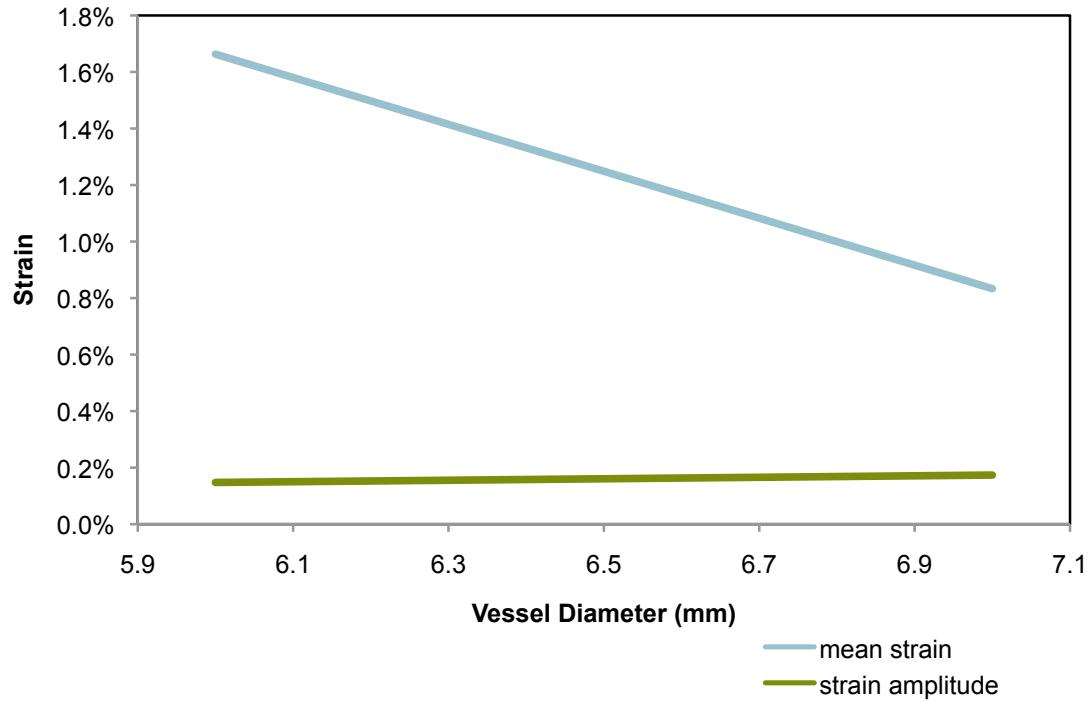


Figure 4.4: Strain sensitivity to Vessel Diameter. Mean strain decreases with increasing vessel diameter, as this reduces the amount of “oversizing” experienced by the stent. Strain amplitude is substantially constant, with a slight trend toward increasing with increasing vessel diameter, as the larger stented vessel is slightly less stiff.

