Stent Design for a Percutaneous Heart Valve

A Major Qualifying Project submitted to the Faculty of
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Abstract

Surgical Valve Replacement is the standard of care for patients with severe aortic valve calcification, which restricts blood flow from the left atrium to the rest of the body. Valve calcification is common with aging but patients are often refused surgery due to comorbidities present. Minimally invasive placement of tissue valves has recently been introduced to the market and has demonstrated applicability to patients not qualified for open heart surgery. The purpose of this project is to design a self-expanding Nitinol stent with features to enable attachment to a polyurethane valve, facilitate deployment and repositioning as well as secure placement within the aortic annulus while avoiding obstruction of the aortic nodes. The design was performed in collaboration with Nitinol stent manufacturers, private consultants, and surgeons. Various stent configurations were designed and ANSYS was used to conduct finite element analyses on the stent iterations. The most promising stent design was ordered to be custom manufactured and the polyurethane valve was attached to the stent for deployment and bench-top performance testing.

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Introduction

Background and Significance

Surgical Aortic Valve Replacement (AVR) is the standard of care for patients with severe aortic stenosis (AS) in which calcific disease has created an increase in valve leaflet stiffness. This causes a reduction in leaflet range of motion and the effective valve orifice area during systolic ejection (Chiam, Koh, & Chao, 2009). AS is common with aging and is the most common valve condition for which AVR is performed in the United States. Standard indications for severe AS include symptoms such as external chest pain, syncope and dyspnea. Once these symptoms develop, the average survival is 5, 3, and 2 years, respectively (Varadarajan, 2006) and the only effective therapy is AVR. Without surgical AVR, symptomatic patients have a 60% chance of seeing another year and a 32% chance of living an additional five years. However, according to a study, the estimated operative mortality for a patient undergoing a routine AVR procedure is 4% and this number increases significantly with advanced patient age and the presence of comorbidities (Edwards, 2001). Additionally, high-risk surgical patients due to pre-existing co-morbidities are not offered the treatment option of a surgical AVR and are left with no option other than a difficult adjustment to a relatively poor quality of life until they succumb to congestive heart failure.

Transcatheter aortic valve implementation (TAVI) is a new technology specifically developed to address this high-risk population. Bioprosthetic valves have been modified to allow their delivery to the aortic valve position using transcatheter techniques similar to those employed for the placement of balloon expandable stents to the coronary arteries. One of the first generation stent-valves, the Cribier-Edwards PHV (Cribier, 2006) consisted of three leaflets fabricated from horse tissue sewn onto a stainless steel balloon expandable stent as shown in .

Figure 1.13: The Cribier-Edwards percutaneous bioprosthesis (Cribier, 2006)

The Edwards PHV can be delivered transfemorally or transapically. Transfemoral insertion is a process where the Edwards PHV is threaded through the patient's circulatory system from the leg, as shown in Figure 1.14. Transapical insertion, on the other hand, is when it is inserted through the ribs, into the apex of the left ventricle and delivered to the site of the patient's native diseased valve, as depicted in Figure 1.15.

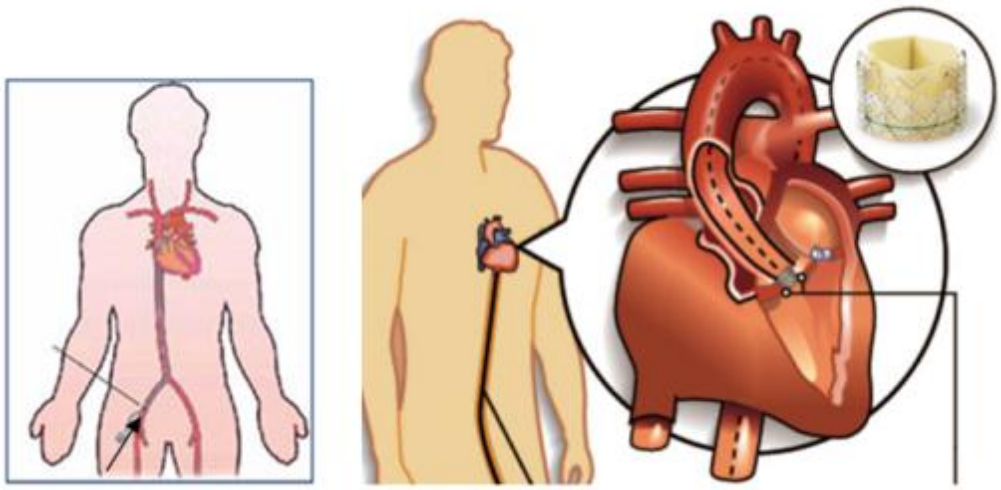

Figure 1.14: Transfemoral/retrograde approach (Webb, 2006)

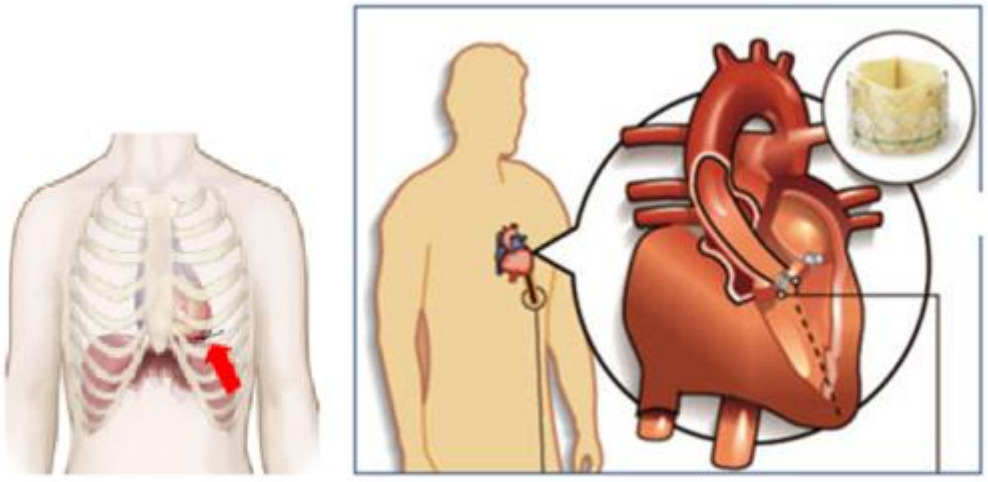

Figure 1.15: Transapical/antegrade approach (Webb, 2006)

Out of 5001 patients, the Euro Heart Survey identified 284 with AS and 216 of those had severe AS. Of the patients with symptomatic severe AS, 38% were deemed high risk patients and were refused surgery. These high-risk patients can currently receive balloon valvuloplasty. However, a study

concluded that 75% of patients having undergone balloon valvuloplasty exhibit hemodynamic evidence of restenosis (Lieberman, 1995).

The CoreValve Revalving System, as shown in Figure 1.16, utilizes an hourglass shaped self-expanding multi-level nitinol stent, which obviates the need for a balloon (Zajaras & Cribier, 2009). An 18 French catheter is used during transfemoral insertion. The small size of the delivery catheter not only improves overall maneuverability but also eliminates the need for surgical access to the femoral artery for device insertion. The bioprostheses is sutured to the nitinol frame, and the valve leaflet pattern and attachment geometry are key to the valve's flow and durability characteristics.

Figure 1.16: CoreValve Revalving System (Cribier, 2006)

The Abiomed Inc. Approach

The Abiomed trileaflet polyurethane valve, shown in Figure 1.5, was developed for use in ventricular assist devices. The valve has demonstrated excellent durability and hemocompatibility (Rusell, 1980). Although the valve is commercially available as part of the Abiomed devices, the current configuration is not compatible with the requirements of a replacement valve since it is contained within a conduit.

Figure 1.17: Trileaflet valve within a conduit (Abiomed Inc.)

The polymeric trileaflet valve prosthesis to be modified for transcatheter delivery to the aortic position differs from the existing valve in that it has three flexible stent posts. The redesigned valve will remain similar to the native aortic valve with three crescent shaped leaflets in a partially opened

position as this is a proven design. The contoured leaflets are fabricated from Angioflex®, a proprietary polyurethane material, and have a flat free edge and a different thickness distribution compared to the existing valve. This new valve seeks to ensure uniform opening and closing characteristics and reduce forward flow pressure losses, while simultaneously increasing durability, and minimizing the risks of thrombus formation and calcification. To accommodate a range of patients, the outer diameter of replacement valves normally range between 19 – 29mm for the aortic prosthesis and 24 – 33mm for mitral prosthesis. For the scope of this project, one valve diameter will be developed specifically for transcatheter delivery. The need for a wider range of valve diameters is appreciated and development will proceed once the first generation transcatheter valve is successfully developed and demonstrated feasible and functionally acceptable.

The major challenge is the incorporation of the trileaflet valve into a support structure that is compatible with incorporation into a delivery catheter similar to the CoreValve Revalving System's self-expanding stent. In addition to stent mounting, a means for anchoring the device securely within the aortic annulus is of equivalent importance. Existing stent systems rely on the presence of annular and leaflet calcific disease to improve stent stability following deployment. While this will certainly apply for the developed polyurethane valve, a reliable anchoring system will have merit should the valve be used to treat non-calcific aortic or mitral valve disease.

Project Objectives

The objective of this project was the development of a polymeric heart valve that can be implanted at low risk using a percutaneous approach, initially for use in patients considered high-risk for conventional surgical valve replacement. Pending success in the incorporation of the valve into a low profile, efficient and safe delivery system, the valve could have indications for use in a wider range of patients with degenerative valvular disease. Key innovations include improved durability and hemodynamic properties, lower manufacturing costs, and simplified delivery over existing transcatheter bioprosthetic valves.

Scope of Work

To prove feasibility of the replacement valve, an iterative approach was observed throughout the different stages of the project. To better define the scope of the assignment, several sub components were identified:

- Use of off-the-shelf stents to allow for rapid attachment mechanism
- Self-expanding Nitinol stent design
- Valve attachment to stent
- Bench-top testing
- Placement testing
- In vitro performance evaluation

Generic stents were ordered from a Nitinol stent manufacturer and were used to investigate several ways to attach a polyurethane valve to a Nitinol frame. Different stents were designed to enable a crimped down size of 18 French and facilitate the attachment process. These were analyzed for static and dynamic structural loading using ANSYS Workbench. The most viable designs were custom ordered and the polyurethane valve leaflet attachments were assessed for forward pressure drop, backflow leakage and high cycle failure. Based on results, the budget allowed for a third round of stents where the focus was on delivery and in vitro performance.

Design Requirements

The design requirements have been defined in collaboration with the project sponsor, Abiomed. The following list has been divided into subgroups for ease of navigation.

Methods/Procedural

1. The valve must be an acceptable alternative to balloon valvuloplasty for patients who are ineligible for surgical valve procedures due to age or comorbidies
2. A percutaneous valve attachment that is design scalable for range of valve sizes
    - *Scalable to accommodate valve sizes from 21 – 24 millimeter*
    - *23mm valve leaflets will be attached on a Nitinol stent ranged from 20-24 millimeter*
3. A means of crimping the valve stent to the appropriate size should be optimized
4. A percutaneous valve attachment method so that when crimped does not jeopardize durability or functionality of the valve
    - *Valve/Stent system to be implemented into an 18 French (6.0 millimeter) delivery catheter*
5. The method of attachment must be bio/hemocompatible
6. Should be able to re-ploy stent during initial procedure in case that positioning needs to be improved
    - *The delivery catheter should support re-deployment of the stent*
7. Extreme aortic stenosis must be considered in the case that radial expansion methods are utilized
8. The valve must be able to be delivered with the apical antegrade approach, and should be able to be placed femorally

Mechanical Strength/Stability

1. A leaflet/stent attachment method that is proved feasible and durable
    - *Design a 3 leaf polyurethane (angioflex) valve to be mounted on a nitnol stent*
    - *Design an attachment to withstand a 380 million (12 years) cycle life-span or more with 90 millimeter mercury (mmHg) closing pressures*
    - *Design an electro-polished stent to keep the E_{bd} (breakdown potential/corrosion resistance) roughly around 800 mV. NOTE: greater than 500 mV is considered anti-corrosive*
2. The valve-stent attachment must reduce shear stress (stress concentration) at commissure and attachment points

- *Wall shear rates must be greater than 10 sec^{-1}, smooth surfaces must be maintained throughout Ra less than 0.4 micrometer, step transitions must be less than 100 micrometer*

3. The leaflet folding pattern must reduce the effect of fatigue/creep
4. The stent and valve attachment must be able to go around the aortic arch
5. Fixation of the valve to the aortic wall must prevent migration of the valve
   - *Want a secure fixation method in the aorta with less than 1 millimeter of displacement with closing pressures of 250 mmHg*

Dynamics

1. A percutaneous valve attachment to improve hemodynamic properties comparable to surgical valves
   - *The pressure drop should be less than 8 mmHg @ 10 L/m and must be less than 10 mmHg*
   - *The volume loss closing should be less than 1 milliliter (mL) and must be less than 2 mL*
   - *The backflow leakage should be less than 5 mL/sec and must be less than 10 mL/sec*
2. A percutaneous valve attachment that does not block any blood pathways nor require any anticoagulants
   - *Use of anticoagulants such as Coumadin should not be required due to valve/stent attachment*
3. Obstruction of the coronary ostia must be avoided
   - *An opening in the stent of at least 1 cm^2 must exist over each sinus to allow flow into the coronary ostia*
4. The valve-stent attachment must reduce thrombus formation
5. The valve-stent attachment must reduce paravalvular leakage
6. The valve must be able to be tested with a modified mock loop system already in existence
7. Obstruction of the aortic nodes must be avoided

Cost

1. The method of attachment must reduce manufacturing costs
   - *COGS must be less than $500*
2. The valve should be a lower cost alternative to currently available percutaneous tissue valves ($30-40k selling price)

Background Information

Nitinol is an acronym for Nickel Titanium Naval Ordinance Laboratory and it is used to describe a family of materials, which contain a nearly equal mixture of nickel and titanium. The Nitinol alloys were originally developed at the Naval Lab and are attractive to the medical device industry because they are biocompatible and are at their optimum superelastic behavior at body temperature, when processed correctly.

As a replacement to stainless steel components, Nitinol is often used. A comparison of nominal properties between Nitinol and Stainless Steel is provided in the Table 2.1 (Peter & Daniel):

Table 2.1: Nitinol vs Stainless Steel Properties

Property	NiTi	Stainless Steel
Recovered Elongation	8%	0.8%
Biocompatibility*	Excellent	Fair
Effective Modulus**	~ 48 GPa	193 GPa
Torqueability	Excellent	Poor
Density	6.45 g/cm^3	8.03 g/cm^3
Magnetic	No	Yes
Ultimate Tensile Strength (UTS)	~ 1,240 MPa	~ 760 MPa

Figure 2.1 illustrates the loading and unloading material behavior seen in Shape Memory material models when used in their superelastic state. At low levels of stress, the material exists in an austenite phase but upon further loading, the material undergoes a stress-induced transformation to a martensite phase. The material behaves as linear elastic in both austenite and martensite phases, however, the modulus of elasticity in the two phases is different. During the stress induced transformation from austenite to martensite there is very little change in stress, but a large increase in strain. Beyond the transitions region, the martensite phase ultimately results in permanent unrecoverable set in the material. Unloading for cases that do not reach the transformation state follow the elastic modulus.

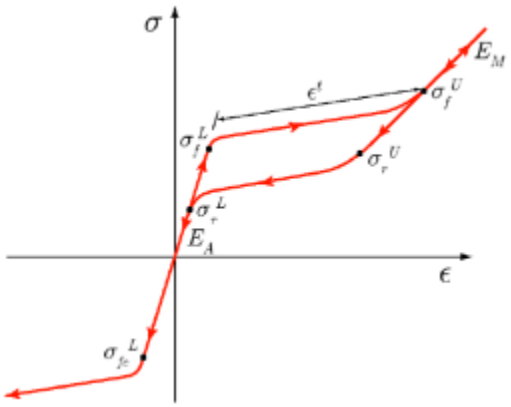

Figure 2.1: Superelasticity Hysteresis of Nitinol (Duerig, Melton, Wayman, & Stockel, 1990)

The superelastic behavior of Nitinol is used in stent design where the transformation temperatures are set to be slightly below body temperature. The superelastic effect is caused by the stress-induced formation of some martensite above its normal temperature. The martensite reverts immediately to un-deformed austenite when the stress is removed. This occurs because it was formed above its normal temperature which results in the process providing the elasticity in these alloys for strains up to about 8%.

Nitinol stents have an advantage in that they can be self-deployed. They rely on the superelasticity of the material to expand the stent against the artery walls after angioplasty. This eliminates the need for balloon expansion and guarantees residual forces between the stent and artery wall.

To help with the design of Nitinol stents, information regarding currently available stents has been gathered. Analyzing and understanding the design considerations that go into making a Nitinol stent is a key factor to a successful execution of creating a Nitinol stent that will effectively attach to a polyurethane valve.

Survey of Current Stent Designs

Over 100 different stent designs are currently being marketed or are in evaluation for vascular and non-vascular indications. These stents compete for a market that is estimated to be near $3 billion, and is expected to double with the advent of drug eluting devices. A stent design pyramid is presented, as seen in Figure 2.2 (Stoeckel, Bonsignore, & Duda, 2002), which breaks the differentiating aspects into materials, raw material forms, fabrication methods, geometrical features, and additions. The primary distinguishing factor in all groups is balloon-expansion versus self-expandability.

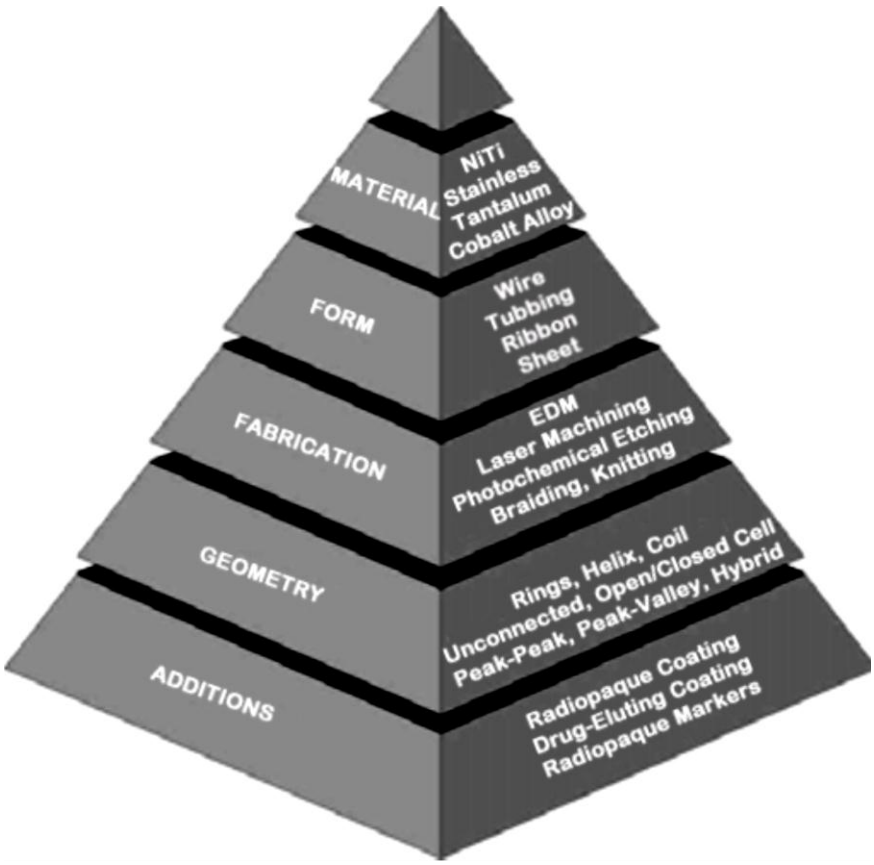

Figure 2.2: Stent Design Pyramid (Stoeckel, Bonsignore, & Duda, 2002)

The top of the pyramid and the chosen starting point is the materials used. This distinguishes between balloon expandable and self-expanding stents. From there, the classifications branch out into the different forms of materials used, such as sheet, wire or tube and fabrication methods, such as laser-cutting, waterjet-cutting, and photo-etching. Next, the vast arrays of geometrical configurations that have been explored in stent designs are considered. The classification ends with additions to stents, such as grafts, and radiopaque markers and coatings.

Materials for metallic balloon-expandable or self-expanding stents must exhibit excellent corrosion resistance and biocompatibility. They should be adequately radiopaque, and create minimal artifacts during MRI. Balloon-expandable stents are made from materials that can be plastically deformed through the inflation of a balloon. After the balloon is deflated, the stent remains in its expanded shape, except for a slight recoil caused by the elastic portion of the deformation. The ideal material for these stents, therefore, has a low yield stress in order to make it deformable at manageable balloon pressures, has high elastic modulus for minimal recoil, and is work hardened through expansion for high strength.

Balloon-expandable stents are manufactured in the 'small diameter', that is, deliverable configuration, and balloon-dilated to the expanded shape at the target site inside the vessel. Self-

expanding stents, on the other hand, are manufactured in the expanded shape, then compressed and constrained in a delivery system. Upon release from the delivery system they spring back, that is, self-expand, to the preset diameter. Their function, therefore, is based on the elastic properties of the material used. Ideally, the material should have a low elastic modulus and a high yield stress for large elastic strains. Alternatively, the shape memory effect of Nitinol can be utilized. Here, large strains can be achieved either superelastically, or via the thermal memory of the material.

The most widely used self-expanding stent that exhibits large elastic strains is Nitinol, a nickel–titanium alloy that can recover elastic deformations of up to 10%. This unusually large elastic range is the result of a thermo-elastic martensitic transformation. The limited elastic range of more conventional materials, such as stainless steel or certain cobalt-based alloys also limits design options.

Stents can be made from sheet, wire (round or flat) or tubing. The majority of balloon-expandable and self-expanding stents are made from wire or tubing. Figure 2.3 shows an example of one made from sheet metal. Stents made from sheet metal have to be rolled up to a tubular configuration after the pattern has been created.

Figure 2.3: Stent Formed From Stainless Steel Sheet, Featuring an Axial Backbone with Integral Gold Markers (Stoeckel, Bonsignore, & Duda, 2002)

The choice of fabrication method depends mainly on the raw material form used. Wires can be formed into stents in various ways using conventional wire-forming techniques such as coiling, braiding, or knitting. The simplest shape of a wire stent is a coil; all coil stents marketed today are made from Nitinol and are self-expanding. Welding at specific locations after wire forming produces closed-cell wire stents or increases longitudinal stability, refer to Figure 2.4.

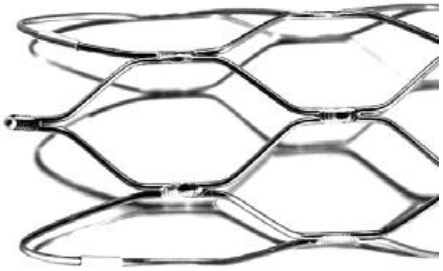

Figure 2.4: Nitinol Wire Welded to Form a Closed-Cell Structure (Stoeckel, Bonsignore, & Duda, 2002)

The most common wire-based self-expanding stent is a braided design using multiple elgiloy (cobalt-based alloys). This allows continuous production, that is, the stents can be cut to length from a long wire-mesh "hose". The vast majority of coronary and peripheral vascular stents are produced by laser cutting the tubing. Intricate patterns can be produced using tube sizes from 0.5mm diameter. Balloon-expandable stents are cut in the crimped or near crimped condition, and only require post-cutting deburring and surface treatment, typically electropolishing to achieve adequate levels of corrosion resistance. Self-expanding Nitinol stents can be cut in either the "small" configuration, requiring post cutting expansion and shape-setting, or in the expanded condition. In either case, they have to be deburred and polished. Laser cutting produces a heat-affected zone along the cut edge, which has to be removed for better performance. A cutting method that does not produce a heat-affected zone is waterjet cutting. A focused jet of water with some abrasive additives is used to cut the pattern instead of a laser beam. Another interesting fabrication method is photochemical etching. Although this method is being used to produce stents from tubing, its real benefit is in sheet processing, when large numbers of parts can be processed in a single run.

Early designs were generally classified as either slotted tube geometries or coil geometries. While slotted-tube type designs had excellent radial strength, they lacked stability. The opposite was true of coil designs. Conflicting design imperatives spawned a rich variety of stent geometries competing in a very crowded marketplace, each seeking an optimal balance of strength and flexibility. This section classifies stent geometries into five high-level categories:

1. Coil

Most common in non-vascular applications, as the coil design allows for retrievability after implantation. These designs are extremely flexible, but their strength is limited and their low expansion ratio results in high profile devices. Figure 2.5 shows an example of the "InStent Esophacoil" device.

Figure 2.5: Coil Stent Fabricated from Nitinol Ribbon (Stoeckel, Bonsignore, & Duda, 2002)

2. Helical Spiral

These designs are generally promoted for their flexibility. With no or minimal internal connection points, they are very flexible, but also lack longitudinal support. As such, they can be subject to elongation or compression during delivery and deployment and, consequently, irregular cell size. With internal connection points, some flexibility is sacrificed in exchange for longitudinal stability and additional control over cell size. The Crossflex stent depicted in Figure 2.6 is an example of a minimally connected helical spiral geometry.

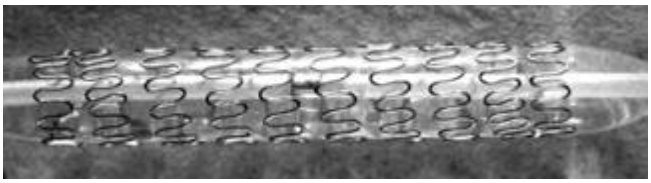

Figure 2.6: Crossflex – A Minimally Connected Helical Spiral Stent Fabricated from Stainless-Steel Wire (Stoeckel, Bonsignore, & Duda, 2002)

3. Woven

This category includes a variety of designs constructed from one or more strands of wire. Braided designs are often used for self-expanding structures. While these designs offer excellent coverage, they typically shorten substantially during expansion. The radial strength of such a braided structure is also highly dependent on axial fixation of its ends. The Strecker stent (Figure 2.7) is an example of a balloon-expandable knitted tantalum stent, while the Cook ZA (Figure XX) stent demonstrates a self-expanding knitted Nitinol wire design.

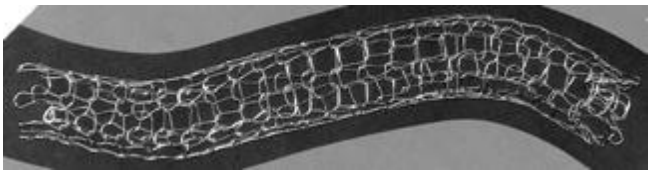

Figure 2.7: Strecker Stent Made of Knitted Tantalum Wire (Stoeckel, Bonsignore, & Duda, 2002)

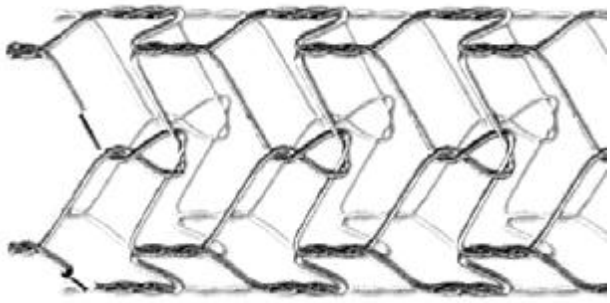

Figure 2.8: Cook ZA-Knitted Nitinol Wire Design, Featuring Sleeve-Type Gold Markers (Stoeckel, Bonsignore, & Duda, 2002)

4. Individual Rings

Single “Z”-shaped rings are commonly used to supports grafts or similar prostheses. They can be individually sutured or otherwise attached to the graft material during manufacture. These structures are not typically used alone as vascular stents.

5. Sequential Rings

This category describes stents comprised of a series of expandable Z-shaped structural elements (known as 'struts') joined by connecting elements (known as 'bridges', 'hinges', or 'nodes'). This type of construction accounts for the majority of commercially available stents. Regular connection describes bridging elements that include connections to every inflection point around the circumference of a structural member. Periodic connection describes bridging elements that include connections to a subset of the inflection points around the circumference of a structural member. Connected inflection points alternate with unconnected inflection points in some defined pattern. "Peak–peak connection" or "peak–valley connection" are terms used to describe the locations at which the bridging elements join adjacent structural members. "Peak–peak" bridging elements join the outer radii, and "peak–valley" bridging elements join outer radii to inner radii of the inflection points of adjacent structural members.

Closed Cell describes sequential ring construction wherein all internal inflection points of the structural members are connected by bridging elements. Such a condition is typically only possible with regular peak-to-peak connections. Early slotted-tube type designs, such as the Palmaz stent (Figure 2.9), were strong, but inflexible.

Figure 2.9: Palmaz-Schatz Stent, Each Half Represents a Closed Cell Slotted Tube Structure

Later designs, such as the NIR stent (Figure 2.10), improved upon this concept by adding a flex connector. These U-, V-, S-, or N-shaped elements plastically deform during bending, allowing adjacent structural members to separate or nest together, to more easily accommodate changes in shape. The primary advantages of closed-cell designs are optimal scaffolding and a uniform surface, regardless of the degree of bending. However, these advantages result in a structure that is typically less flexible than a similar open-cell design.

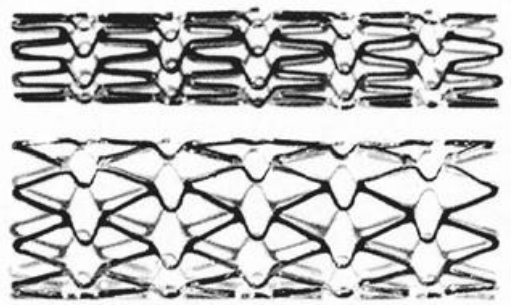

Figure 2.10: NIR stent, a closed-cell structure featuring "V" flex hinges

Open Cell describes construction wherein some or all the internal inflection points of the structural members are not connected by bridging elements. This allows periodic peak-to-peak connections, peak-to-valley connections, and mid-strut to mid-strut connections, as well as innumerable hybrid combinations. In open-cell designs, the unconnected structural elements contribute to longitudinal flexibility. Periodically connected peak-to-peak designs are common among self-expanding stents, such as the SMART stent (Figure 2.11), as well as balloon-expandable stents, such as the AVE S7 (Figure 2.12).

Figure 2.11: SMART Stent – Self-Expanding Open Cell Sequential Ring Design with Periodic Peak-to-Peak Non-flex Connectors

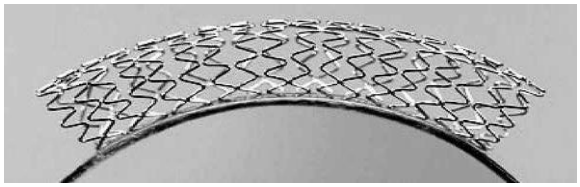

Figure 2.12: AVE S7 Stent – Balloon Expandable Open-Cell Sequential Ring Design with Periodic Peak-to-Peak Non-flex Connectors

The peak-to-valley connection of the ACS Multilink (Figure 2.13) virtually eliminates foreshortening and assures that adjacent structural peaks are aligned peak-to-valley throughout the expansion range of the stent, optimizing scaffolding characteristics. However, the peak-to-valley connectors take up material that could otherwise be used for structural members. Consequently, structures with this type of peak-valley connection are generally not as strong as similar structures with peak-to-peak connections. While these peak-to-peak and peak-to-valley connections are most common, there are also examples of other variations, such as the BeStent (Figure 2.14).

Figure 2.13: ACS Multilink – Balloon Expandable Open-Cell Sequential Ring Design, with Peak-to-Valley Connections

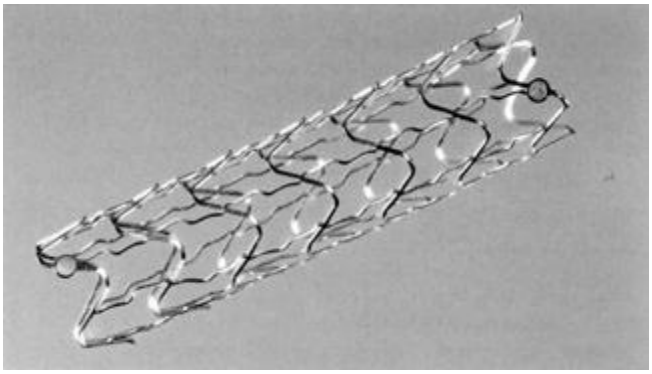

Figure 2.14: BeStent – Balloon Expandable Open-Cell Sequential Ring Design, with Midstrut-to-Midstrut Connections and Integral Gold Markers

More than 100 different stent designs exist today because this development has been mainly driven by patent and marketing issues rather than actual scientific considerations. However, that many brands are not needed. Therefore, there are currently solid investigations underway testing biocompatibility, potentiodynamic polarization, corrosion resistance, thrombogenicity, radiopacity, chronic fatigue behavior in addition to more classic properties like flexibility, trackability and sheaf compatibility.

Appendix A presents a table of the most commonly known stents along with their fabrication methods and comments. Pictures for some of the stents can also be found in the aforementioned section.

Nitinol Stents - Material and Design Considerations

Conventional stent materials, like stainless steel or cobalt based alloys, exhibit a distinctly different elastic deformation behavior from that of the structural materials of the living body. The elastic deformation of these metals and alloys is limited to approximately 1% strain, and elongation typically increases and decreases linearly with the applied force. In contrast, natural materials, like hair, tendon and bone can be elastically deformed, in some cases, up to 10% strain in a non-linear way (S, 1996).

When the deforming stress is released, the strain is recovered at lower stresses. As shown in Figure 2.15, the loading/unloading cycle is characterized by a pronounced hysteresis.

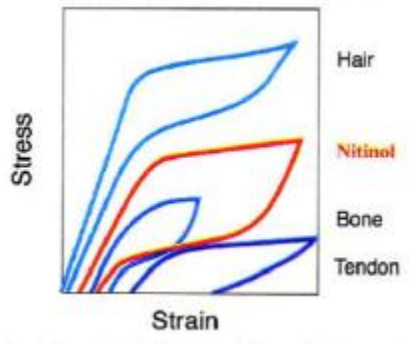

Figure 2.15: Deformation Characteristics of NiTi and Living Tissues (Stoeckel, Pelton, & Duerig, 2003)

A similar behavior is found with Nitinol alloys. As with natural materials, the loading and unloading curves show plateaus, along which large strains can be accumulated on loading, or recovered on unloading, without significant increase, or decrease, respectively, in stress. The schematic stress-strain diagram for Nitinol at body temperature and that of stainless steel is shown in Figure 2.16. Deformation of more than 10% strain can be elastically recovered.

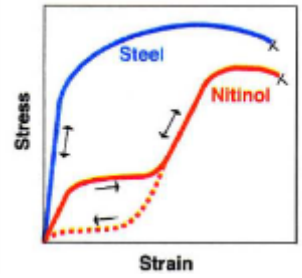

Figure 2.16: Stress-Strain Diagram for Nitinol and Stainless Steel (Stoeckel, Pelton, & Duerig, 2003)

Superelastic Nitinol appears macroscopically to be simply very elastic. However, the mechanism of deformation is quite different from conventional elasticity, or simply stretching of atomic bonds. After a rather modest elastic deformation, when a stress is applied to Nitinol, the material yields to the applied stress by changing its crystal structure. This stress induced phase transformation allows the material to change shape as a direct response to the applied stress. When the stresses are removed, the material reverts to the original structure and recovers its original shape. While superelasticity is the result of a stress induced phase transformation, shape memory is the result of a thermal phase transformation. In fact, the superelastic Nitinol also changes its crystal structure when it is cooled to below a critical temperature, the transformation temperature, which is dependent on alloy composition and processing history. If no force is applied, this phase change is not accompanied by a shape change.

The material can be plastically deformed in the low temperature phase but the original shape can be restored by heating above the transformation temperature (Duerig, Melton, Wayman, & Stockel, 1990).

Self-expanding Nitinol stents are manufactured with a diameter larger than that of the target vessel. Their transformation temperature is typically set to 30^{o}C. They can be easily crimped at or below room temperature and placed in a delivery system. To prevent premature expansion during delivery into the body, the stent is constrained by a retractable sheath or other means. At the treatment site it is released from the delivery system and expands until it hits the vessel wall and conforms to it. Now at body temperature, the stent is superelastic.

Nitinol has found widespread acceptance as a material of choice for medical implants and devices (Stoeckel D. , 2000). It derives its unique properties from a solid state transformation which may be triggered thermally or mechanically, which adds another level of complexity to the material specification. On top of the commonly known material characteristics such as chemical composition, Young's Modulus, yield strength, ultimate tensile strength and elongation to failure, properties like transformation temperature, upper and lower plateau stress, recoverable strain and permanent set have to be taken into account. These properties are strongly dependent on the processing history and play an important role in the design and manufacturing of self-expanding stents.

Nitinol requires controlled processing to achieve optimal shape memory and superelastic properties (Pelton, DiCello, & Miyazaki, 2000) and properly treated Nitinol implants are very corrosion resistant and biocompatible (Wever, Veldhuizen, Sanders, & Schakenraad, 1997). Just like titanium and stainless steel, Nitinol forms a stable surface oxide layer that protects the base material from general corrosion (Wever D. e., 1998). Considering the high nickel content of the alloy, there are concerns that nickel may dissolve from the material due to corrosion and cause adverse effects. On the other hand, other alloys that contain high levels of nickel, such as MP35N (a Co alloy with 35 weight % Ni), or 300 series stainless steel (approx. 10 weight % Ni) exhibit good biocompatibility, and have long been used as implants in orthodontics, orthopedics and cardiovascular applications (Brown, Hughes, & Merritt, 1988). Several studies have measured nickel release during the exposure of Nitinol implants to body fluids. During an in vitro dissolution study of Nitinol dental archwires in saliva (Barrett, Bishara, & Quinn, 1993), it was found that Nitinol appliances released an average of 13.05 mg/day nickel, which is significantly below the estimated average dietary intake of 200-300 mg/day.

To evaluate the effect of different surface treatment methods on the Ni-ion release, Trepanier et al (Trepanier, Venugopolan, Messer, Zimmerman, & Pelton, 2000) immersed mechanically polished and electro-polished samples of Nitinol, MP35N and 316L stainless steel in saline solution at 37^{o}C for a period of greater than 1000 hours. It was found that samples that were prepared by mechanical polishing released higher amounts of Ni-ions than those prepared by electropolishing. Surface analysis data demonstrated that the electropolishing process removes excess nickel from the surface and forms a layer enriched in titanium (in the form of$Ti0_2$). In contrast, the mechanically polished samples have a relatively high concentration of nickel in the surface. Furthermore, the mechanically polished Nitinol and MP35N samples show an increase in Ni ion release after 1000 hours. This may be due to corrosion activity (pitting) after the initial 1000 hour time period in the non-passivated samples.

ASTM standard F2129 provides a quantitative method recognized by the FDA for the accelerated assessment of the corrosion resistance of implant materials (F2129-01, 2002). The most relevant data derived from this test is the break-down potential E_{bd} since most biomaterials corrode locally by pit formation. A high breakdown potential indicates that the material is very stable and resists pitting. Although no official limits have been established, materials with an $E_{bd} \geq 500$ mV are considered sufficiently corrosion resistant and safe for the use as implants.

Anodic polarization tests per ASTM F2129 have been used to evaluate the influence of surface preparation on the corrosion susceptibility of Nitinol stents. Trepanier at al. (F2129-01, 2002) have shown that electro-polished Nitinol stents have excellent corrosion resistance with breakdown potentials greater than 800 mV, whereas the E_{bd} of non-electro-polished stents was on the order of 200 mV. It was further shown that the breakdown potential of electro-polished stents was degraded to less than 500 mV after thermal treatments in the 400^{o}C to 500^{o}C range. This led to the conclusion that optimal corrosion and biocompatibility results are obtained with a thin, titanium oxide (TiO_2) surface layer formed after electropolishing (passivation) treatments. It further appears that uniformity, rather than thickness, of the oxide is most important to protect the material from corrosion.

In 1999, the medical community and the device industry were alerted to the corrosion issue by reports by Riepe et al (Heintz, et al., 2001) on the observation of severely corroded Nitinol graft scaffolds from explanted Stentor aortic stent grafts after five months implantation (Figure 2.17). It was preliminarily speculated that cell-induced electrochemical corrosion or active cellular destruction of the surfaces might have been responsible for the severe corrosion. However, subsequent cell culture testing with Nitinol test samples performed by Riepe's group did not induce any corrosion (E, 2002). Further analysis of the failed components revealed an oxide thickness of 0.2-0.3 µm (determined by Auger analysis) and an E_{bd} of 280 mV (from anodic polarization tests). In contrast, 12 month explants of electro-polished graft scaffolds examined by Pelton et al showed no signs of corrosion. The oxide thickness on these devices was approximately 0.01 µm and the $E_{bd} > 900$ mV. This highlights the importance of optimized surface preparation. Most Nitinol stents marketed today have electro-polished surfaces.

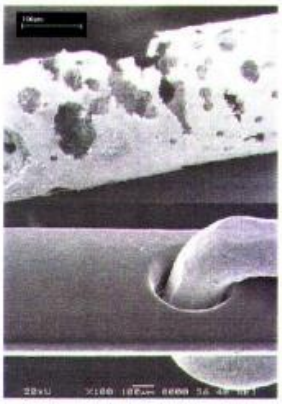

Figure 2.17: Top – Heavily Corroded NiTi Explant; Bottom – Electro-Polished NiTi Explant (Brown, Hughes, & Merritt, 1988)

The most unusual property of Nitinol alloys is stress hysteresis. While in most engineering materials stress increases linearly with strain upon loading and decreases along the same path upon unloading, Nitinol exhibits a distinctly different behavior. After an initial linear increase in stress with strain, large strains can be obtained with only a small further stress increase. This is called the loading plateau. The end of this plateau is reached at about 8% strain. Unloading from the end of the plateau region, causes the stress to decrease rapidly until a lower plateau (unloading plateau) is reached. Strain is recovered in this region with only a small decrease in stress. The last portion of the deforming strain is finally recovered in a linear fashion.