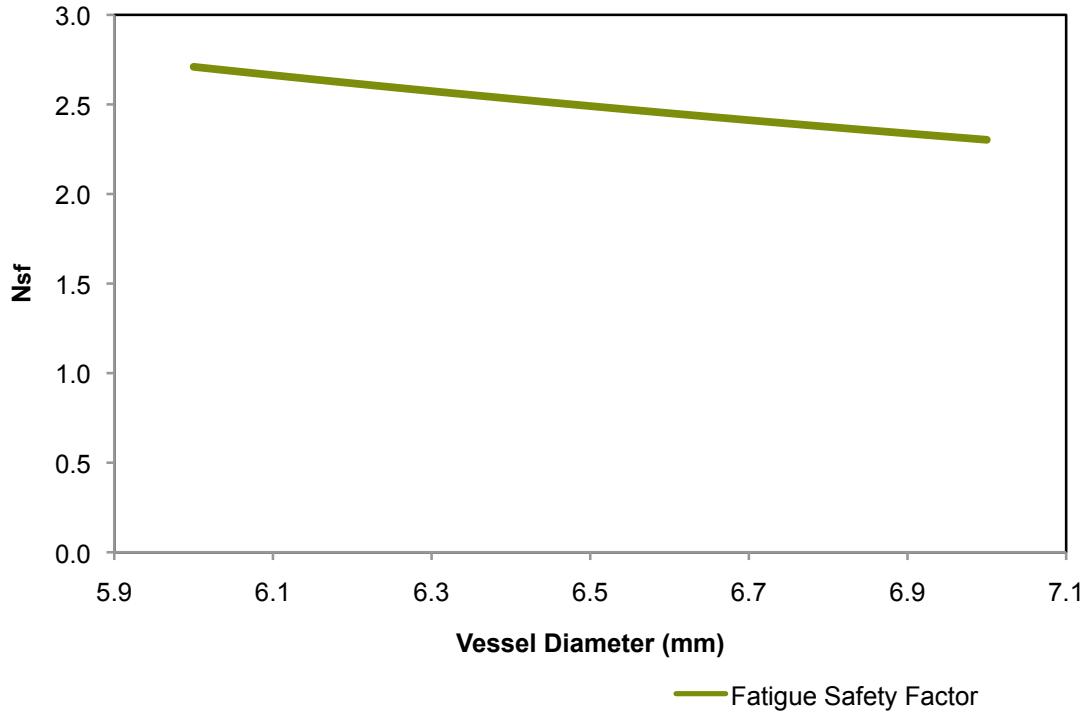


Figure 4.5: Fatigue Safety Factor sensitivity to Vessel Diameter. The slightly increasing value of strain amplitude noted above results in a slightly decreasing safety factor with increasing vessel diameter. All else being equal, the maximum vessel diameter (minimum oversizing) is therefore a worse case than minimum vessel diaemter (maximum oversizing) when fatigue performance is driven by strain amplitude.

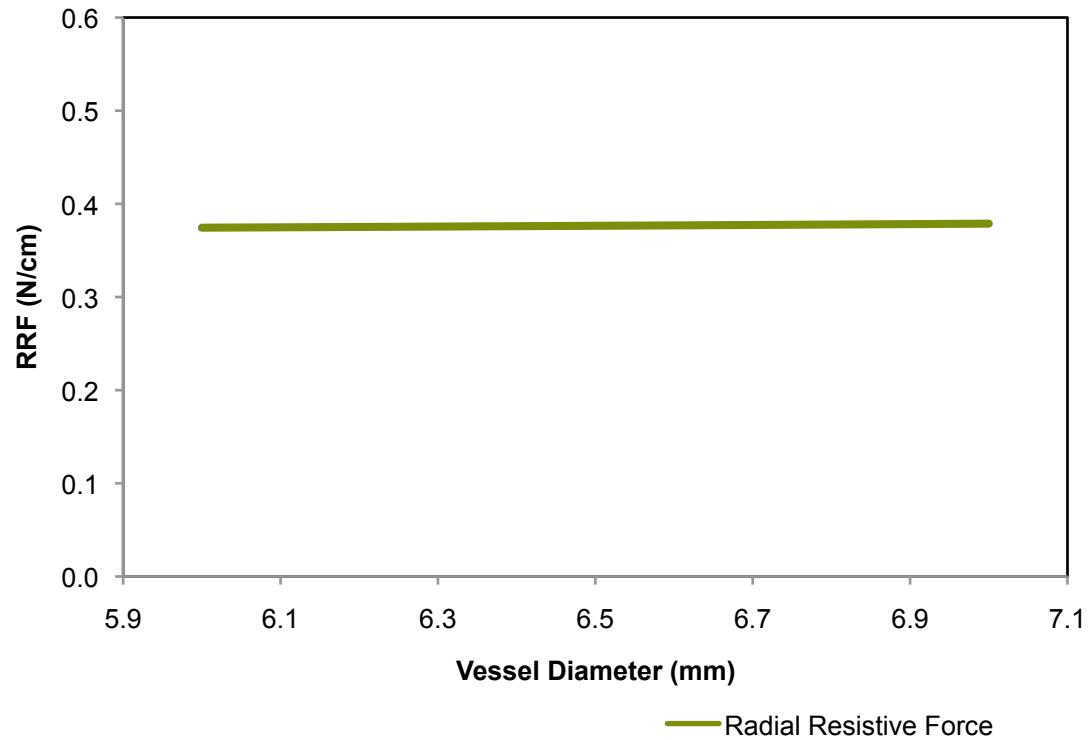


Figure 4.6: Radial Resistive Force sensitivity to Vessel Diameter. RRF is virtually constant as vessel diameter varies.

4.1.2 Trend Analysis: Wall thickness

The baseline Open Stent Design assumed a nominal starting wall thickness of 0.170mm. This section applies the Stent Calculator Spreadsheet to consider the impact of using a starting wall thickness ranging from 0.120mm to 0.220mm.

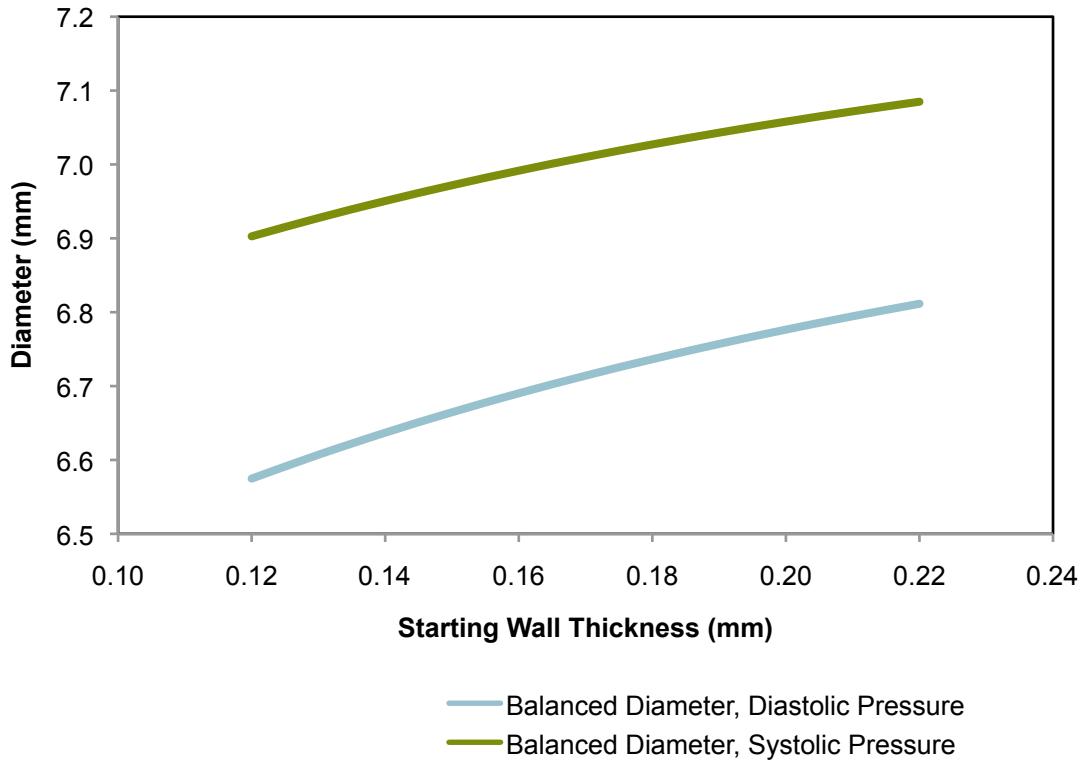


Figure 4.7: Balanced Diameters sensitivity to Wall Thickness. The nominal diameter of the vessel is 6.5mm in this example. Nearly doubling the wall thickness has minimal impact on the balanced diameter of the stented vessel.