The stress hysteresis or path dependence of Nitinol results in a device feature termed biased stiffness (Duerig, Pelton, & Stoeckel, The use of Superelasticity in Medicine, 1996). This concept is illustrated in Figure 2.18, which shows a schematic superelastic stress-strain curve for Nitinol, demonstrating both non-linear response and hysteresis. Using this graph, the cycle of crimping a stent into a delivery system, deploying it and have it expand and interact with the vessel will be followed. For this purpose, the axes have been changed from stress vs. strain to hoop force vs. stent diameter. A stent of a given size larger than the vessel (point **a**) is crimped into a delivery system (point **b**). After insertion to the target site, the stent is released into a vessel, expanding from **b** until movement is stopped by impingement with the vessel (point **c**). At this point, further expansion of the stent is prevented. Because the stent did not expand to its pre-set shape, it continues to exert a low outward force, termed chronic outward force or COF. However, it will resist recoil pressures or any other external compression forces with forces dictated by the loading curve from point **c** to **d**, which is substantially steeper (stiffer) than the unloading line (towards **e**). These forces are called radial resistive forces or RRF.

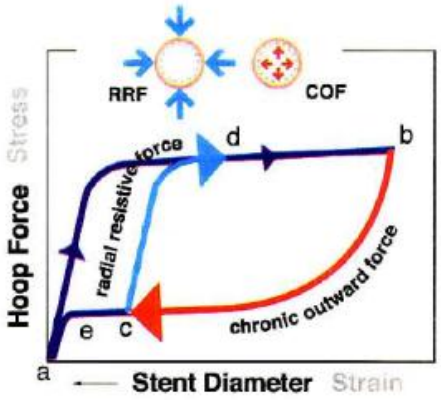

Figure 2.18: Stress Hysteresis and Biased Stiffness (Stoeckel, Pelton, & Duerig, 2003)

Another unusual feature of Nitinol stents is their temperature dependent stiffness. Stents with a transition temperature of 30 degrees Celsius feel quite weak when squeezed or crushed at room or lower temperature. In contrast, they feel much stiffer when squeezed at temperatures above 30 degrees. Figure 2.19 shows actual unloading curves of a Nitinol stent (Cordis SMART Stent) with a diameter of 10 mm at different temperatures. The test setup is described in (Duda, et al., 2000). As can

be seen from this graph, the chronic outward force actually doubles when the temperature is increased from 20 to 37 degrees Celsius. The transition temperature of the stent can be adjusted to a certain extent during processing, which gives the designer another option to increase or decrease the radial forces of the stent without changing the design or physical dimensions. For each degree that the transition temperature is below body temperature, the loading and unloading forces increase by approximately 4 N/mm^2.

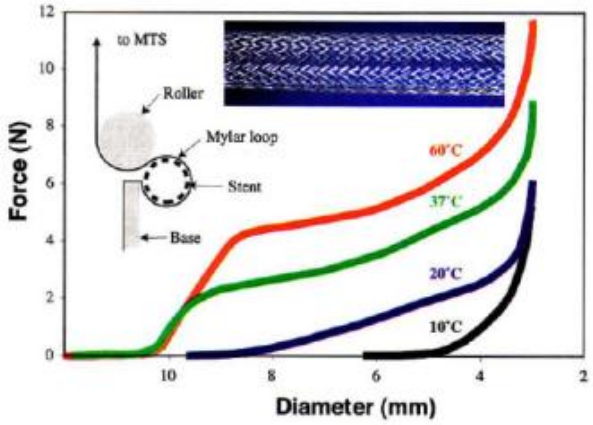

Figure 2.19: Unloading Curves of Nitinol Stents at Different Deployment Temperatures (Stoeckel, Pelton, & Duerig, 2003)

Kink resistance is an important feature of Nitinol for stents in superficial vessels that could be deformed through outside forces. The carotid artery is a prime example. There is a perceived risk for balloon-expandable stents in carotid arteries to be permanently deformed through outside pressure resulting in a partially or completely blocked vessel once the buckling strength of the stent is exceeded. Although Nitinol stents typically do not have the buckling strength of stainless steel stents, they cannot be permanently deformed through outside forces. Nitinol stents can be completely compressed flat and will return to their original diameter when the deforming force is removed (Figure 2.20).

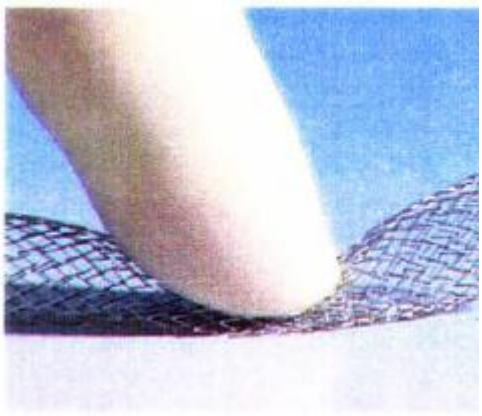

Figure 2.20: Extreme Deformation of a NiTi Stent

Basics of Nitinol Stent Design

Despite the information gathered on the currently available stents and the design and material considerations involved in designing a stent, the team was still lacking direction as to how to model the stent. It was understood that transformation temperature plays in role in the COF and RRF and that electropolishing is important for corrosion resistance. However, there is little background as to how the stent geometry affects performance. Figure 2.21 shows a 3D model generated in SolidWorks with the different parameters that make up the stent geometry.

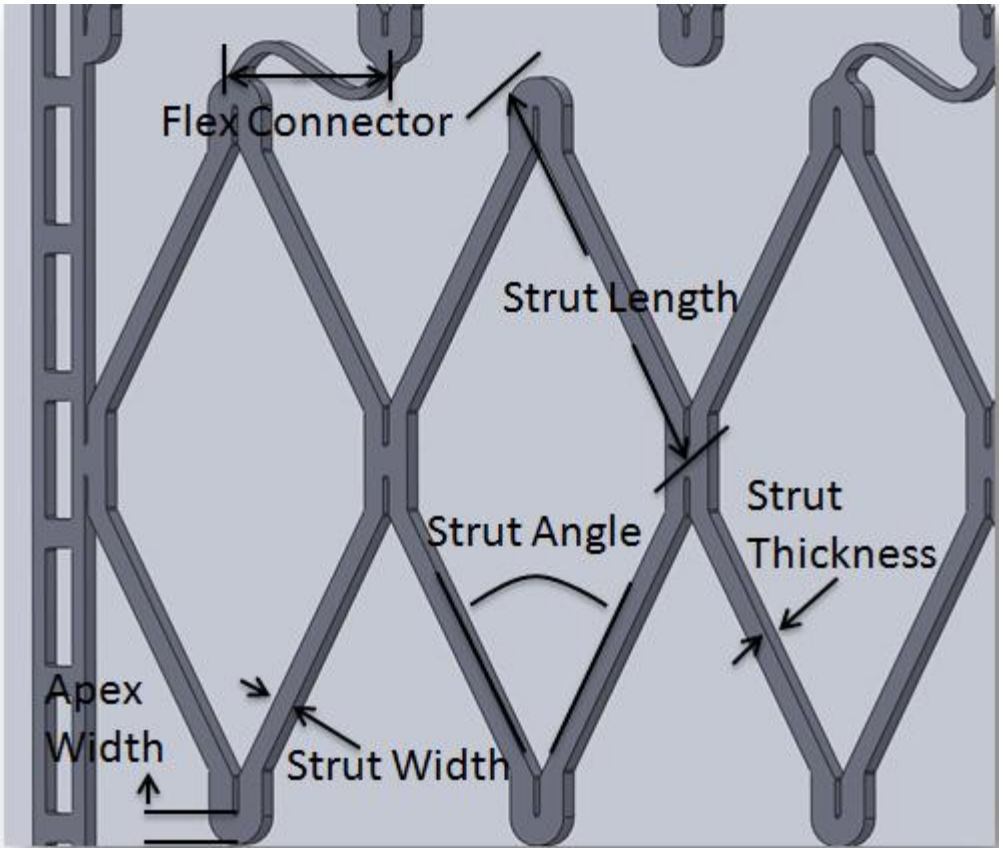

Figure 2.21: Stent Geometry

To gather more information about the specifics of designing a stent, Abiomed Inc. hired a Nitinol consultant to present a Basics of Stent Design seminar. The consultant was referred to the team by Admedes, a stent manufacturer, with which the team worked closely during the course of this project.

The reader must keep in mind that the information presented in this section represents the team's understanding and interpretation of the information provided during the seminar. Since Nitinol is a very novel material in the medical industry, most information available is based on experience rather than hard facts. The most relevant design criteria covered during the presentation are listed below:

- Crossing Profile

The crossing profile is the diameter of the starting raw tube size. For any percutaneous valve, the outside diameter of the delivery system defines the size of the stent. Most valves currently on the market have an 18 French (6.00 mm) diameter. For a valve to be crimped down to an 18 French diameter, it is advised to start with a 16 French starting raw tube size.

- Over-sizing

Over-sizing the stent for anchoring is very common. Looking at the stress-strain diagram and taking into account the high RRF and low COF, over-sizing does present a sound means of anchoring the valve to the aortic annulus. Moreover, calcification of the aortic valve renders the tissue around the replacement valve stiffer and reduces the risk of tissue relaxation and migration of the stent. These are however, only theoretical assumptions that haven't been validated. Other means of anchoring should be explored. Using surface finishes that promote tissue growth, stents with more apexes and flared ends stents are options that should be considered when trying to improve anchoring.

- A_F temperature

The A_F temperature is the transformation temperature that was described in earlier sections. The A_F temperature is specified to the stent manufacturer and typically should be higher than room temperature (23^{o}C) but lower than body temperature (37^{o}C).

- Foreshortening

When the stent is crimped down, its height increases and it becomes shorter during radial expansion. This is an important consideration when designing a stent as the peak-to-peak or peak-to-valley connectors need to have the ability to elongate or shorten. An example of a viable connector is shown in Figure 2.22.

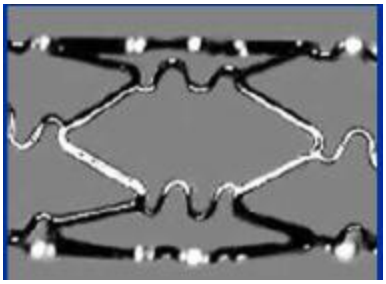

Figure 2.22: Peak-to-Peak Connector

- Radial Strength

As discussed in earlier sections, the radial strength of the Nitinol stent was covered during the presentation. The information provided was in line with the literature review conducted and will not be presented again.

- Flexibility

Depending on the insertion method (femoral or apical), the stent needs to have a certain degree of flexibility. For an open cell stent, the flexibility can be adjusted by the addition of flex connectors. For apical insertion, where the stent is introduced through the rib cage and delivered in a straight line, the stent can be more radially stiff. However, for femoral insertion, where the stent has to go around the aortic bend, the stent needs to be more flexible.

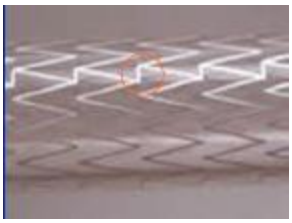

Figure 2.23: Flex Connector in an Open Cell Stent

- Strain

A self-expanding Nitinol stent will experience two major types of strains during its lifetime. The first type of strain is during the crimp down phase before insertion into the delivery system. From experience, it was recommended to the team that the strain endured during this process be no more than 6-8% of the ultimate tensile strength (S_{ut}) of the stent. The second occurs throughout the lifetime of the stent, while it is in use within the aortic valve. It experiences a pulsatile step with each heart beat and due to the fatigue nature of the loading, the alternating strain should be kept under 0.4% of the S_{ut}.

- Strut Width

Once again, due to the lack of hard evidence, the team has to rely on the consultant's experience. The ratio of width to wall thickness was recommended to be 1 to 1.5 to avoid out-of-plane deformation. Figure 2.24 shows a schematic of the strut width and wall thickness.

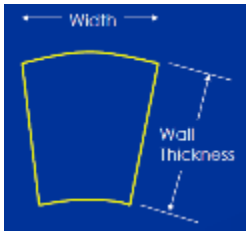

Figure 2.24: Strut Width and Wall Thickness

- Apex Geometry

The ratio of apex width to strut width should be roughly 1 to 1.3 to have an optimum strain distribution over the apex area. "Overloop" sometimes occurs during crimping and is a result of the gap being too small. Overloop is the overlapping of two adjacent struts connected by the same apex.

Increasing the gap and introducing a “keyhole” feature also help in reducing strain. Figure 2.25 provides a drawing of the apex geometry and Figure 2.26 shows a keyhole feature meshed for finite element analysis. The stent designer needs to be careful when increasing the gap size. Too much gap can cause a “train wreck” failure. A “train wreck” failure happens when the apexes deform past what was accounted for by the engineer and effectively buckles.

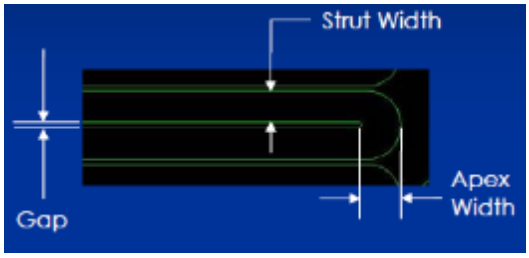

Figure 2.25: Apex Geometry

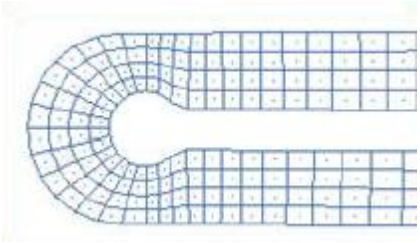

Figure 2.26: “Keyhole” Feature

- Apex/Strut Angle

The apex angle should be kept under 90 degrees. Apex angles over 90 degrees decrease the stability of the structure and can lead to crimping issues. They also induce high strains which have caused cracks during shape setting, even with annealing of the stents in between each incremental heat set. Shape setting is discussed in more detail later in this section.

- Strut Length

A short strut length enhances flexibility of the stent due to the presence of less material. A shorter strut means that the stent needs more struts and therefore more apexes. They add to the radial strength of the stent. A longer strut increases the stress/strain resistance of the stent due to the amount of material present.

- Stent Manufacturing

Each stent manufacturer has its own proprietary technique for manufacturing stents but they usually consist of the following six steps. Stent designers have little control over these steps as they only

reflect what the stent manufacturer has to offer. It is however, good background for the reader who seeks to learn more about state-of-the-art Nitinol stent manufacturing.

1. Laser cutting: Stent manufacturers usually know the design intent but there is a lead in and lead out mark that is caused by the point of entry of the laser and its point of exit. While this consideration is beyond the scope of this project, later stages of stent design need to consult with the manufacturer as to where these marks are located on the stent.
2. Cleaning: Once the raw tubing is cut, it is cleaned. The individual process used by each company was not disclosed to the design team. The design team anticipates the use special solutions in ultrasonic baths to that end.
3. Shape-setting/Thermal Processing: To increase the diameter of the tube from the raw starting size to that of the final stent, incremental steps are used. After each heat set, the stent is annealed to prevent formation of micro-cracks and prepare it for the next heat set. This thermal processing is also responsible for setting the A_F temperature of the stent.
4. Oxide removal: During heat set, heavy layers of TiO_2 are formed. A TiO_2 layer is beneficial for corrosion resistance but an electro-polished stent provides more corrosion resistance at a reduced thickness. Since stent profile is very important, the stent is usually sand-blasted or chemically etched to remove the layer of TiO_2.
5. Electro-polishing: As mentioned, electro polishing increases corrosion resistance. Some companies use a methanol-based electrolyte but electro-polishing removes material at the apexes at a greater rate than along the struts, as shown in Figure 2.27. That is one of the reasons why a ratio of 1 to 1.3 should be respected for strut width to apex width.
6. Passivation: Once again, the design team does not have much information regarding the passivation process but as discussed earlier, it improves corrosion resistance.

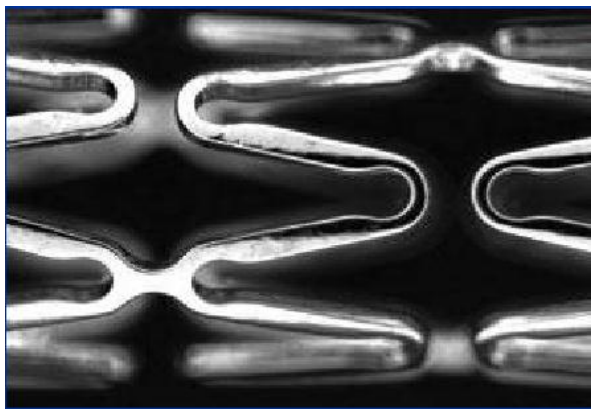

Figure 2.27: Extreme Deformation of a NiTi Stent

- Testing

Different test methods were discussed during the presentation but since Abiomed Inc. does not possess any of the test equipment and the design team did not account for additional testing in the budget, a discussion of the test setups was omitted in this section.

FEM of Nitinol Stents

The superelasticity, which results in an order of magnitude increase in recoverable strain, is one of the most attractive assets of Nitinol. Finite element modeling has been used for many years as a predictive tool for capturing the stress and strain response of metallic structures. Isotropic and Kinematic plasticity laws have allowed analyst to predict the response of steels well beyond their initial yield point. Material laws have also been able to capture the hysteretic behavior using material laws such as the rate-independent nonlinear kinematic hardening model (Chaboche J. L., 1989) (Chaboche J. , 1991) to simulate the ratcheting response under cyclic loading. These material laws however cannot capture the unique loading and unloading response of Nitinol. In order to simulate the unique cyclic structural response of Nitinol products, a new material model is required.

While there are numerous FEM programs on the market, ANSYS was selected as the most appropriate one for the purpose of this project. Abiomed Inc. has licensing rights to ANSYS only and any work undertaken for this project must be compatible with the software available at the sponsor. Moreover, the literature review has indicated that ANSYS has the most user friendly interface to create a material model that can accurately mimic the behavior of shape memory alloys.

Analytical material models currently used to evaluate the response of metallic parts in ANSYS are inadequate to characterize the unique hysteretic behavior of Shape Memory Alloys such as Nitinol. In traditional plasticity laws, the unloading behavior of the material follows the elastic modulus slope. With Nitinol the behavior follows a hysteresis where the unloading curve follows neither the non-linear loading nor elastic modulus unloading curves.

During the development of a new material model, a one element problem is usually sufficient to test the initial implementation of the constitute model. The Nitinol material model undergoes large strain behavior that can be tested by performing a displacement controlled solution simulating a uniaxial stress and strain state. By comparing the input with the computed stress and strain state, checking of the correct implementation of the material model is obtained.

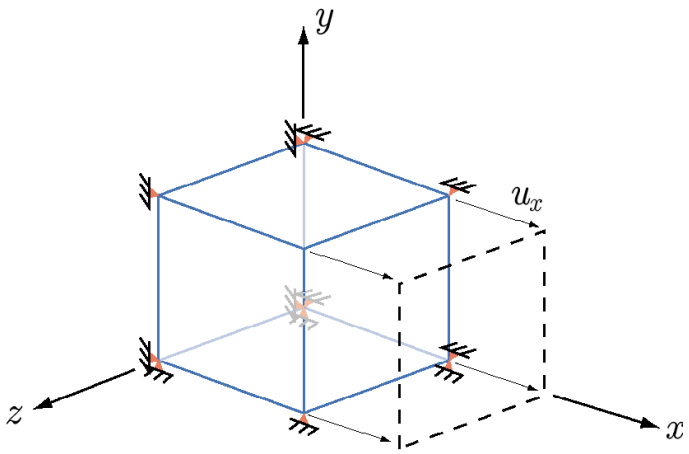

Figure 2.28: Single Element Test Model (Peter & Daniel)

Figure 2.28 illustrates the one element model used in the testing of the Nitinol material model. Symmetry boundary conditions were used on all faces to create a uniaxial stress state. Checking of the stress state in all directions was used to indicate proper implementation. Figure 2.29 illustrates a history plot of the material model input vs. the calculated stress vs. strain response. Note that a number of runs are superimposed where different levels of hysteretic behavior are modeled. Strain levels of 2% - 7% are included in both loading and unloading curves. The hysteretic behavior is clearly seen in these curves. The data extracted from the time history postprocessor matches within acceptable error the material properties input into ANSYS. By using a single element model, testing of highly nonlinear analyses can be performed in seconds. Although this analysis does not guarantee an acceptable model has been achieved, it is the first step in the verification process.