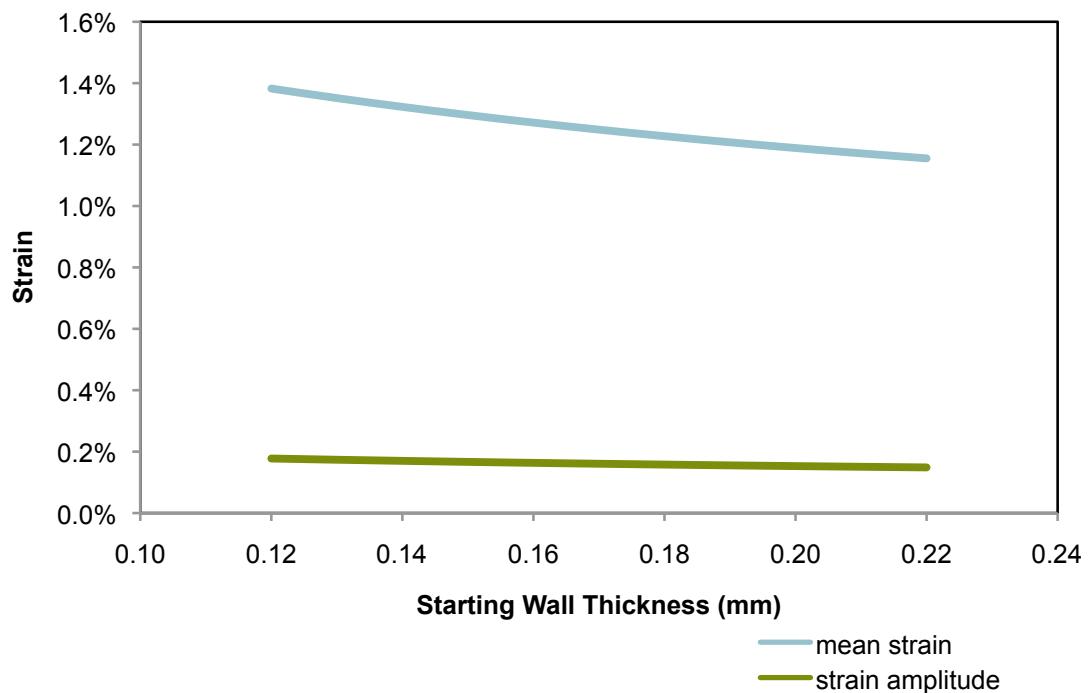


Figure 4.8: Strain sensitivity to Wall Thickness. Mean strain and strain amplitude decrease slightly with increasing wall thickness.

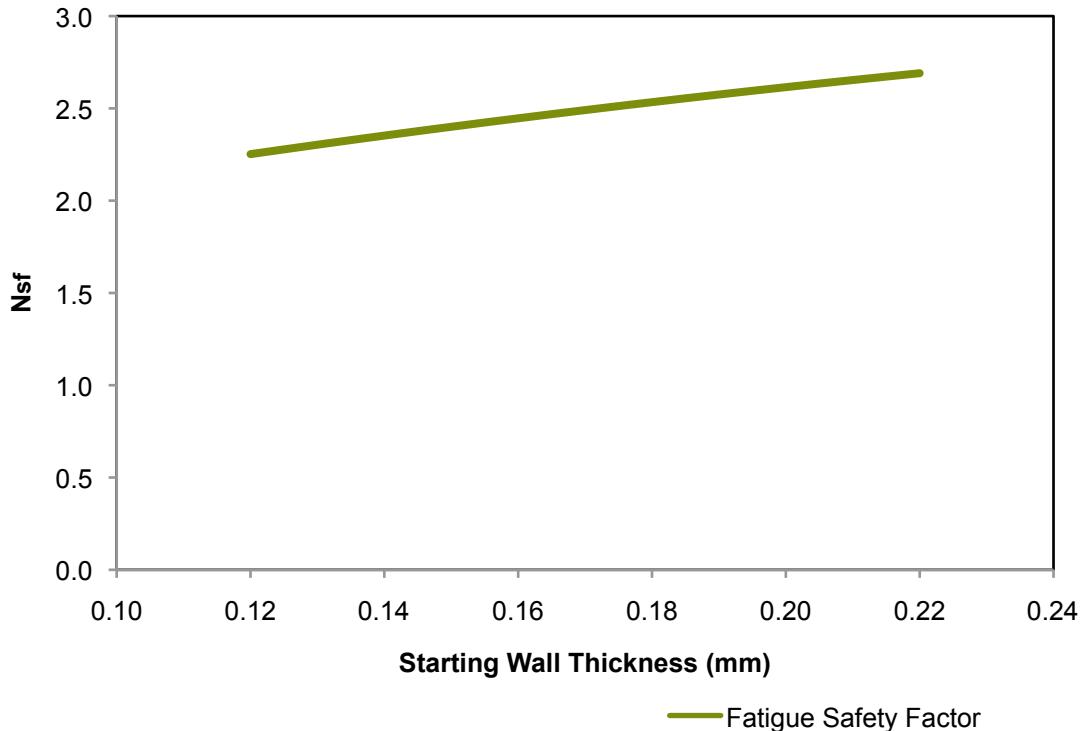


Figure 4.9: Fatigue Safety Factor as a function of Wall Thickness. The slight decrease in strain amplitude leads to a slight increase in fatigue safety factor with increasing wall thickness, as this increases the overall stiffness of the stented vessel. Consequently, the minimum wall thickness condition will tend to be more critical for fatigue than the maximum wall thickness condition.