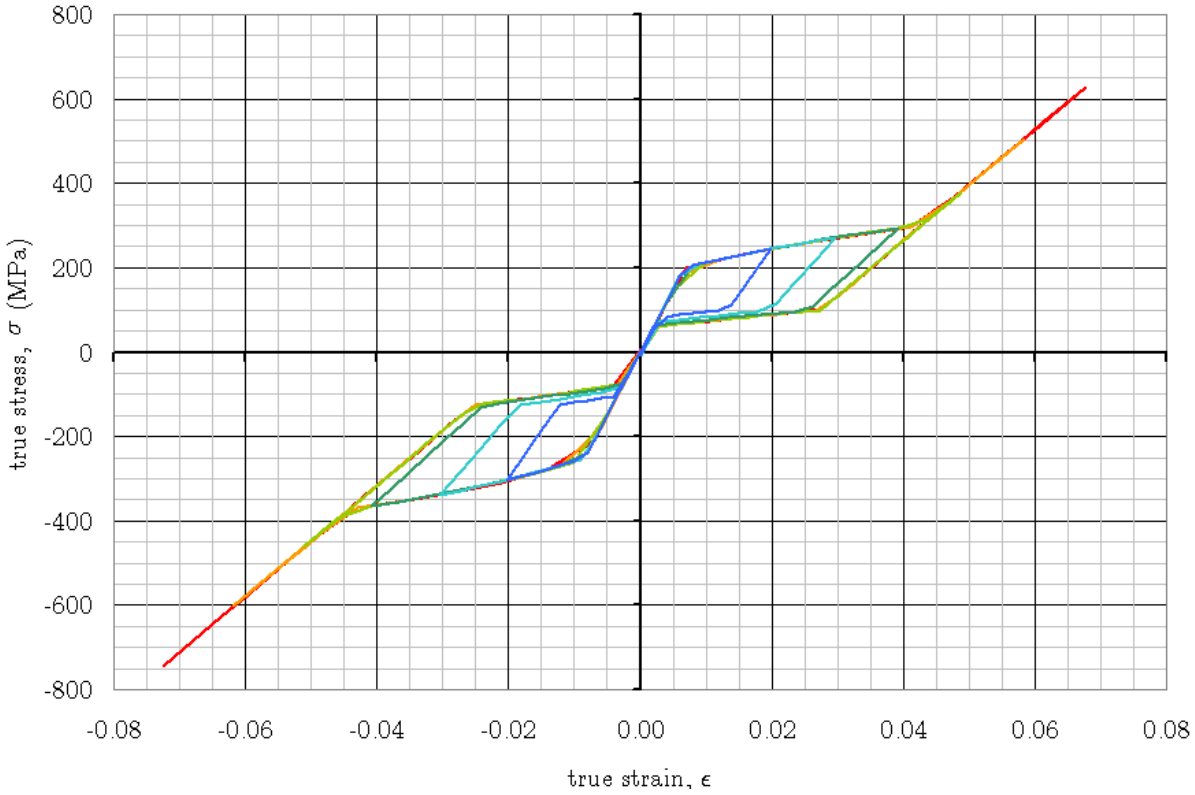

Figure 2.29: Single Element Uniaxial Stress-Strain Response (Peter & Daniel)

The following analysis procedure is used to characterize the response of Nitinol Stents. The loading procedure consists of the typical steps performed in the design of Nitinol stents:

1. The Laser-cut polished stress free geometry is the starting point of the analyses. Often this is provided to the engineer in the form of a 2D drawing, where a geometry transformation is necessary to generate a 3D model of the smallest repeatable segment. Figure 2.30 illustrates the results of extruding the given 2D geometry into a flat 3D meshed repeatable segment of the device followed by a coordinate transformation from Cartesian to Cylindrical to create the 3D model.

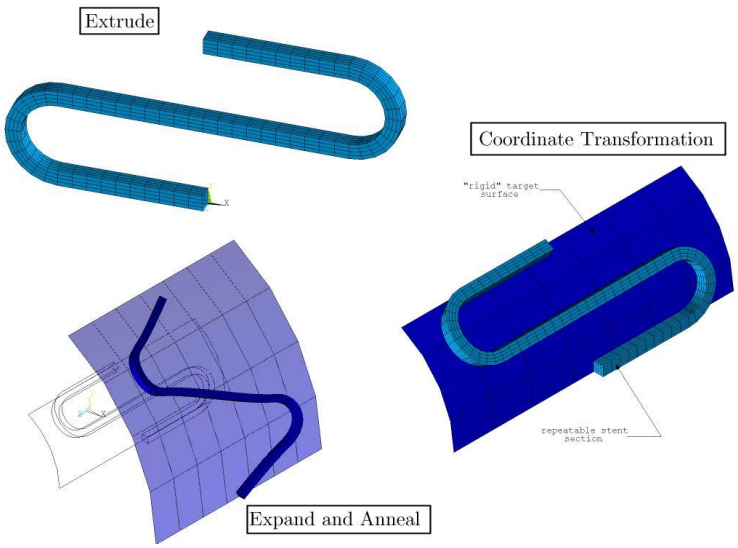

Figure 2.30: Stent Analysis Steps Conclusion
(Peter & Daniel)

2. The stent is next compressed onto the delivery device, which is typically at a similar diameter to the original tubing. A “rigid” cylinder contact surface is used for this stage of the analysis process. (Figure 5)

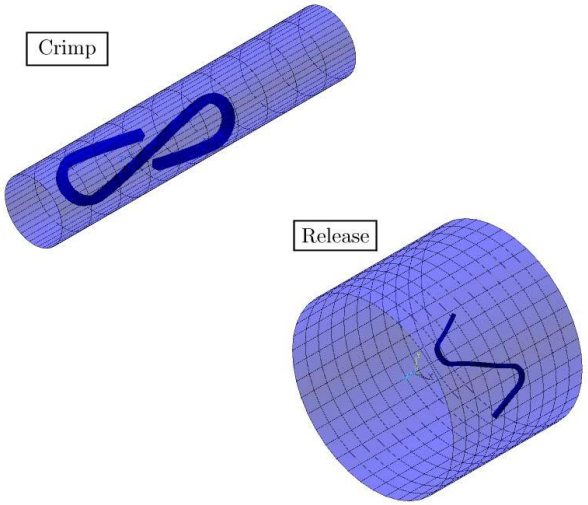

Figure 2.31: Stent Analysis Steps
(Peter & Daniel)

3. Releasing the stent from the delivery device simulates deployment. In the finite element model enlarging the “rigid” cylinder to the vessel diameter can simulate this deployment.

Abiomed Inc. Polyurethane Valve

Abiomed Inc. has developed a polyurethane valve platform technology, which has performed well in the BVS 5000, a ventricular assist device developed and commercialized by Abiomed Inc. (Jett, 1996). To ensure unidirectional flow, the Abiomed BVS 5000 makes use of two 25mm trileaflet (Figure 2.32) polyurethane valves fabricated from Angioflex™ (Renè, Daniel, & Gregory, 2001). After the success of this valve, Abiomed Inc. developed a surgical version of this valve which is currently used for surgical valve replacement procedures. The surgical valve is based on the same trileaflet pattern attached to the commissures. The surgical version however, features a velour sewing cuff as shown in Figure 2.33.

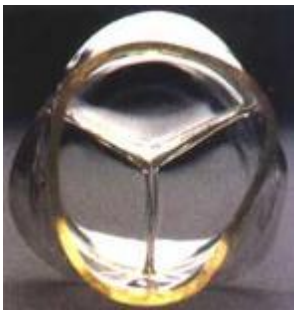

Figure 2.32: Trileaflet valve used in BVS 5000

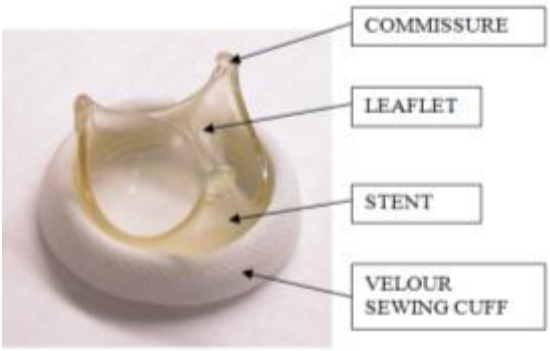

Figure 2.33: Abiomed Surgical Valve

As mentioned in earlier sections, the medical device industry, including Abiomed Inc., soon realized the need for percutaneous valves. Since it had experienced success with its polyurethane valve, Abiomed decided to attempt to create a percutaneous version of the valve and attach it to a stent. For the very first iteration, a piece of plastic tubing was cut into the shape of a stent and the percutaneous version of the polyurethane valve was attached as proof of concept. The resulting valve and stent assembly is shown in Figure 2.34.

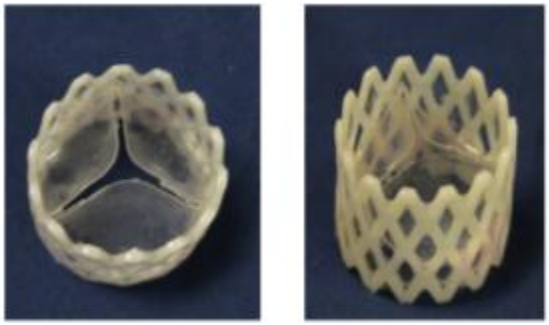

Figure 2.34: Abiomed 1st Valve and Stent Assembly

Benefits

The Abiomed Polyurethane valve is believed to be superior to tissue valves and mechanical valves for the reasons listed below. These reasons were not investigated by the design team as it was outside the scope of the project to identify superiority of the polyurethane valve. The reader needs to understand that the reasons listed below were accepted by the design team based on good engineering judgment as opposed to facts backed by testing.

As opposed to a polymeric valve,

1. A tissue valve is more likely to be affected by calcification.
2. Tissue valves can only be sutured onto the stent. Several attachment techniques are plausible with a polyurethane valve.
3. The thickness of a tissue valve leaflet cannot be varied during manufacture.
4. A mechanical valve requires the patient to be on blood thinners.
5. Tissue valves are not reproducible; each one is unique and will have slightly different properties.

Manufacture

Abiomed's standard dip casting process is used with stainless steel mandrels to build the valve leaflets and mounting geometry. The mandrels are dipped into a proprietary, highly purified polyurethane (Angioflex^{TM}) solution, followed by evaporation curing. During evaporation curing, the mandrels are rotated at a constant speed to achieve a uniform valve leaflet thickness. Figure 2.35 and 2.36 show mandrel in the dipping position and the mandrel fully submerged respectively.

Figure 2.35: Mandrel in Dipping Position

Figure 2.36: Fully Submerged Mandrel

Attachment

Unlike tissue valves, there are numerous ways that a polyurethane valve can be attached to a Nitinol stent. The four methods that the design team is considering are:

1. Dip casting
2. Solvent Bonding
3. Suturing
4. Thermoforming

These attachment techniques will be explained in more detail under the Methodology section. The design team will attempt to perform all these attachment techniques except for suturing. Abiomed Inc. has clean room operators who currently perform suturing operations for other products and possess significantly more experience. Dip casting, solvent bonding and thermoforming are very convenient techniques as the attachment can be dissolved in solvent. In other words, should the attachment of the valve leaflet to the stent not be as desired, the stent can be placed in solvent which will dissolve all the polymeric materials present, leaving a brand new stent behind. Since manufacturing new valves can be done overnight, this feature will certainly prove to be very convenient.

Methodology

Evaluation of Generic Stents

Prior to the approval of this project, the project lead, S. Corbett met with representatives of Admedes GmbH and they drafted three generic stent iterations that Abiomed Inc. could use in its future endeavor of designing a percutaneous valve. For the first and second iterations, the only information that was provided was the 23mm diameter of the valve that the stent had to hold. (Note: Appendix B of this report shows a schematic of a French catheter scale for easy conversion between metric and French scales.) The third iteration had to follow the contours of the valve leaflet for added support. S. Corbett quickly drafted the valve leaflet pattern on a piece of napkin at the lunch meet. Admedes GmbH created three versions of stents based on these two requirements and delivered them to Abiomed Inc. These stents are shown in Figure 3.1 - 3.3.

Figure 3.1: Generic Curved after dip casting leaflet

Figure 3.2: Generic Straight

Figure 3.3: Generic Crown after dip casting valve leaflet

A visual inspection of the stents revealed that the Generic Straight had 18 apexes, the Generic Curve had 12 and the Generic Crown had a total of 36 apexes. Squeezing the stents with the thumb and first finger confirmed the theory that the number of apexes is directly related to the radial stiffness of the stent.

The strut thickness of each stent was measured with a calibrated micrometer. The micrometer used was a Mitutoyo Spherical Face Micrometer Series 395-251. Figure 3.4 shows a picture of the micrometer used. 10 readings were taken at different places on each stent and the average values for each was calculated. Appendix C displays the 10 individual readings used to obtain the average values:

Generic Straight: 0.63mm

Generic Curved: 0.47mm

Generic Crown: 0.56mm

Figure 3.4: Spherical Face Micrometer (Mitutoyo)

The Spherical Face Micrometer was used as it is specifically designed to measure tube thickness. It decreases contact area significantly and unlike regular flat faced micrometers, the Spherical Face causes less deflection when applying pressure on the struts. Precision instruments such as the Mitutoyo Micrometer get calibrated on a regular basis at Abiomed Inc. and the device had been calibrated within the past 6 months.

To take thickness measurements, the desired area was clamped with the micrometer prongs very gently. Instead of using the ratchet, the micrometer would be lifted up until the stent would not be in contact with the work space anymore. The prongs were adjusted so that they would only barely hold the stent when lifted off the table by the micrometer. This method assured that no excessive pressure was exerted on the strut and that accurate readings were being monitored.

A set of calipers were used to obtain the diameter of the stents. The same approach was used to avoid stent deformation and ensure accurate data capture. All three were found to have diameters very close to 23mm. Appendix C of this report shows the exact diameter measurements for each stent.

The next step was to try and crimp down the stent to its minimum diameter size. The previous monitoring tests were performed before crimping down the stent in case the stents experienced permanent deformation or strut fracture was observed. To identify the minimum crimp down size of the stents, they were forced into an off the shelf funnel with a minimum 18 French diameter size bore. A 150mm long, 30mm diameter delrin rod with a circular groove was used to push the stents into the plastic funnel. Delrin was chosen as it is easy to machine and it is a readily available scrap part at Abiomed Inc. The design team ensured that the diameter of the rod was slightly bigger than the size of the stents. The circular groove had a 23mm diameter, and a 2mm depth. It was machined using a 1/8" (3.175mm) drill bit. The edges were then deburred to obtain a fillet of roughly 0.1mm. A 3D model of the Delrin Push Rod with the aforementioned features is shown in Figure 3.5.

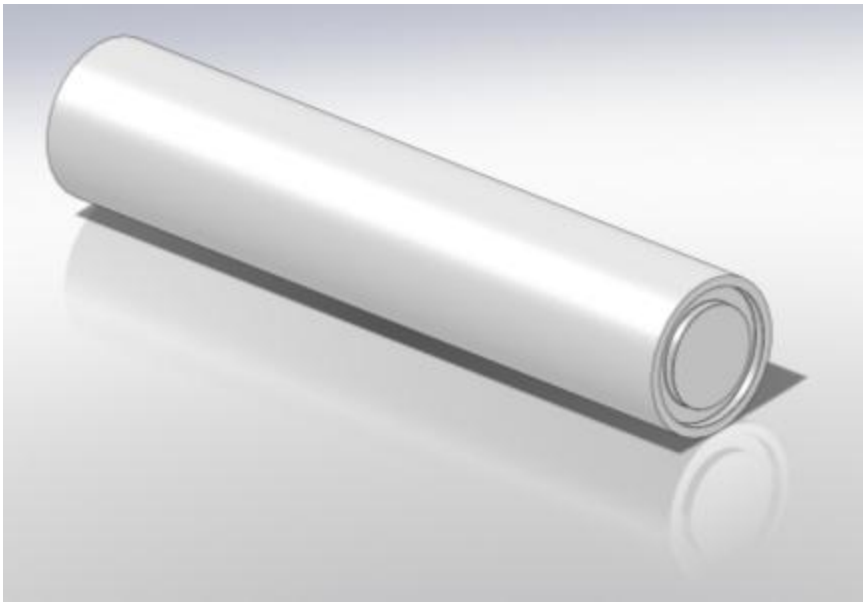

Figure 3.5: 3D model of Delrin Push Rod

Using the Delrin Push Rod, the Generic Curved stent would buckle and the Generic Crown and Generic Straight stents would simply refuse to go into the funnel. A second approach was to pull the stents into the funnel instead of pushing them into the decreasing radius. To that end, threads were tied to three equidistant apexes of each stent and they were pulled into the funnel. Once more the

Generic Crown and Generic Straight stent did not go into the funnel significantly but the Generic Curved stent was successfully crimped down to the minimum diameter of the funnel, that is, 18 French.

After it was demonstrated that the Generic Curved stent could be crimped into the funnel, it was inserted through a tube with an 8mm (24 French) inner diameter using the threads and funnel approach. As shown by Figure 3.6, when the Generic Curved Stent was placed into the tube, the polyurethane valve had been thermoformed onto the stent. The polyurethane valve was added to investigate the struts' behavior under compression while being attached to the valve. The side-view of the collapsed stent (Figure 3.7) shows a very uneven strut deformation. From this picture, it can be concluded that the pressure distribution when the stent is crimped down is non-even and particular struts are experiencing more stress and are more likely to fail.

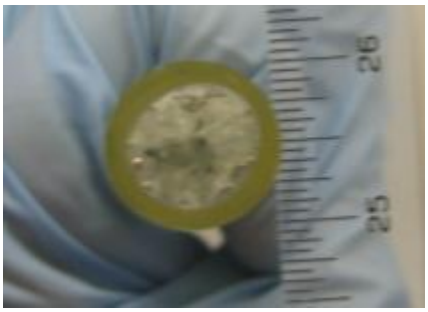

Figure 3.6: Generic Stent in a 10mm OD tube

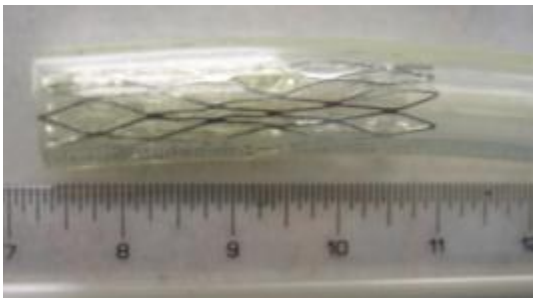

Figure 3.7: Uneven Strut Deformation

To investigate whether the uneven strut deformation was due to the unorthodox crimp down mechanism currently being utilized or the valve attachment, a stent crimper was purchased. Using a certified stent crimper would remove this unknown factor and help the design team converge on a root cause. From talking to more experienced employees at Abiomed Inc., Machine Solutions (Valve crimping device) was recommended as a transcathether heart valve crimping equipment provider. Their three devices that would be suitable were the HV200, HV 500 and HV 950, shown by Figure 3.8 and Figure 3.9. The catalogue pages and the detailed specifications of each crimper can be found under Appendix D of this report.

Figure 3.8: Machine Solutions HV 200 (Crimper Catalogue)

Figure 3.9: Machine Solutions HV 200/950 (Crimper Catalogue)

The HV 200 was the cheapest of all three but it only accepted stents with a diameter of up to 34mm, which was relatively close to the size of our stents. The HV 950 was too expensive and it would not have been utilized to its full potential. The HV 500 was found to be most appropriate for the purposes of this project because of the following:

1. 1mm to 50mm diameter range
2. 90mm maximum specimen length
3. Reasonable Cost

However, there was a two weeks to one month lead time on the crimper from Machine Solutions. In the meantime, the polyurethane valve was removed from the Generic Curve Stent and using the threads, it was pulled into the funnel. The goal of this experiment was to assess any damage caused to the struts after observing the uneven pattern under the crimped down configuration. Strut fracture resulted from pulling the Generic Curved stent into the 18 French funnel. Figure 3. and Figure 3. show the Generic Curved Stent after strut fracture. The fractured struts have been pulled out for effect.

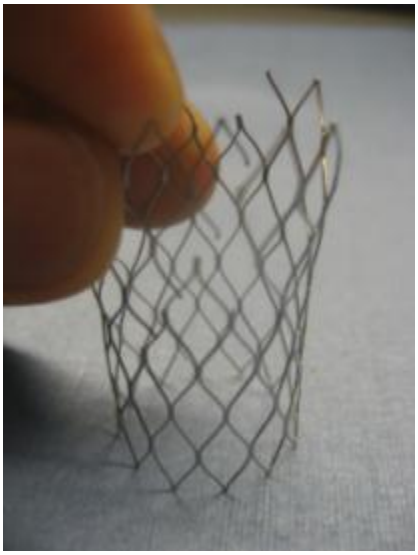

Figure 3.10: Broken struts from Generic Curved Stent - vertical

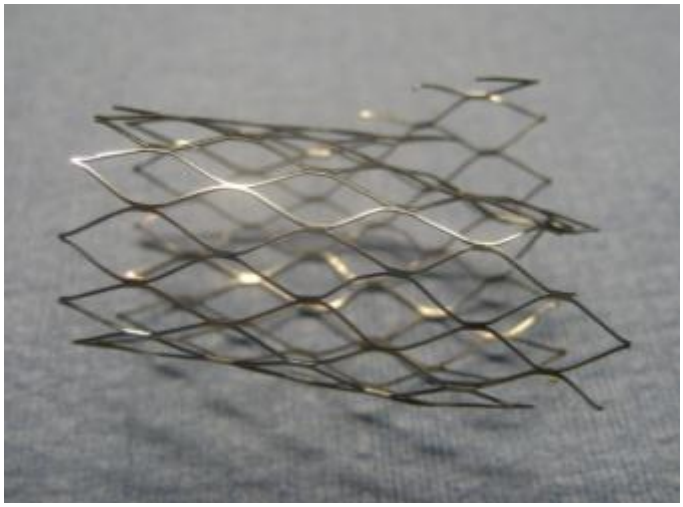

Figure 3.11: Broken struts from Generic Curved Stent – horizontal

When the crimper was received roughly three weeks later, the Generic Straight and Generic Crown stents were successfully crimped down to 24 French sizes without a polyurethane valve. After the valve leaflets had been attached using the dip casting technique, the stents were successfully crimped down to 26 French sizes. A more uniform stent pattern was observed under the crimped down

configuration which confirmed our theory that it was the unorthodox crimping method that created the irregular pattern, and eventually caused failure, for the Generic Curved stent.