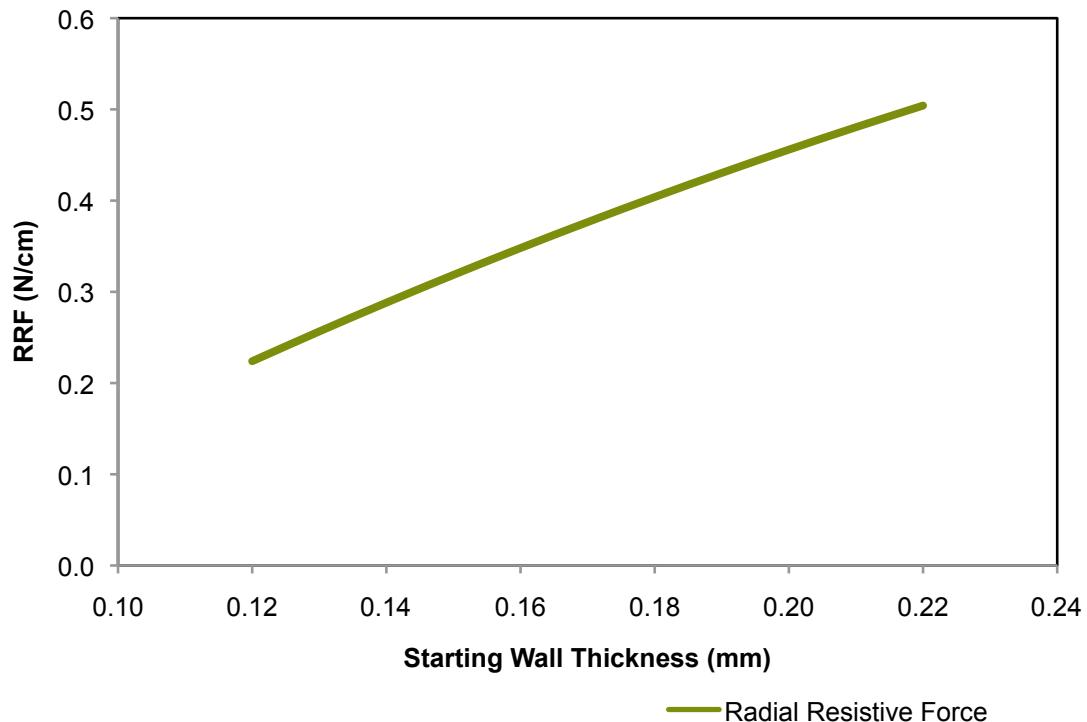


Figure 4.10: Radial Resistive Force as a function of Wall Thickness. RRF has a nearly 1:1 linear relationship with wall thickness. As wall thickness doubles, the predicted RRF also doubles.

4.1.3 Trend Analysis: Strut Length

The Open Stent described above assumes a strut length of 1.2mm. This section applies the Stent Calculator Spreadsheet to consider the impact of changing the strut length from 0.7mm to 1.7mm. These lengths are used for illustration only; in reality, strut lengths less than 1.0mm may not be feasible for this design.