According to the information obtained during background research, the starting raw tube size should be slightly smaller than the targeted crimp down size. Since the Generic Straight and Crown stents were effectively crimped down to 24 French, it was assumed that they were made from 20 – 22 French raw tubes. Crimping the stents with and without the valve leaflets allowed the team insight into the amount by which the valve leaflets increase the stent profile, that is, 2 French.

From earlier observations and the strut failure, a stent with the following specifications would be most appropriate to reach the 18French crimp down size target.

- 12 – 14 French raw tubing start size
- 0.5mm strut thickness
- 15 apexes

The strut thickness and number of apexes were chosen to be values between that of the Generic Straight and Generic Curved stents. The Generic Curved stent was the only stent that was successfully crimped down to an 18 French size but seemed to lack radial stiffness. For the stent and valve assembly to be successfully crimped down to an 18 French diameter size, the size of the starting tube has to be 12 – 14Fr. Since the Generic Curved Stent experienced fracture, the next stent generation will be made thicker for extra resistance to compressive stresses. Last observation was the seemingly lack of radial stiffness of the Generic Curved but over stiffness of the Generic Straight stent, 15 apexes will feature on the new stent iterations.

On top of these design criteria, the team needed more experience with valve attachment techniques to model a new generation of stents that would not only be crimpable to 18 French diameter size, but also enable secure attachment to the polyurethane valve.

Valve Attachment

Abiomed Inc. is experienced with the making and attachment of polyurethane valves due to their other products being currently commercialized. While there may be other, potentially more appropriate attachment techniques, due to the sponsor's familiarity with the proposed techniques, monetary and time constraints, the design team sought to get familiar with the four attachment techniques suggested and to identify the two most promising ones. Once these have been established, stents can be designed with features to enhance the efficiency of these attachment methods.

Dip Casting

Dip casting essentially consists of placing the stent over the preformed valve leaflet and dipping the assembly into the Angioflex^{TM} solution. The procedures for dip casting include the following:

1. After the valve leaflet is manufactured and cured, the top of the valve leaflet is trimmed with a sharp blade, as shown by Figure 3..

Figure 3.12: Trimming cured Angioflex™ off the top flat surface on the mandrel

2. Once the top is removed and a skirt length (typically around 10-15mm) is chosen, the polyurethane is cut at that position as seen in Figure 3.13.

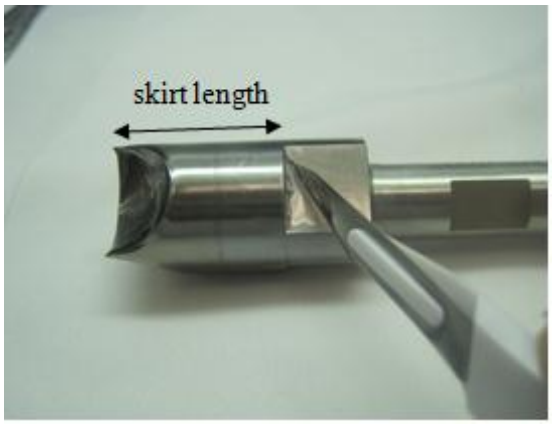

Figure 3.183: Trimming skirt from mandrel sides

3. The stent is then placed over the mandrel and the whole assembly is dipped into the Angioflex™ solution using the same setup as described in the Polyurethane Valve Manufacture section. The stent will be kept in place by frictional forces between the stent and layer of polyurethane on the steel mandrel.
4. The dipping process can be repeated as many times as deemed necessary. Repeating the dipping process makes the outer layer of polyurethane stronger but also adds to the profile of the stent. Two dips were arbitrarily chosen as the most appropriate in terms of bond strength and material thickness. In between each dip, a curing period of 20 minutes must be allowed.
5. Once the outer layer has been cured, the mandrel is placed in a water bath at 37°C for an hour. The water bath separates the valve leaflet from the mandrel.
6. The mandrel is taken out of the bath and dried with a paper towel before using a spatula to separate it completely from the mandrel. Refer to Figure 3.3 from page 34.

After the valve leaflet has been attached, it can be dissolved from the stent using a solvent, which cannot be disclosed for proprietary reasons. The valve assembly is dipped in the solvent for five minutes before being washed under warm water. After several trials with the Generic Crown and Generic Straight Stent, this attachment method was deemed unsuitable for this application. While the bonds formed are very sturdy, the Angioflex^{TM} gets webbed in between the struts thereby preventing crimping.

Solvent Bonding

Abiomed Inc. uses solvents such as TetraHydroFuran (THF) to bond plastic parts together. When applied on the parts that need to be bonded together, THF melts the surfaces and as they get pressed together, they solidify as one part. This same principle was explored to attach the valve leaflet to the stent.

The beginning of the process is the same as the first three steps of dip casting. However, the outer sleeve is formed differently. The process is outlined below:

1. A circular mandrel made out of delrin is dipped into the polyurethane solution on a similar setup as the steel mandrel.
2. Once the sleeve is formed and cured on the mandrel, the assembly is placed in an oven at 100^{o}C for an hour to get rid of surface deformities.
3. The mandrel is then placed in a water bath at 37^{o}C for an hour.
4. The mandrel is taken out of the water bath, dried with a paper towel and the top is trimmed as shown by Figure 3.19.

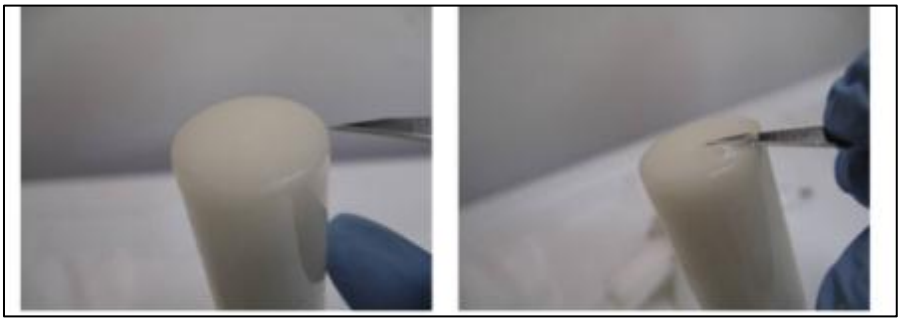

Figure 3.194: Trimming and removing top layer of sleeve from mandrel

5. A polyurethane stent is then placed on the sleeve and adjusted until it is resting about halfway down the length of the sleeve (Figure 3.).

Figure 3.15: Polyurethane stent placed on exterior sleeve mandrel

6. A fine tip marker is used to trace the upper contour of the polyurethane stent. Figure 3. shows a picture of the sleeve mandrel with the upper contour trace marks.

Figure 3.16: Crown shape traced on exterior sleeve

7. The mandrel is screwed off from the base and doing so shears off the lower end of the sleeve in a surprisingly neat manner.
8. A spatula is then used to separate the sleeve from the mandrel. Pouring rubbing alcohol while using the spatula makes the Angioflex™ more flexible and facilitates separation (see Figure 3.).

Figure 3.17: Separating sleeve from mandrel using spatula and alcohol

9. The sleeve is then rolled out of the mandrel and laid flat so that the appropriate skirt length can be cut using a pair of scissors.
10. The contours marked with the fine tip are cut out using the scissors.
11. The sleeve is cut into a flat sheet at the lowest inflection point of any of the three curves.

The remaining steps were to solvent bond a polyurethane valve into a Nitinol stent. This had not been attempted before.

12. Next would be to use a solvent approved paintbrush and apply a solvent (the specific solvent cannot be disclosed due to proprietary rights by Abiomed Inc.) onto the valve leaflet and the flat sleeve sheet.
13. Place the flat sleeve sheet at the right spot around the Nitinol stent so that the wet surfaces would be in contact. Special precaution should be taken to correctly align the cut edges.
14. As a first step, Teflon tape would then be used to apply pressure onto the two layers of Angioflex^{TM} as they solidify back together.

The solvent has a working time of roughly 1 – 2 hours as opposed to THF which has a working time of less than 10 seconds. (Note: The working time of a solvent is the time elapsed between when the surface starts to melt and when the surface solidifies again.) Maintaining pressure during curing is essential to the success of solvent bonding. Specially designed fixtures are available on other production lines to ensure that a uniform and constant pressure is being applied during the working time of the solvent. The design team viewed this need as a potential means to remove bubbles of air that tend to get trapped when two surfaces are mated together.

The first idea was to place the assembly in a vacuum chamber so that the air would be sucked out of the inner layer of Angioflex^{TM} (the valve leaflet) and the outer layer (the sleeve). The reasoning was based on a Ziploc bag which has its two sides pulled together over the food item as air is drawn

away from it. However, drawing a vacuum requires that there is only one opening and that is not the case for the current assembly.

Instead of drawing a vacuum, a pressure was thought to be the solution. By applying a pressure, the air bubbles would be driven out of the two layers of polyurethane which would also be pressed together. This assumption was based on the increased pressure exerted as an object sinks to bottom of the ocean. A submarine for instance, would get crushed and see all the air bubbles move to an area of lower pressure should it not have been built with specially designed materials. The team then proceeded to find a pressure chamber and connecting it to an air supply and a barometer. Specific values for time and pressure were not yet determined as this was the first attempt.

However, as soon as the sleeve got in contact with the solvent, it lost significant stiffness and placing it over the Nitinol stent proved rather difficult. When the Teflon tape was placed over the two layers for initial support, the sleeve started to melt into the tape. The team decided that the amount of solvent used was the root cause and the experiment was repeated using less solvent but the same results were observed. Because of the poor results obtained, the team decided that solvent bonding was not a viable attachment method for the valve assembly being developed.

Suturing

Suturing is a common attachment technique used to attach tissue valves to a Nitinol frame. Abiomed Inc. employs clean room operators who have experience suturing Angioflex^{TM} and consulting them provided several important design considerations.

The thread and needle that they use to suture have a diameter of 0.4mm. Therefore, if the team decides to pursue suturing as an attachment method, the stent will require features with openings no smaller than 0.5mm that will allow the thread and needle to go through.

Another relevant point that was brought up during the meeting was the fact that the Abiomed Inc. percutaneous valve is too soft for suturing. Another material should be added during the valve manufacture to increase its stiffness and most importantly, prevent backflow leakage (Backflow leakage is discussed under the Testing section of this report). Currently on the market is the Cribier-Edwards Percutaneous valve (see Figure 3.) which makes use of a fabric cuff (Webb, 2006) as well.

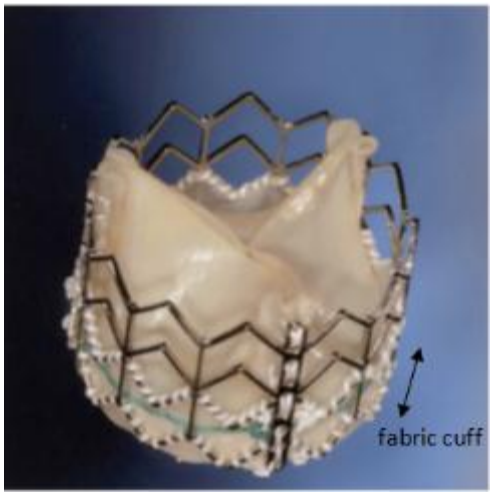

Figure 3.18: Cribier-Edwards Percutaneous Valve (Webb, 2006)

Suturing is a rather time consuming process and the design team had to ask the floor manager for his employee's time. As a result, suturing was tried on only the Generic Crown stent. To prevent backflow leakage, a piece of fabric was placed in between the valve leaflet and the Nitinol stent before suturing. Also, to prevent thread migration on the curved part of the stent, velour sewing cuff similar to the one used on the Abiomed Inc. Surgical Valve (refer to Figure 2.32 on page 29) was placed along the curved strut. Figure 3. shows a picture of the resulting assembly.

Figure 3.19: Generic Crown Stent with Sutured Valve

Two main conclusions can be drawn from the prototype. The sewing cuff adds too much to the profile of the stent and shown be avoided if possible. If the design team is to model a stent that has a crown-like member, it should have features that will prevent the threads from migrating along it. The second inference is that the fabric adds too much to the profile of the stent. A thinner material that will perform the same functions should be identified.

Suturing remains one of the top attachment techniques. While some problems are identified with the current prototype, these can be fixed for the next iteration. If done correctly, the presence of

threads and knots does not add much to the profile and it provides for a secure means of attaching the leaflet to the Nitinol Stent.

Thermoforming

The thermoforming attachment technique follows the same steps as solvent bonding up until the contours of the sleeve are cut out. Instead of cutting the sleeve into a flat sheet, the following steps are carried out:

1. The contour marks are washed off with rubbing alcohol.
2. The sleeve is carefully placed over the stent so that the commissure posts of the valve leaflet and those of the sleeve match (see Figure 3.).

Figure 3.20: External sleeve on stent and aligned with mandrel commissure tips

3. A piece of PTFE heat shrink tube is cut and placed over the stent as shown by Figure 3..

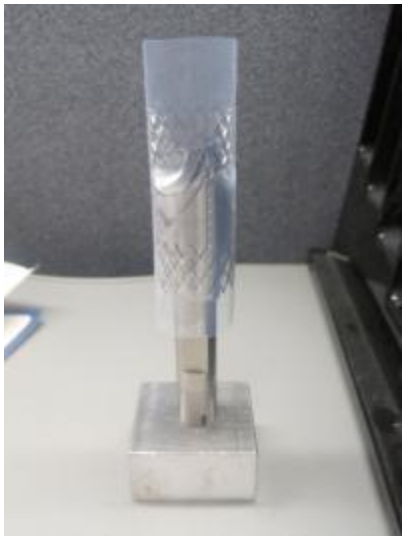

Figure 3.21: PTFE heat shrink tubing

Heat shrink tube shrinks at a certain temperature and as it does, it applies pressure on any object that is resisting the decrease in size. Heat shrink tubing is typically used to provide a protective layer against heat, corrosion, shock, moisture and other critical environmental conditions (Zeus, 2011). The PTFE tubing used has a shrink ratio of 4:1 with an ordered inner diameter of 25.4mm. Zeus specifies a 340^{o}C recovery temperature and reports an inner diameter of 7.06mm after complete recovery. The size was chosen as it was the closest one bigger than the diameter of the stents under assessment (approximately 25mm diameter). The shrink ratio was preferred over the 2:1 as it would apply more pressure as it tried to recover under the application of heat.

4. The mandrel and valve assembly are placed on a rotator.
5. A Steinel heat gun is used to apply heat onto the valve assembly to bond the valve leaflet and outer sleeve, see Figure 3..

Figure 3.22: Steinhel heat gun

Applying heat melts and bonds the valve leaflet and outer sleeve together while causing the heat shrink tubing to contract and exert pressure on the sleeve. The first trials were completed by placing the assembly in an oven at 340^{o}C (the heat shrink tubing recovery temperature) but the uniform distribution of heat was undesired for this application. The polyurethane valve leaflets get deformed under the application of heat. This deformation will presumably affect their closing/opening abilities which will in turn impede their hemodynamic performance. Moreover, the optimum time to leave the stent in the oven was unknown. By leaving the stent in the oven for too long increases the risk of over melting the layers of Angioflex^{TM}. Over melting introduces the risk of affecting the uniform thickness of the valve leaflet and outer sleeve leaving creating weak attachment points. If the assembly is not left in the oven for long enough, the valve leaflet and outer sleeve do not have enough time to melt and bond together.

The heat gun used is a HG 2000E from Steinel and has a temperature range of 90^{o}C to 570^{o}C. Using the heat gun allowed the team members to vary the amount of heat, apply heat to the desired position for the required amount of time and visual feedback was available. When using the heat gun, the heat shrink tubing contracts almost instantly to form a snug fit with the valve assembly. When the sleeve melts onto the valve leaflet, the struts become more pronounced and the heat shrink forms an even tighter seal over the stent. The area under heat is typically melted together when this second contraction typically occurs. At this point, the heat was directed at a different point as the stent continued its rotation. The areas that needed most time under the heat gun were areas where attachment was crucial, in other words, along the commissure posts, the valve leaflet contours and at the bottom of the valve skirt.

As observed after the valve assembly was removed from the oven, the valve leaflets would be deformed. To avoid deformation, compressed air is continually blown at the valve leaflets as heat is applied at the various locations. Figure 3. shows the thermoforming arrangement.

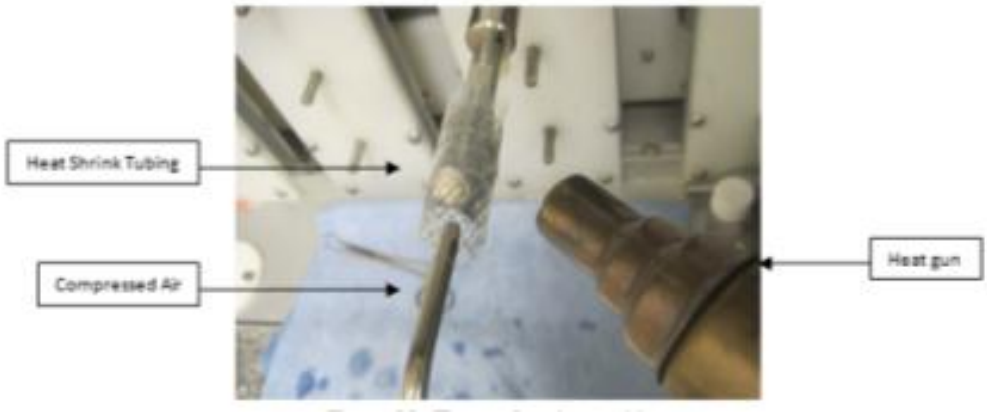

Figure 3.23: Thermoforming arrangement

After the outer sleeve and valve leaflets have been bonded, the mandrel and valve are allowed to cool for one hour. After that the heat shrink tubing is cut and removed. The rest of the post thermoform procedure is the same as the post dip casting processes.

Upon inspection, the commissure tips were found to be somewhat weak. A 1cc syringe with an applicator tip was used to apply two drops of Angioflex™ at each commissure posts. After curing, these points were found to be much stronger.

The overall strength of the Nitinol to polyurethane was also found to be somewhat poor. To increase the efficiency of the bond, a primer was used. The most suitable primer was found to be Cilbond 49SF (refer to Appendix E for the technical data sheet). "Cilbond® 49SF is the industry standard bonding system for hot-cast high performance PU elastomer systems and TPU's. Recommended by many PU system houses worldwide, Cilbond 49SF offers unbeatable performance in the toughest environments." (Vita, 2011).

To prime the stent, forceps were used to clamp its top. The stent was slowly lowered into a beaker containing the Cilbond 49SF solution for 20 seconds. The primed stent was placed in an oven at 100°C and allowed to cure overnight. The thermoforming process was repeated with the primed stents. The bond was noticeably stronger but the drops of Angioflex™ at the commissure tips were still needed.

Due to the low increase in stent profile, manufacturability of process and efficiency, thermoforming was retained as one of the two most viable attachment techniques. After careful review of the results, the design team concluded that thermoforming did not require the stent to have any special features on top of the ones already identified.

Stent Development

Along with experimenting with valve attachment techniques, the design team worked closely with Admedes GmbH to identify what information was needed for them to manufacture the Nitinol stent. They made it clear that if the team wanted feedback on the stent designs before they were manufactured, the 3D models would have to be generated in SolidWorks. To manufacture the stents,

Admedes GmbH requires an as-cut model of the stent. An as-cut model of the stent is a flat pattern of the stent when it is cut from the starting tube. For instance, if a 40mm long 12 French (4.0mm) starting tube is specified to the manufacturer, the stent pattern should be drawn onto a rectangular sheet with the following dimensions:

- The length of the rectangle should be equal to the length of tube specified to the manufacturer. In this case, the length of the rectangle is 40mm.

The design team acknowledges the fact that the length of the tube changes as the stent is thermally processed to achieve the desired final diameter. However, for the purpose of proving feasibility of concept it was safe to overlook this change.

- The width of the rectangle corresponds to the circumference of the tube. A tube with a 4.0mm diameter has a circumference of 12.568mm ($Circum = \pi * d = \pi * 4.0mm$). Therefore, the width of the rectangle has to be 12.568mm.

3D models will be generated using the final tube size which would then be used to create the as-cut models once the order was finalized. Careful attention will have to be paid when shrinking the horizontal dimensions when the as-cut model is created from the 3D part.

3D Modeling

Admedes GmbH sent over a SolidWorks part to illustrate their way of generating a 3D model of a Nitinol stent. However, Admedes GmbH uses SolidWorks 2010 and Abiomed Inc. only has licensing rights to the 2006 version of the software. The most effective approach was to open the file at Worcester Polytechnic Institute (WPI). Subsequently, all CAD related work was completed at WPI.

Admedes starts the process by creating a hollow tube with the specified expanded diameter and thickness, see Figure 3..

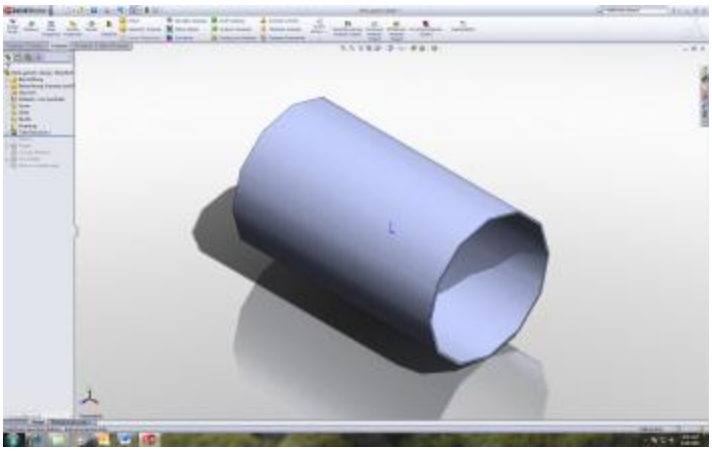

Figure 3.24: Admedes step 1 - Tube extrusion

Their second step is to create a plane parallel to the length of the tube and tangent to the surface. A Wrap feature is then created and the sketch is drawn on the plane. The sketch is started at

the point where the plane is tangent to the tube to obtain the most accurate results. The Wrap feature allows the user to sketch a pattern onto a plane before it is embossed to or debossed from a curve surface. Figure 3. shows a normal view of the sketch and plane used in the Wrap feature and Figure 3.26 shows an isometric view of the resulting after applying the Wrap feature.

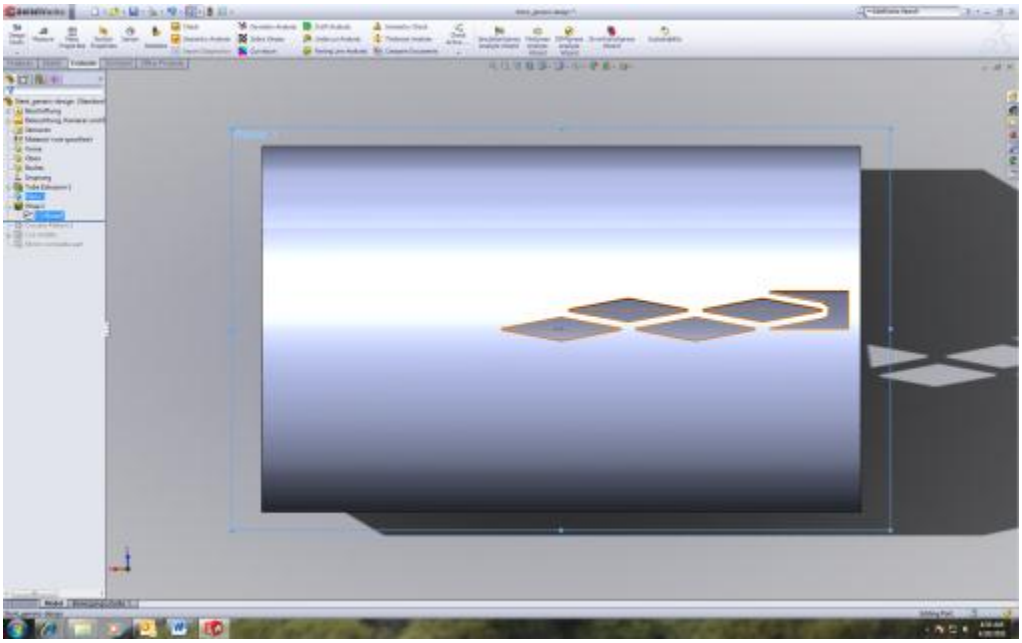

Figure 3.25: Normal view of sketch and plane

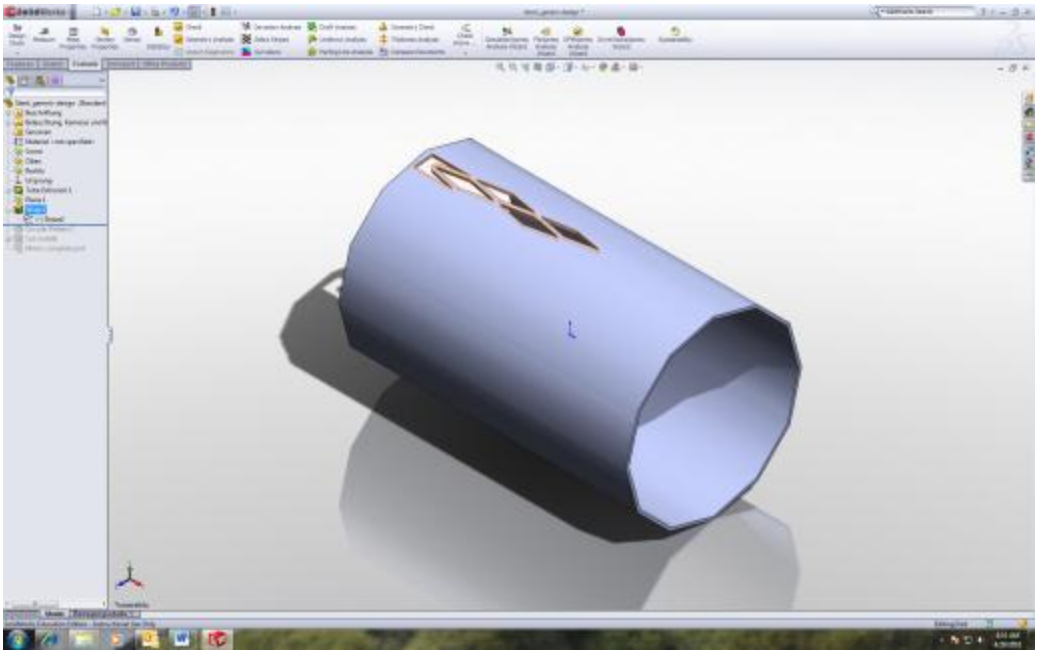

Figure 3.26: Admedes step 2 - Isometric view of Wrap feature

A circular pattern is then used to generate the pattern shown in Figure 3. followed by a cut-middle feature, Figure 3..

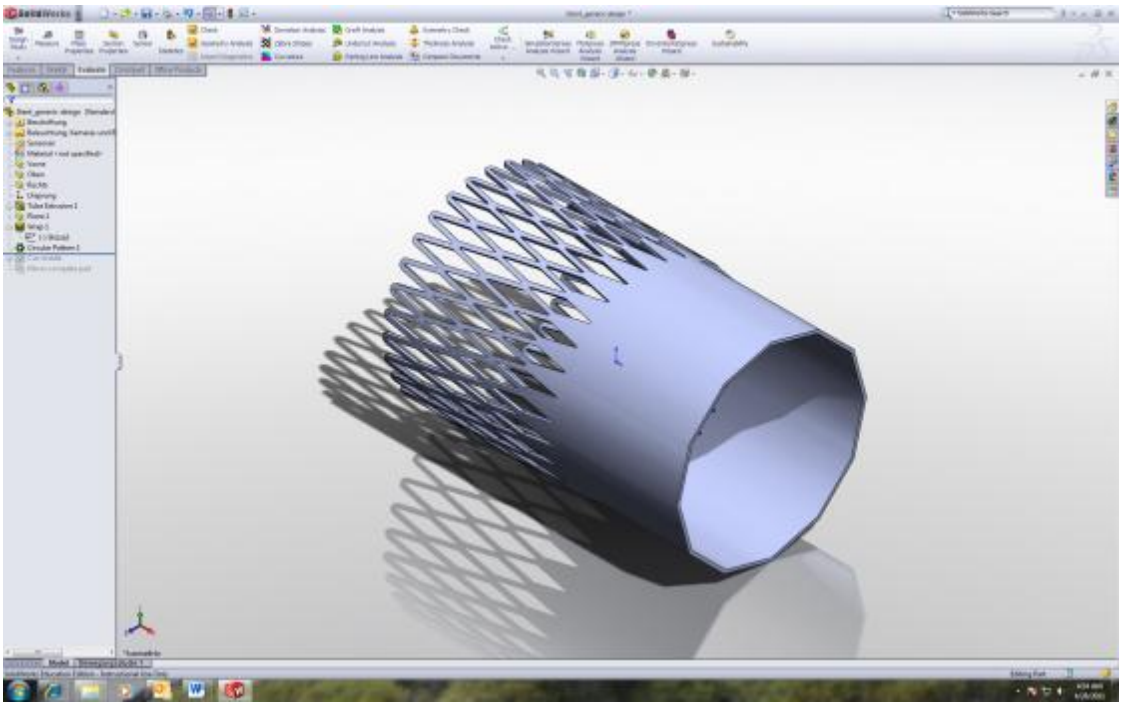

Figure 3.27: Admedes step 3 - Circular pattern of wrap feature

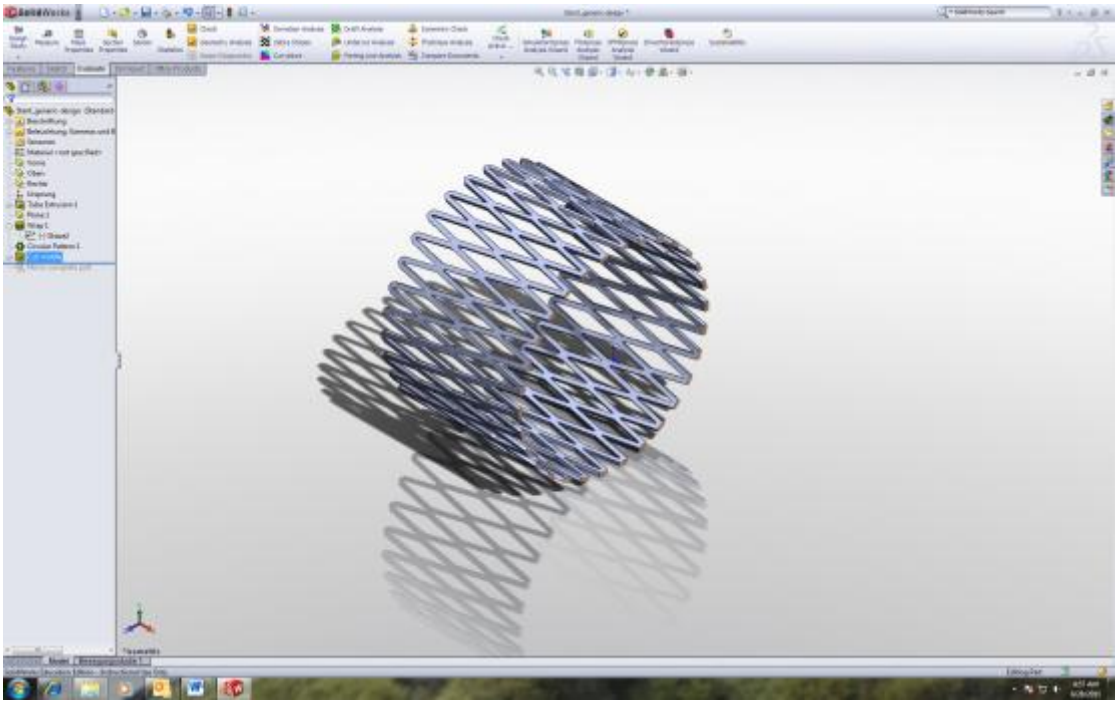

Figure 3.28: Admedes step 4 - cut-middle feature

Lastly, the half stent is mirrored to create the full generic stent as shown by Figure 3..

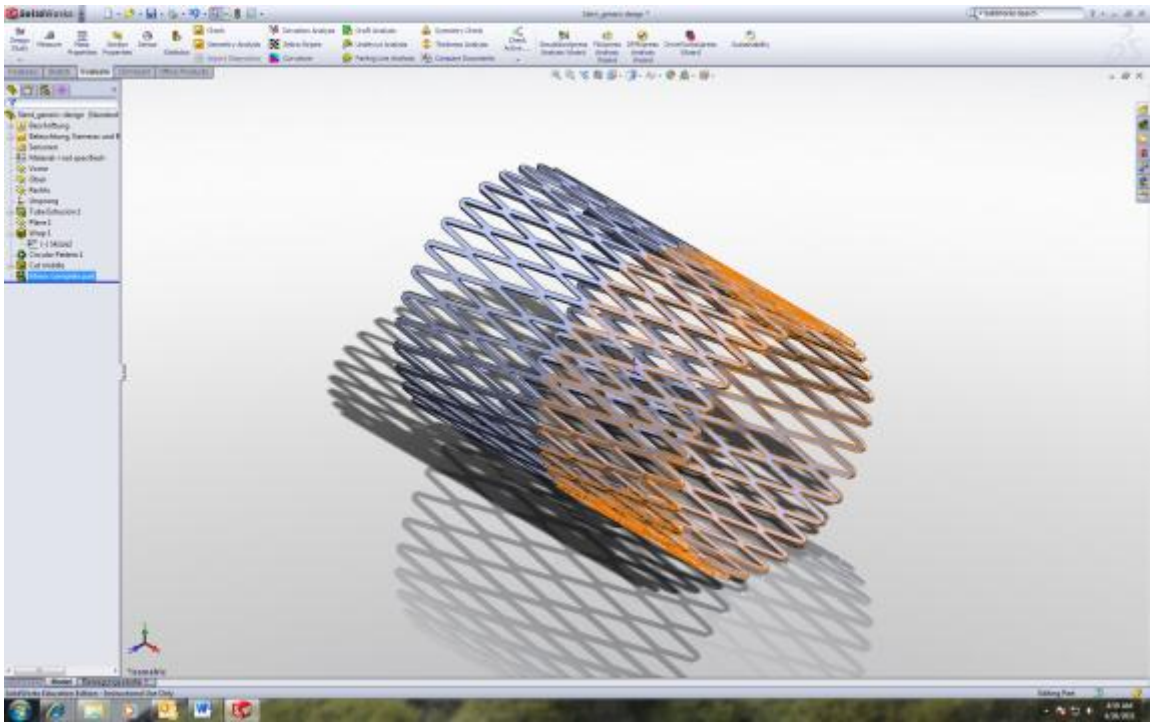

Figure 3.29: Admedes step 5 - mirror half stent

The design team successfully created several iterations with the wrap feature, Figure 3. – Figure 3.

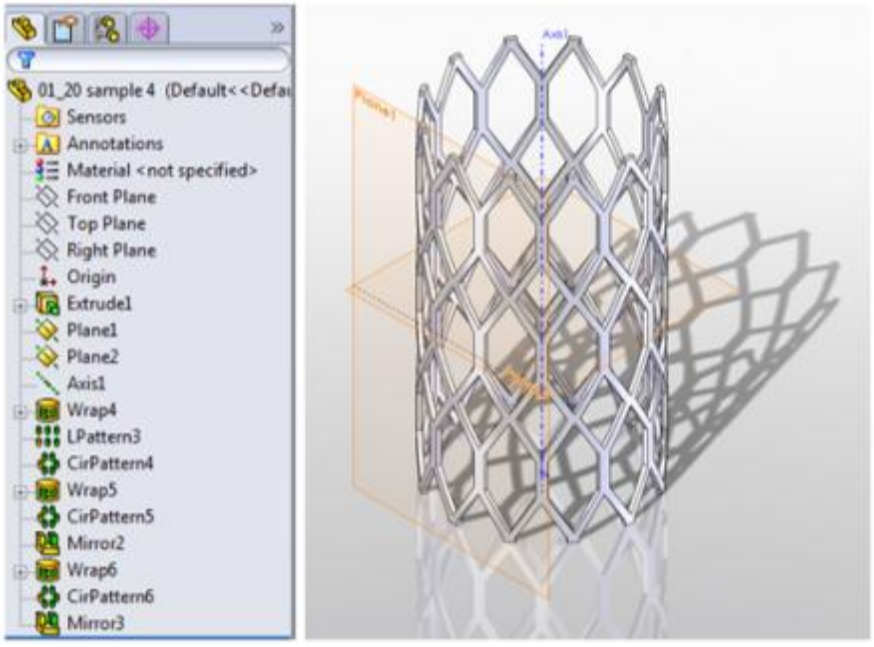

Figure 3.30: Wrap iteration 1

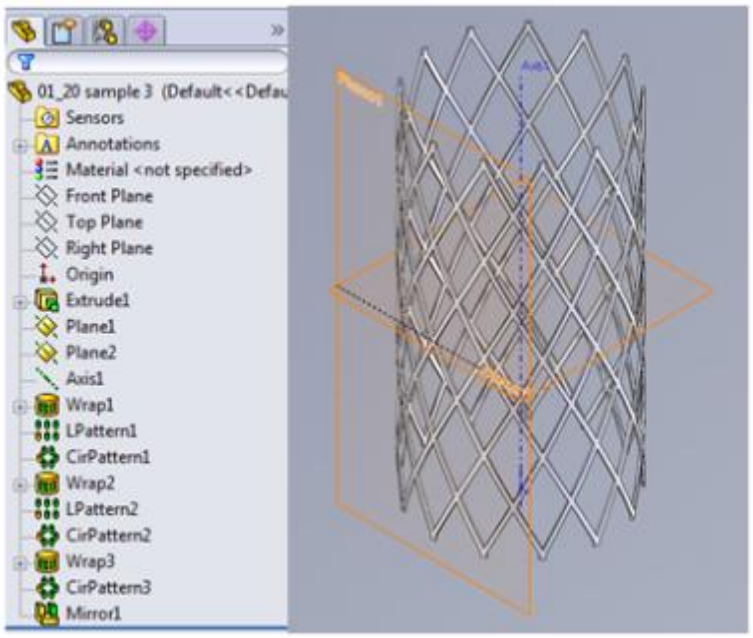

Figure 3.31: Wrap iteration 2

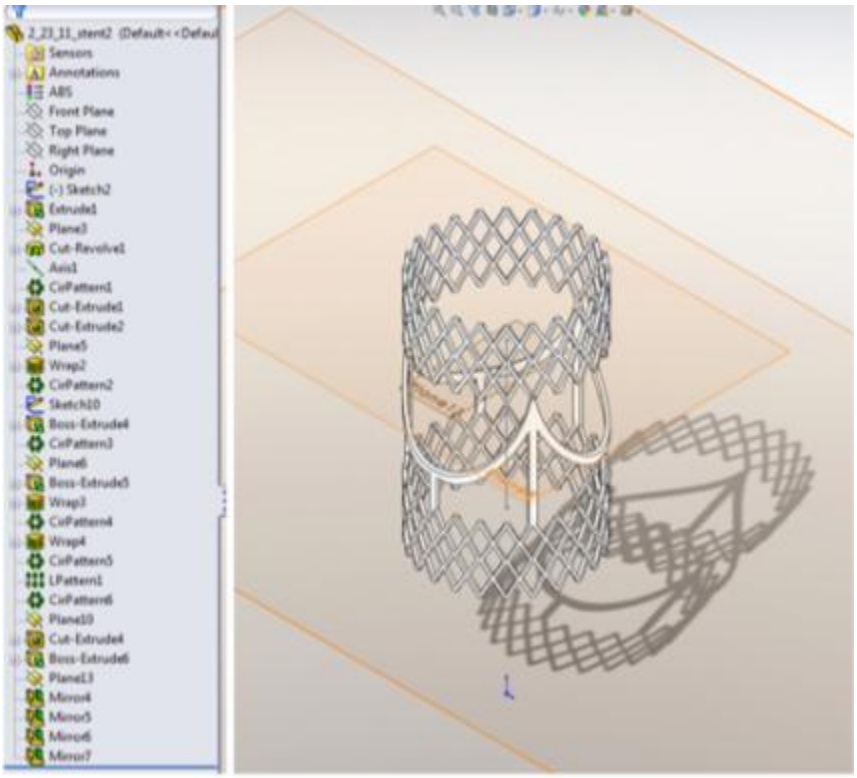

Figure 3.32: Wrap iteration 3

However, as the design team introduced new features into the stent to meet the design criteria, the Wrap feature soon became very cumbersome and did not seem like the most effective and accurate way of modeling the stents. The main source of error occurred when the sketch was not drawn where

the plane was a tangent to the tube. Taking reference geometries based on the tube was misleading and new means of creating the stent were investigated.