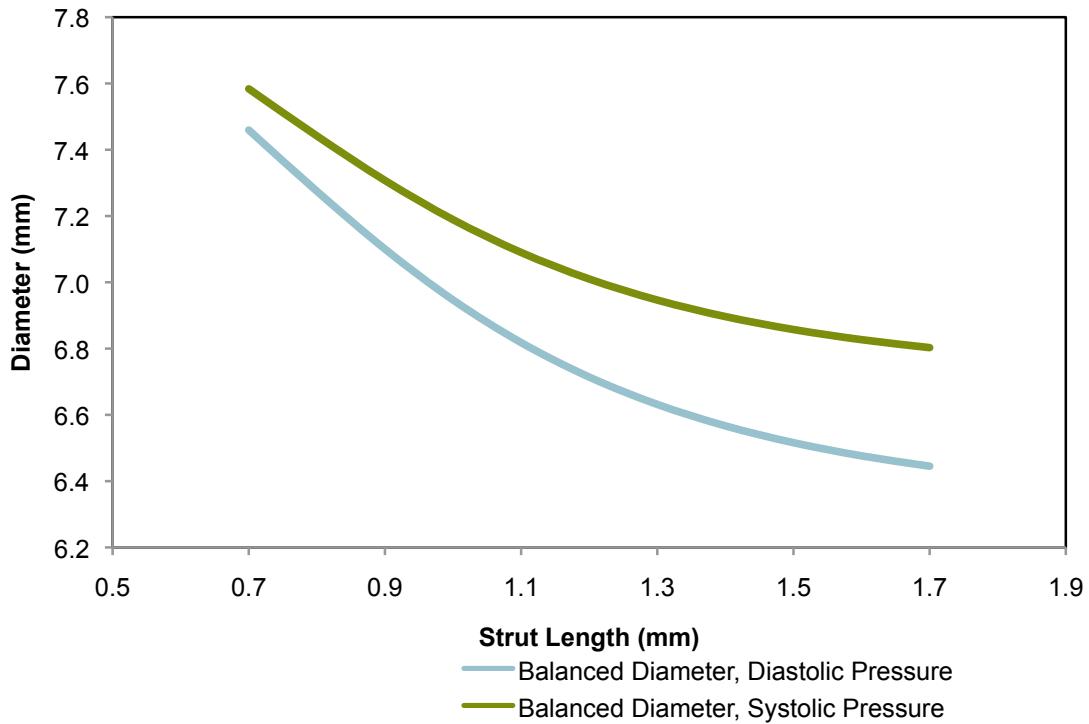


Figure 4.11: Balanced Diameters sensitivity to Strut Length. As the strut length is decreased, the stiffness of the stent increases dramatically. Consequently, with short struts, the balanced diameter rises steeply to approach 8.0mm, the set diameter of the stent. The trend of decreased pulse variability with increasing stiffness is also very apparent in this figure.

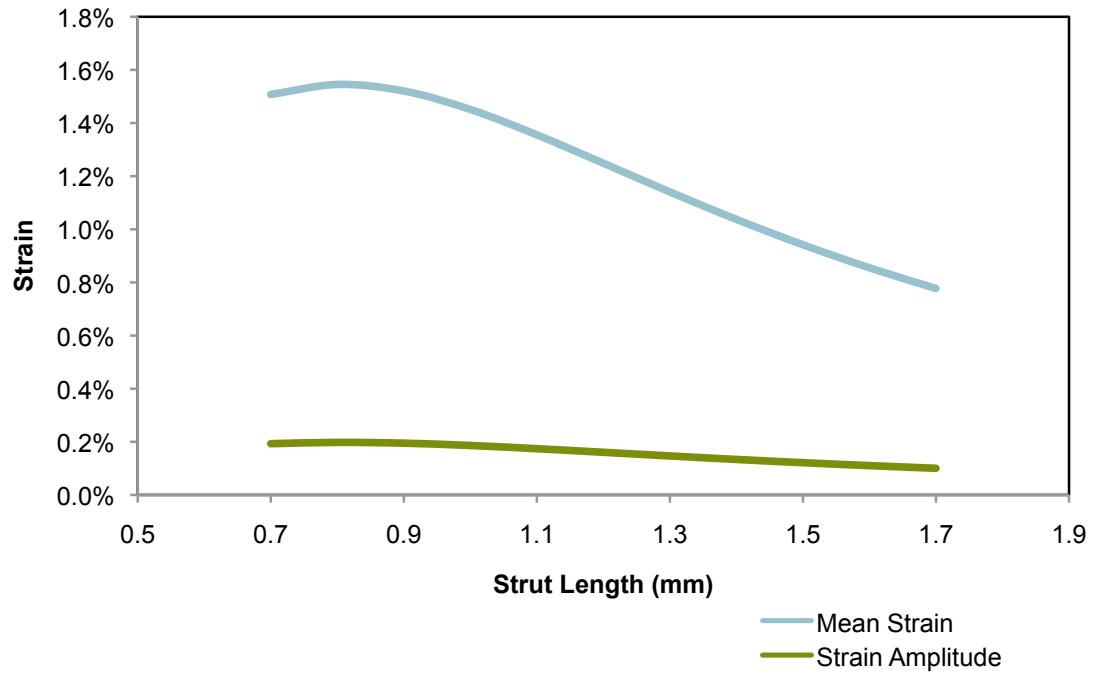


Figure 4.12: Strain sensitivity to Strut Length. Strut length has a powerful influence on the expected strain levels in the stent. Shorter struts generally increase the expected magnitude of mean strain and strain amplitude. The local maximum in mean strain at a strut length of 0.8mm represents the point at which the stent and vessel stiffnesses are equivalent, as seen in the next Figure.