The Flex feature was tried as the user could create the cut on a flat sheet, hence eliminating the source of error noticed when using the Wrap feature. The Flex feature seemed very intuitive and user friendly as shown by the complex cut that was created under one sketch, Figure 3..

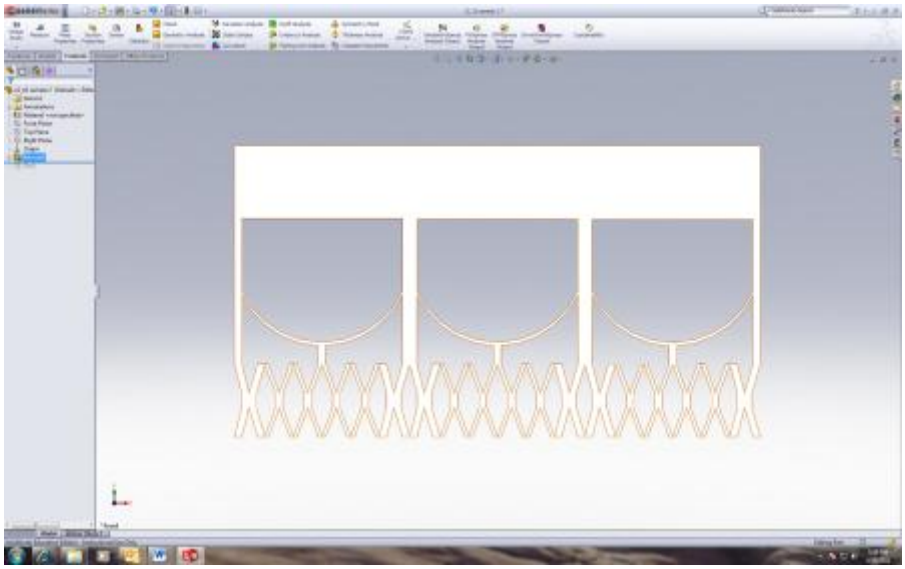

Figure 3.33: Sketch for Flex feature

Applying the Flex feature rotates the sheet about a specified axis and with a correctly placed axis; the sheet is flexed on itself to create a stent. However, as shown by Figure 3.34, a perfect cylinder is not created. The Flex feature could not be used as a stent generated using the Flex feature would not be suitable for FEA.

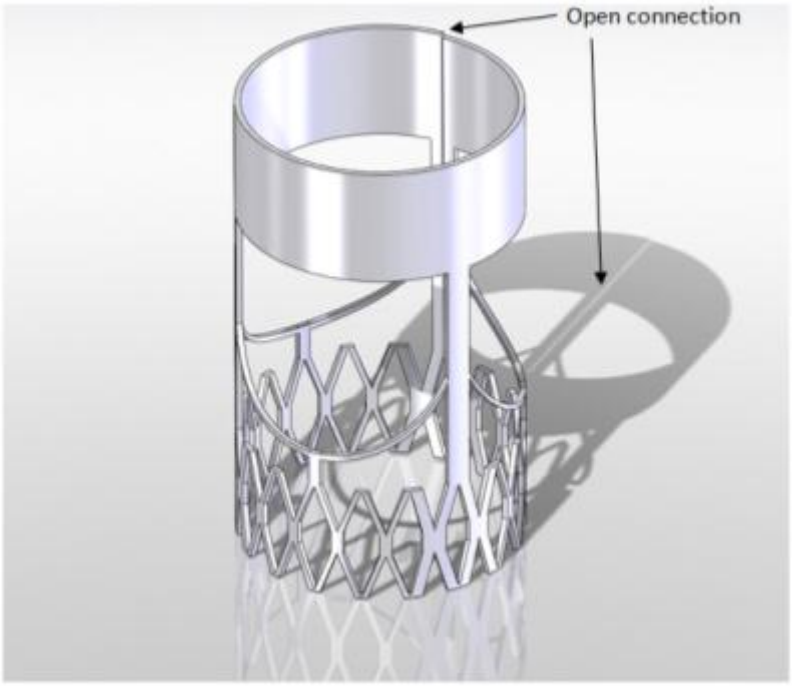

Figure 3.34: Open connection with Flex feature

As a result, a new feature had to be identified to properly model the stent. The Sheet Metal Feature was used. To illustrate how it is used, one of the final two iterations that were ordered to be manufactured will be detailed.

1. Model a hollow tube with the inner and outer diameter specified for the stent size in the expanded configuration, Figure 3.35.

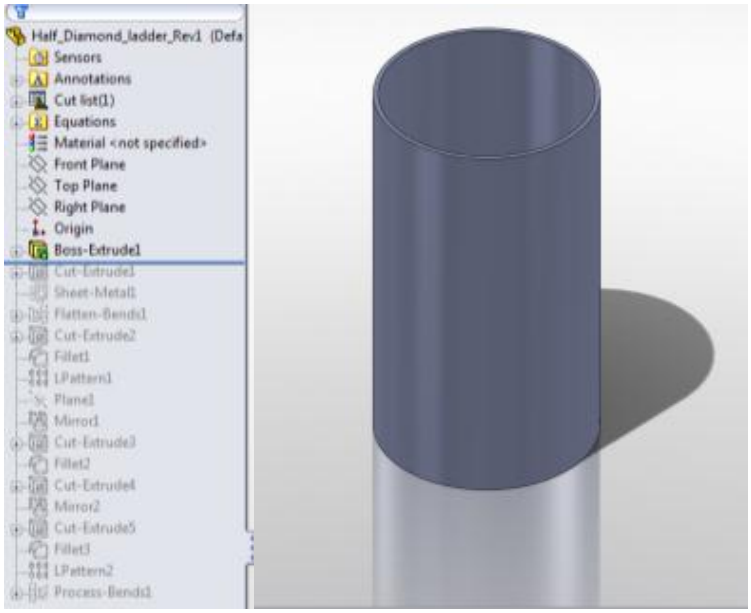

Figure 3.35: Sheet metal step 1

2. Cut out two-thirds of the tube along its length, Figure 3..

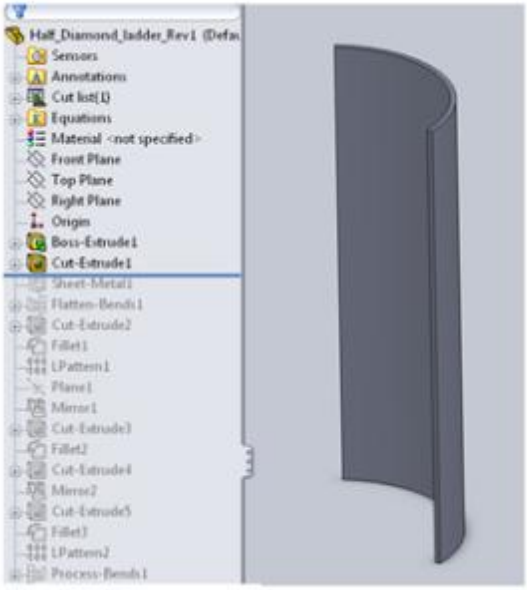

Figure 3.36: Sheet metal step 2

3. Create a sheet metal from the one-third tube and flatten into a rectangle, Figure 3.

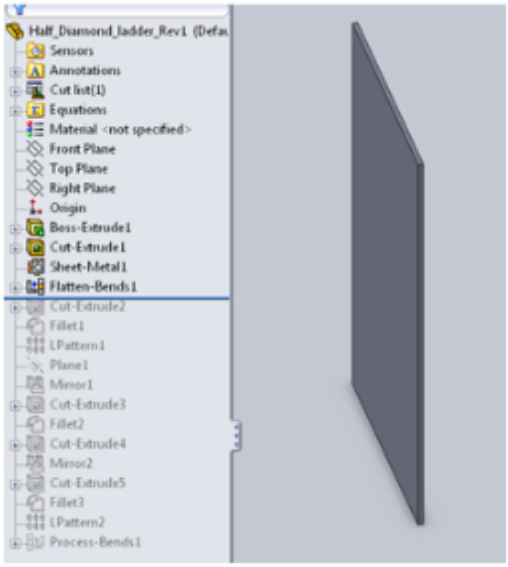

Figure 3.37: Sheet metal step 3

4. Once a flat sheet is obtained, it is easy to create any complex geometry accurately. When creating the pattern, it is sometimes natural to assume that this is the full stent but that is not the case. The rectangle shown represents only one-third of the entire stent. Figure 3. shows the pattern created on the flat sheet for the Half Diamond 1 stent.

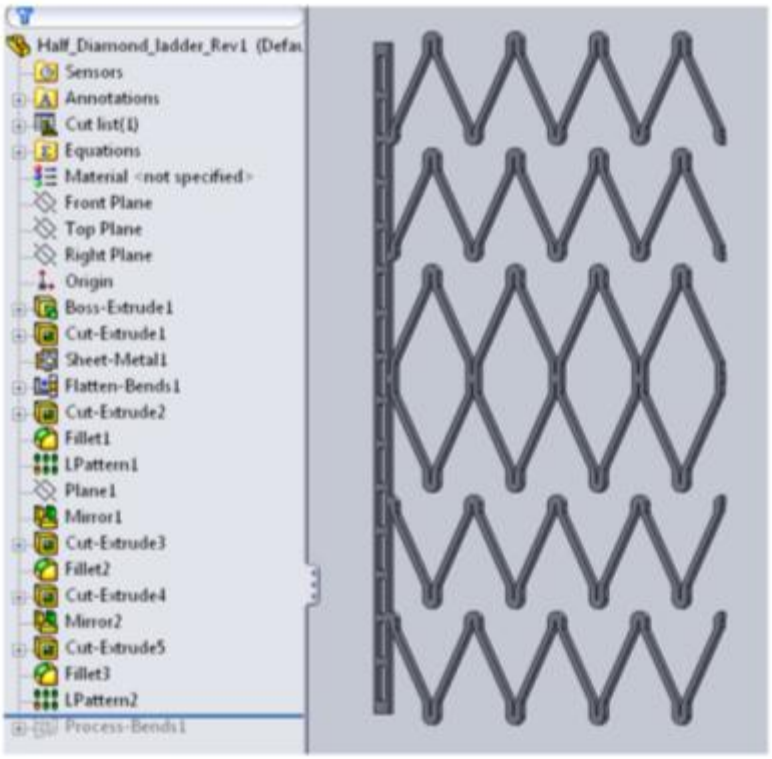

Figure 3.38: Sheet metal step 4

5. The flat sheet can then be curved back into the one-third tubing, see Figure 3..

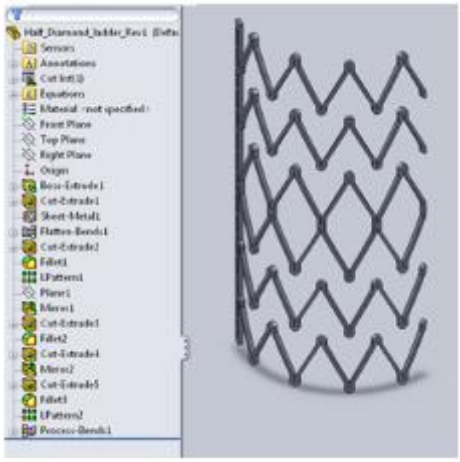

Figure 3.39: Sheet metal step 4

6. An assembly is then created where the three thirds are mated together to form a full stent, Figure 3..

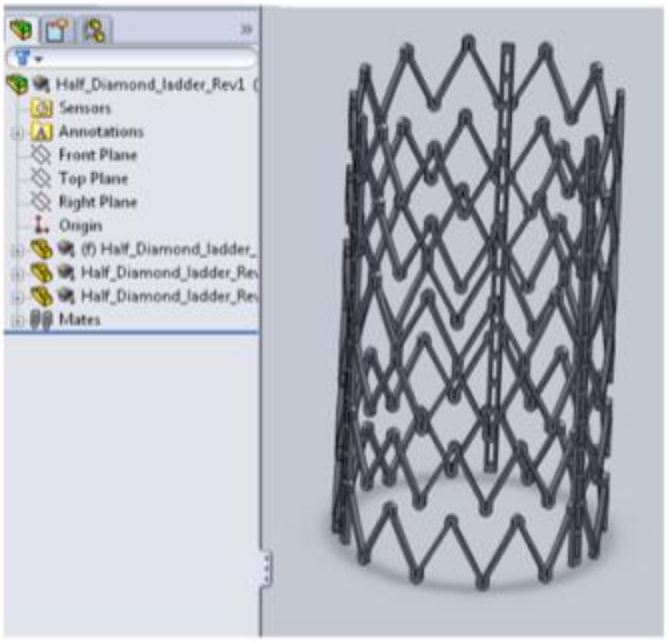

Figure 3.40: Sheet metal - finished assembly

The Half Diamond 1 stent uses a half diamond pattern similar to the Cribier-Edwards Percutaneous Heart valve. Exact dimensions for the stent cannot be disclosed at this point. The reasoning behind each feature is explained below:

- The vertical struts were placed at 120^{o} intervals to act as support for the commissure posts. They run through the whole length of the stent for added rigidity and to allow for a broader range where the valve can be located in the stent. The rectangular windows will prevent thread migration if suturing is used and will allow the valve leaflet and outer sleeve to make contact and create a better seal with the Nitinol frame.
- The Half Diamond 1 is a relatively short stent. Short stents were thought to risk being tilted during use but due to severe aortic stenosis, the natural valve becomes very stiff and tilting can be considered to be low risk.
- An open cell pattern is used (except for the middle row) to minimize pinching of the Angioflex^{TM} layers as the stent is crimped down. When the two layers of polyurethane are thermoformed together, they form webs between four neighboring struts. As the stent crimps down, these can act as scissor blades and potentially damage the polyurethane.
- The open cell pattern is radially weak by principle because of the decreased number of linked struts. However, the increased number of apexes promotes the anchoring aptitude to the aortic valve.
- To relieve stress at the apexes, a track-like pattern is used instead of a keyhole pattern (refer to Background section). This feature was recommended by Admedes GmbH as they had seen it work better with stents similar to the Half Diamond 1.

The Crown Stent 1 was the second stent iteration ordered. It is based off of the Generic Crown 1 stent. Figure 3. through Figure 3. show strategic views of the stent.

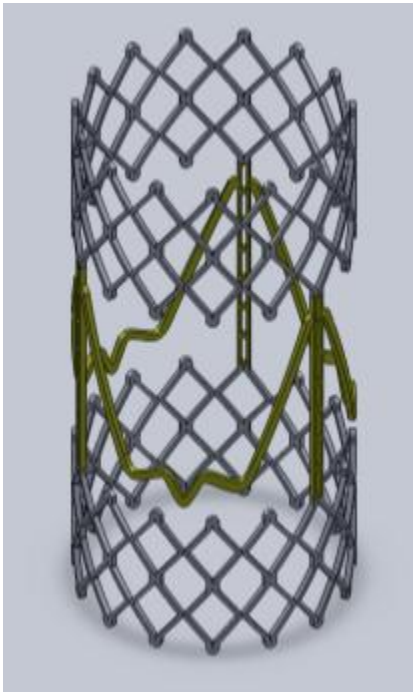

Figure 3.41: Isometric view of Crown Stent 1

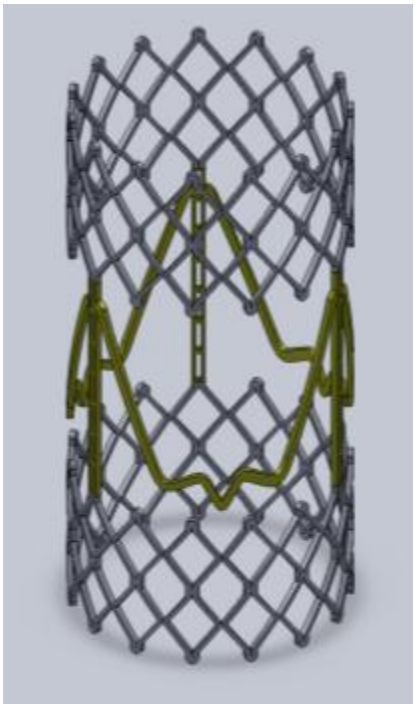

Figure 3.42: Dimetric view of Crown Stent 1

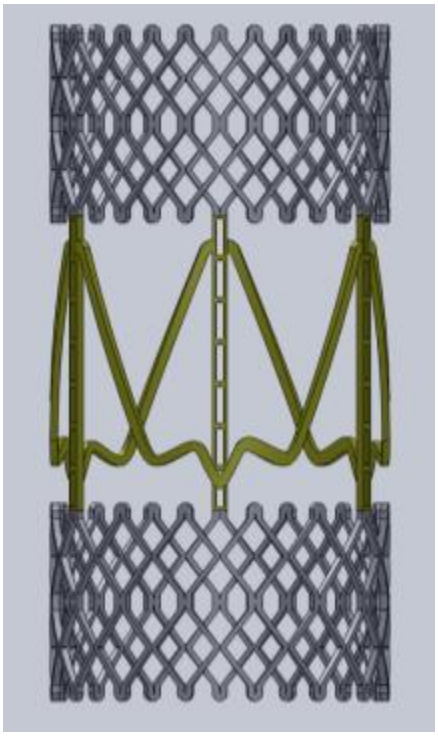

Figure 3.43: Front view of Crown Stent 1

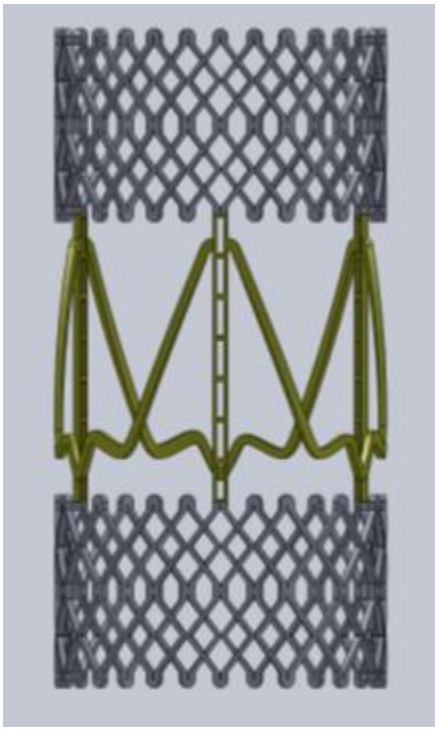

Figure 3.44: Right view of Crown Stent 1

The reasoning behind each design criteria is explained here, however, the specific dimensions of the Crown Stent 1 cannot be disclosed due to proprietary rights currently owned by Abiomed Inc.

- The top part of the stent is added as the commissure tips for the Generic Crown 1 stent were very flexible. The top stent will provide more radial stiffness and will decrease commissure posts movement during use.
- The vertical struts are not well supported and the team understands that this represents a potential weakness. As a result, a closed cell pattern is used as it is more radially stiff and is acceptable for this design as the valve leaflet will not be webbed in between the struts. The valve leaflet will be limited to the middle part and potentially the top half of the first row of stents.
- The path of the corn-like member is meant to follow the contour of the valve leaflet and provide extra support.
- Along the crown-like member, there are seven inflexion points to prevent thread migration. The inflexion parts are also present to act as predictable points for the member to flex.
- The lowest inflexion point is placed above an area where there is no apex from the bottom stent. This was done to allow enough clearance as during crimping, the apex will be lowered to allow for the decrease in diameter size.
- The reasoning for using the rectangular windows along the strut is the same as the Half Diamond 1 stent.

As-Cut Models

After these designs were converged on, as-cut models were created. These were relatively simple to generate. The outside diameter of the stent under expanded configuration was specified to be 23mm. A 14 French (4.7mm) raw tube size was specified. Therefore, when creating the as-cut drawings, the horizontal dimensions were reduced by a factor of (23.0 ÷ 4.7 = 4.89) 4.89. Admedes GmbH is somewhat versatile regarding the as-cut drawings. As seen in Figures 45-46, either a sketch or a flat sheet will be accepted.