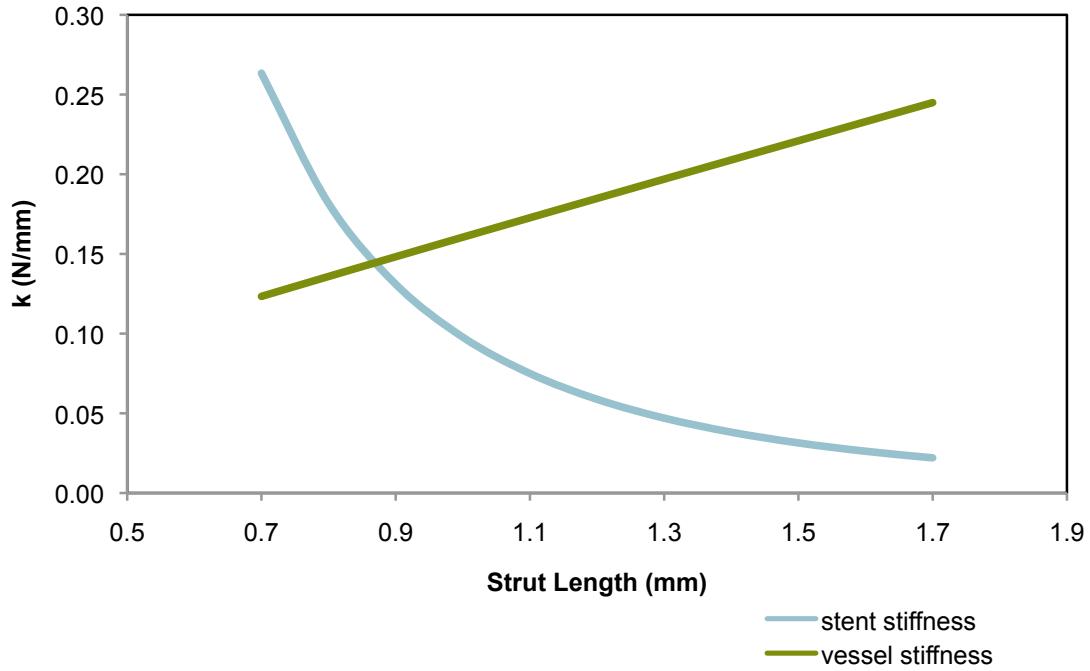


Figure 4.13: k sensitivity to Strut Length. At approximately 0.8mm, the “ k ” (effective “spring stiffness”) of the stent and vessel cross each other, creating the characteristic curve observed in Figure 4.12. The k value for the vessel varies with strut length here because this value is normalized by diameter, *not normalized by length*. Rather, k_{vessel} is calculated for a length of vessel equal to the axial length of a stent unit cell. Because the stent length is a variable in this study, so too is k_{vessel} .

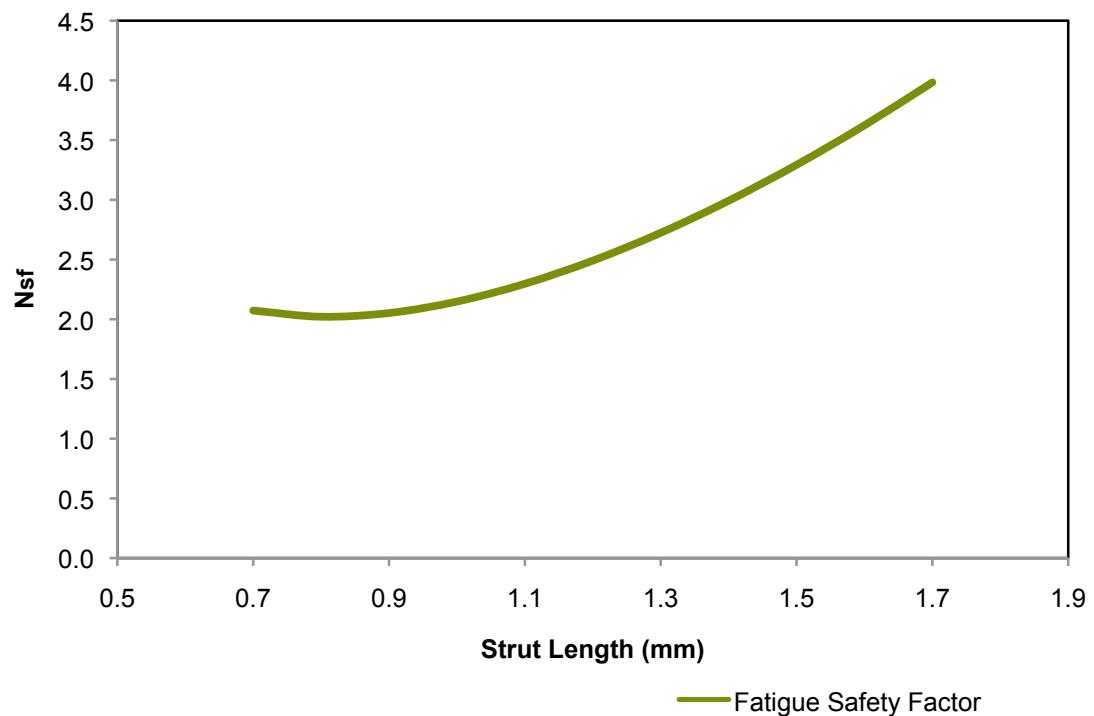


Figure 4.14: Fatigue Safety Factor as a function of Strut Length. The predicted fatigue safety factor generally increases with increasing strut length.

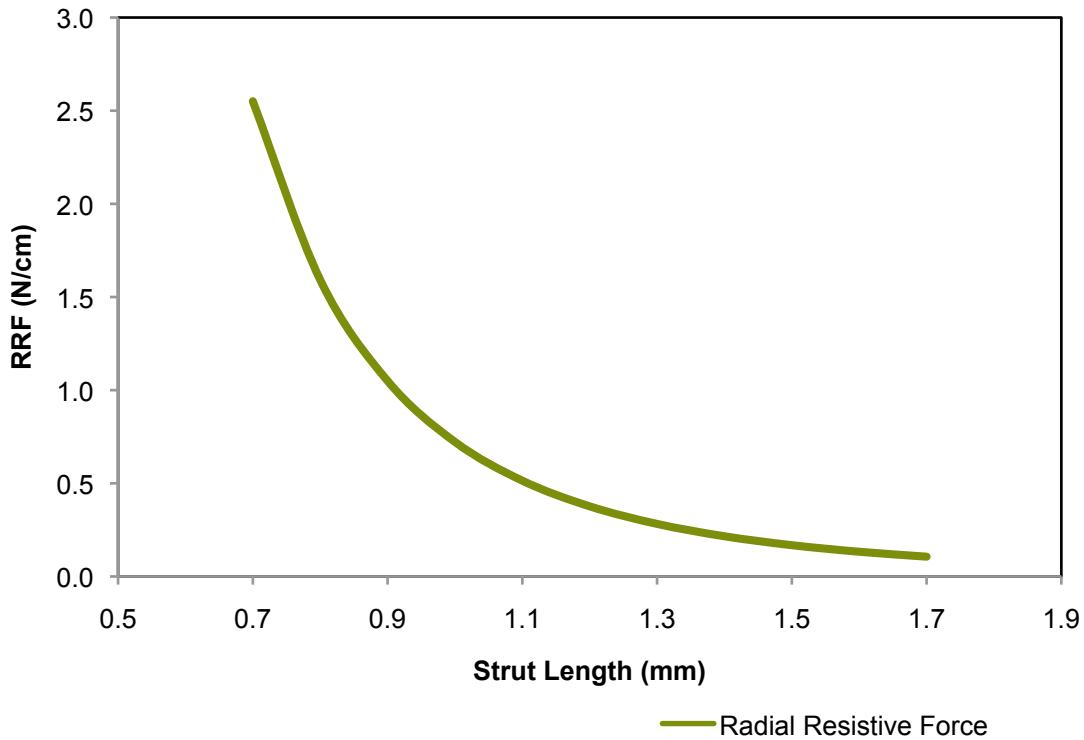


Figure 4.15: Radial Resistive Force as a function of Strut Length. RRF is very strongly influenced by strut length, with sharply increasing strength as strut length decreases.

4.2 Stent Calculator Python

A future draft will describe a Python adaptation of the Stent Calculator, along with some more advanced design exploration topics.

Chapter 5

Finite Element Analysis Confirmation

A future draft will describe Finite Element Analysis (FEA) techniques used to simulate pulsatile fatigue conditions using more sophisticated techniques that account for the non-linear nature of the material and loading conditions.

5.1 Abaqus model

5.2 FEA results

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