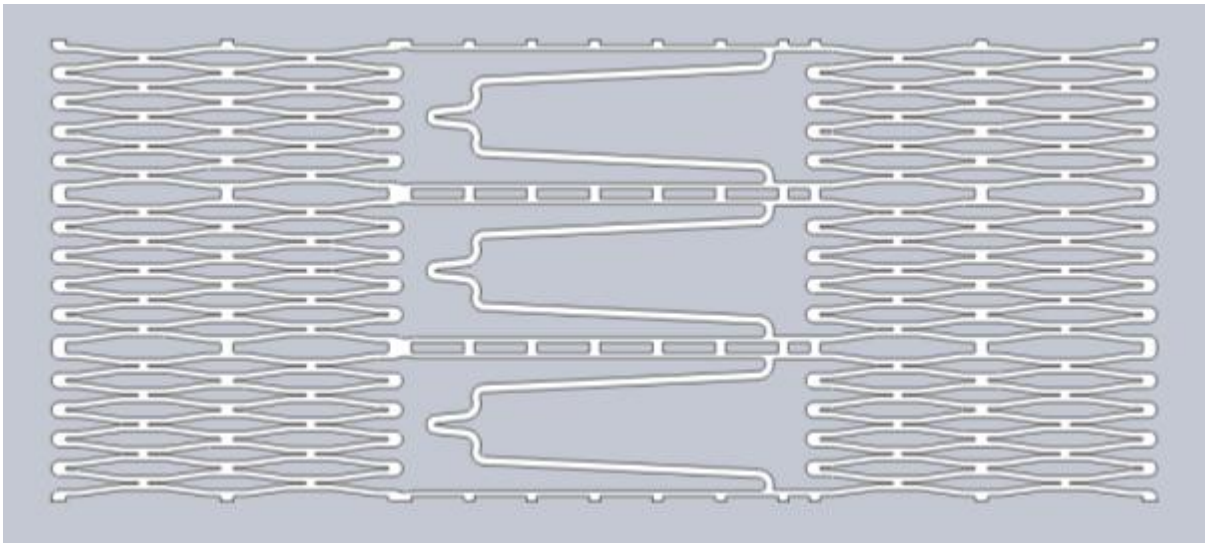

Figure 3.45: As-cut drawing for Crown Stent 1

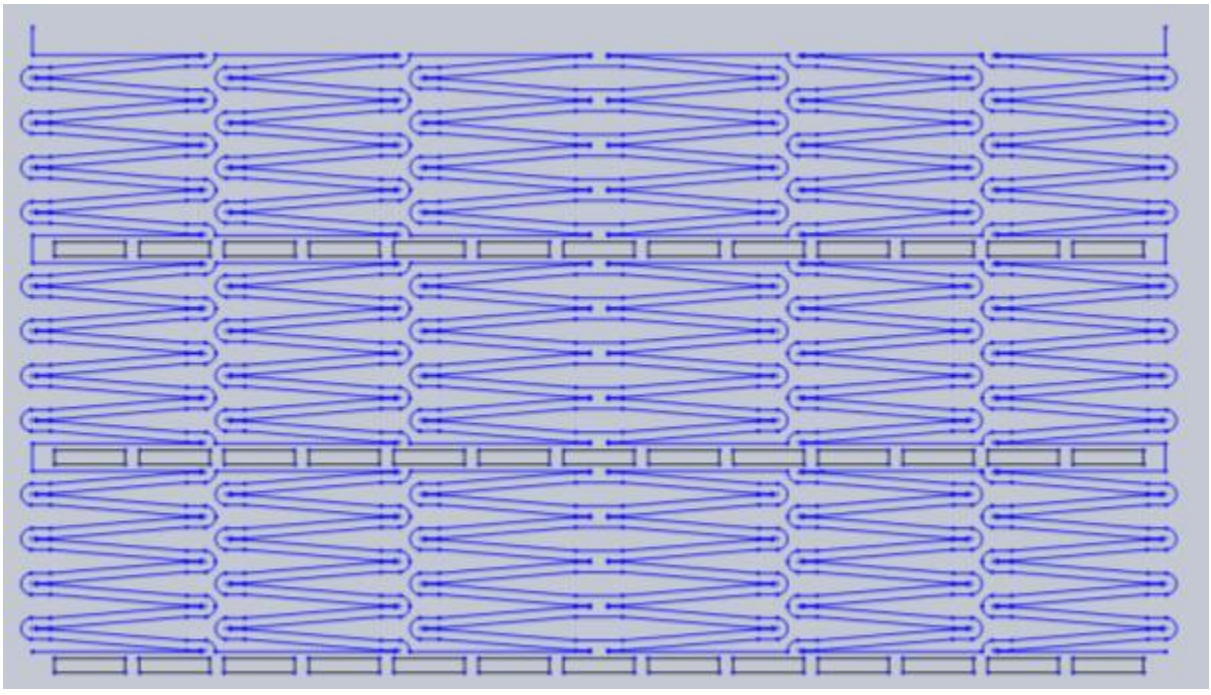

Figure 3.46: As-cut drawing for Half Diamond 1

Test Setup and Results

The following sections detail the effort of the team to assess the theories that have been put forward in the previously by testing the Half Diamond 1 and Crown Stent 1. Finite Element Analysis will be performed while Admedes manufactures and ships the stents. Once the prototypes are received, the efficacy of the valve attachment techniques will be evaluated. If deemed adequate, bench-top testing will follow and ultimately cycle testing will be performed.

FEA Analysis

Admedes GmbH has a one week turnaround time to manufacture and mail the stents after the order and all required information has been received. In the meantime, the team attempted to conduct a finite element analysis of the Half Diamond 1 and Crown Stent 1 models. ANSYS Workbench 12.1 will be used as it is the only FEM package that Abiomed Inc. has licensing rights to.

Nitinol Model

Nitinol possesses very unique material properties. As such, a new material model must be created in ANSYS Workbench 12.1 to obtain satisfactory results. The team understands that Nitinol can have very different properties depending on the thermal processing it is subjected to after being cut. For extremely accurate results, a sample of the Nitinol tubing must be tested for the various parameters listed below:

- Density
- Coefficient of thermal expansion at different temperatures
- Reference temperature value
- Stress vs. strain data points
- Mooney-Rivlin 2 Parameters
    - Material constant C10
    - Material constant C01
    - Incompressibility parameter
- Tensile yield strength
- Tensile ultimate strength

For the purpose of this project, the valve attachment and bench-top equipment will have the most weight in terms of evaluating the stent performance. However, getting acquainted with the implications of conducting a finite element analysis on a Nitinol stent is a very important skill to have in the later stages of stent design.

Abiomed Inc. uses Nitinol in other products and has conducted FEA on these parts. The generic Nitinol model available will be used to analyze the Half Diamond 1 and Crown Stent 1 models. The properties listed in the model are:

- Density: 6500 kg/m^3
- Coefficient of thermal expansion at different temperatures: table empty
- Reference temperature value: 22^oC

- Stress vs. strain data points: see Table 4.1 and Figure 4.1
- Mooney-Rivlin 2 Parameters
    - Material constant C10: -2.5326 X 10^{10} Pa
    - Material constant C01: 2.9905 X 10^{10} Pa
    - Incompressibility parameter: 0 Pa^{-1}
- Tensile yield strength: 9.3 X 10^{8} Pa
- Tensile ultimate strength: 1.1 X 10^{9} Pa

Table 4.1: Stress vs. strain data points for Nitinol model

Strain (m/m)	Stress (X 10^{8} Pa)
0	0.0
0.01	4.0
0.02	6.0
0.03	7.0
0.04	7.8
0.05	8.3
0.06	8.7
0.07	9.0
0.08	9.3
0.09	9.6
0.10	9.9
0.11	10.5
0.12	11.0

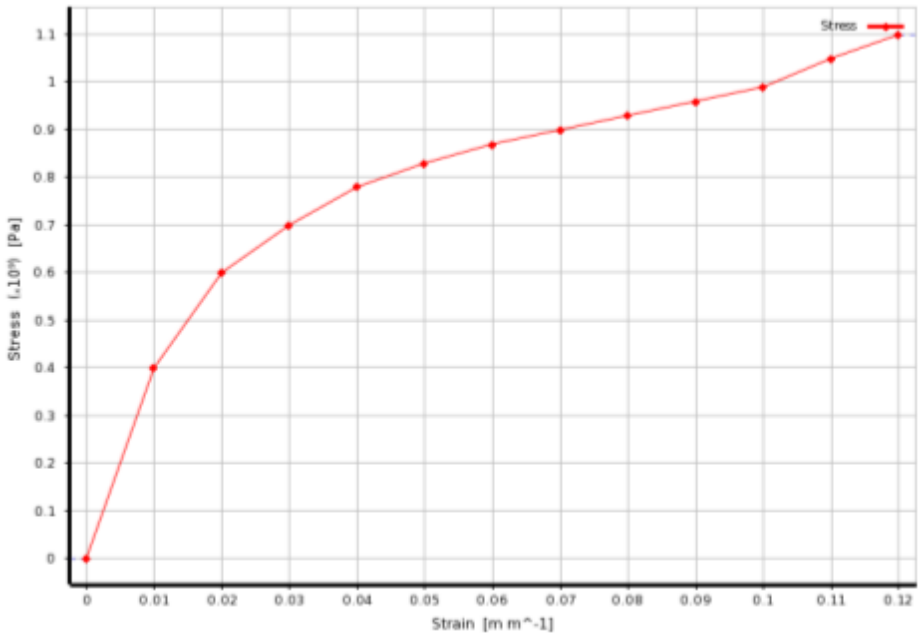

Figure 4.1: Stress vs. strain diagram for Nitinol

ANSYS Workbench 12.1

The first obstacle encountered using ANSYS was that the SolidWorks files could not be properly imported for unknown reasons. The SolidWork Assembly file was converted into the Parasolid format which had better compatibility with ANSYS. After adding the Nitinol model to the Materials library and importing the Half Diamond 1 Parasolid file as the geometry, Mechanical was opened to specify material properties, connection types, support configuration, load type and the desired output. When the file is opened, the stent is shown as three distinct parts bonded together at three contact regions. This subsection lists the different combinations of settings tried with the outcome of each.

Condition 1

Part: Half Diamond 1

File Type: Parasolid file created from a SolidWorks Assembly file

Material: Structural Steel

Connection Type: Bonded

Load Type: Pressure

Load Magnitude: 100 Pa

Support Type: Frictionless

Support Location: Top flat part of 3 vertical struts

Solution Type: Total deformation

Warning messages:

1. One or more bodies may be underconstrained and experiencing rigid body motion. Weak springs have been added to attain a solution. Refer to Troubleshooting in the Help System for more details.
2. At least one body has been found to have only 1 element in at least 2 directions along with reduced integration. This situation can lead to invalid results. Consider changing to full integration element control or meshing with more elements. Refer to Troubleshooting in the Help System for more details.

Results:

Figure 4. and 4.3 show a very odd pressure distribution. The stent is crimped in an irregular pattern and the stress is not symmetrical about the vertical struts.

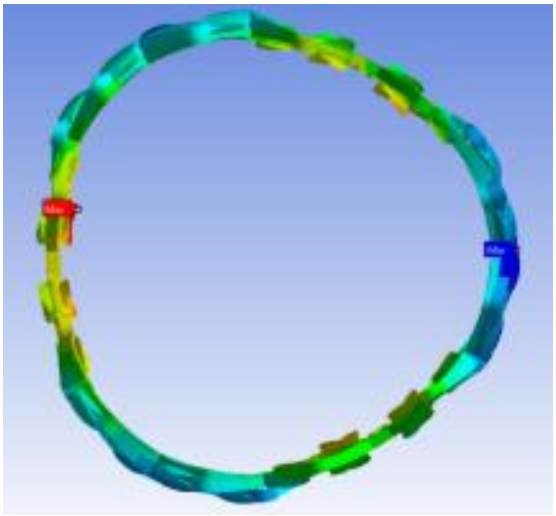

Figure 4.2: Top view of condition 1 results

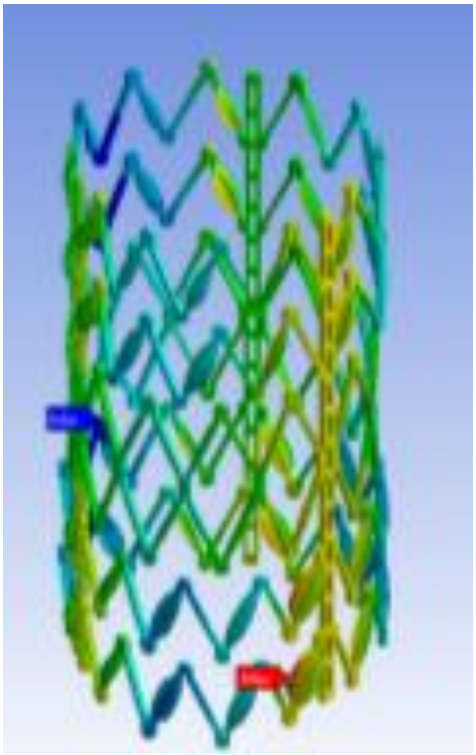

Figure 4.3: 3D view of condition 1 results

Discussion:

- Considering the warning messages, the irregular stress distribution does not seem very out of place.
- Because of the ambiguity of the results, the next step was to apply pressure on a tube. The tube will be made as 1 solid object and the support conditions will be analyzed.

Condition 2

Part: 1 piece 23mm hollow tube

File Type: Parasolid file created from a SolidWorks Part file

Material: Structural Steel

Connection Type: n/a

Load Type: Pressure

Load Magnitude: 100 Pa

Support Type: none

Support Location: n/a

Solution Type: Total deformation

Warning messages:

1. One or more bodies may be underconstrained and experiencing rigid body motion. Weak springs have been added to attain a solution. Refer to Troubleshooting in the Help System for more details.

Results:

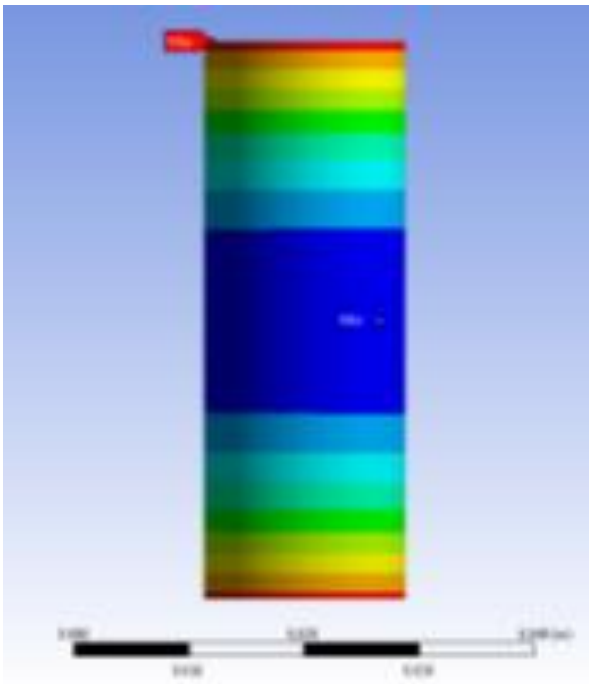

Figure 4.4: front view of condition 2 results

Discussion:

- Before this run, frictionless supports were used at the top of the tube. It created a pressure gradient from the top to the bottom.
- Despite the error message, the pressure distribution seems logical (Figure 4.4) based on best engineering judgment. These seem to be the right conditions for analyzing the stent.
- Since the stent is being viewed as three distinct parts bonded together, the tube will be modeled the same way.

Condition 3

Part: 3 pieces 23mm hollow tube assembly

File Type: Parasolid file created from a SolidWorks Assembly file

Material: Structural Steel

Connection Type: bonded

Load Type: Pressure

Load Magnitude: 100 Pa

Support Type: none

Support Location: n/a

Solution Type: Total deformation

Warning messages:

1. One or more bodies may be underconstrained and experiencing rigid body motion. Weak springs have been added to attain a solution. Refer to Troubleshooting in the Help System for more details.

Results:

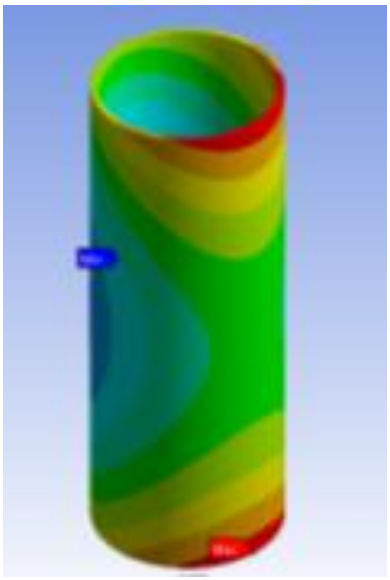

Figure 4.5: Isometric view of condition 3 results

Discussion:

- Various connection types were experimented with Bonded seems to be the most appropriate. Separation of parts occurs with the other connection types.
- It is now clear that ANSYS has trouble treating the three bodies as one, see Figure 4.5. The next step should be to create a one part stent in SolidWorks.

Due to a lack of time, this path was not further explored. The Future Works section of this report outlines potential ways to create a one part stent that could potentially yield sensible results when subjected to a pressure load in ANSYS.

Stent Preparation for Testing

Crimper

The first test that the Half Diamond 1 and Crown Stent 1 iterations were subjected to was the crimp test. Both the Half Diamond 1 and Crown Stent 1 were successfully crimped down to 16 French diameter sizes. This was excellent news as it meant that there was room for the valve leaflet before reaching the 18 French upper limit size.

Thermoforming

The valve leaflets were then thermoformed onto the stents to assess their features that were meant to enhance the technique. Figure 4. and Figure 4. show the results of the thermoforming valve attachment test.

Figure 4.6: Thermoformed Crown Stent 1

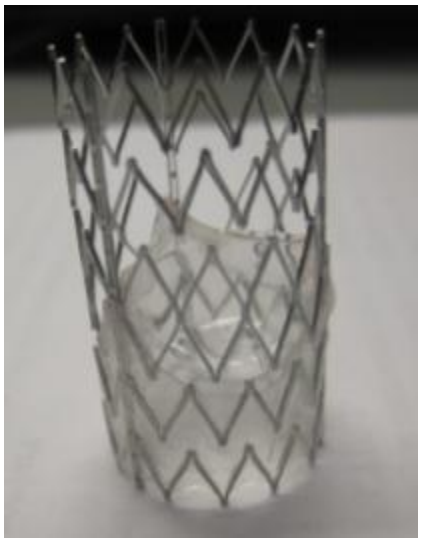

Figure 4.7: Thermoformed Half Diamond 1

The second part of the attachment test was to evaluate the minimum crimp down size of the stents with the leaflets attached and to inspect for any visual damage.

Half Diamond 1 Results and Discussion:

- Successfully crimped down to 18 French with thermoformed valve leaflets
- Crimper did not seem to do any damage to stent, valve or attachment.
- Stent does not require much force to be crimped down to 18 French.
- The stent does feel like it is missing some radial stiffness and that might cause anchoring issues. The design intent was to have more apexes that would allow the stent to anchor better to the aortic node so that the stent would not be relying extensively on radial stiffness.

- Overall, it can be concluded that the Half Diamond 1 passed this test.

Crown Stent 1 Results and Discussion:

- Successfully crimped down to 18 French with thermoformed valve leaflets
- Figure 4. and Figure 4. show the extent of the damage caused by the crimper. The bottom of the valve skirt came off the stent. The lowest inflexion point on the crown-like member seems too sharp and can potentially rupture the valve leaflet. The fact that it bows out so much also increases the pressure that it exerts on the valve leaflet.
- The design intent was that the valve leaflet would only be in contact with the first row of the bottom stent. However, the connection point of the crown member and vertical strut is too high and the top stent interferes with the valve leaflet during crimping.
- The three vertical struts seem very likely to fail in torsion.
- While the stent was effectively crimped down to an 18 French size, the damage sustained was considerable. The different attachment technique should reveal if the stent is a bad design or is thermoforming not the right type of attachment for it.

Figure 4.8: Post collapsed thermoformed Crown Stent 1 - view 1

Figure 4.9: Post collapsed thermoformed Crown Stent 1 - view 2

Suturing

For this iteration, a polyester sheet was used instead of fabric and no sewing cuff was needed. The polyester sheet is placed on the circular mandrel and the polyurethane valve placed over it to trace the valve leaflet contour with a fine tip. The polyester sheet is placed on the steel mandrel in between the second and third dip so that it is enclosed within the valve.

Half Diamond 1 Results and Discussion:

Figure 4.10: Sutured Half Diamond 1 - view 1

Figure 4.11: Sutured Half Diamond 1 - view 2

- With the polyester sheet, the profile is much less than with the fabric and the stent was successfully crimped down to an 18 French diameter size.
- There seems to be no visible sign of damage after crimping, see Figure 4. and Figure 4..

Crown Stent 1 Results and Discussion:

Figure 4.12: Sutured Crown Stent 1 - view 1

Figure 4.13: Sutured Crown Stent 1 - view 2

- Crown Stent 1 with the sutured valves look really clean.
- There seems to be no visible sign of damage after crimping, see Figure 4. and Figure 4.. The bowing of the member is somewhat contained with the valve being on the inside. Also, there is no risk of the member puncturing the valve leaflet.

Bench-top Testing

To further evaluate the performance of the stent, valve leaflet and valve attachment, Abiomed Inc. has a series of bench-top test equipment that was designed to test the surgical valves. However, slight modifications to the mounts made them suitable for the purpose of this project. The benchmark values that the design team is trying to make are based off of the values that the surgical valve is currently expected to exceed. Due to the confidential nature of this project, actual test results will not be included but the information drawn from the test results is presented.

Dynamics

The dynamics tester places the valve under real life simulation with a forward pressure of 120mm Hg and backward pressure of 85mm Hg. A camera is placed directly above the valve and the opening/closing of the valve leaflets is monitored. The dynamics tester evaluates the opening/closing mechanism of the valve leaflets but also the performance of the commissure posts and other valve supporting frames.

Both versions of the Half Diamond 1 stent performed as well as expected, with the valve leaflet maintaining a symmetrical shape during each phase. This implies that the frame supports the valve leaflet well enough that no irregular movement of the leaflet is seen.

The Crown Stent 1 however, experienced more difficulties in the Dynamics tester. The opening phase looked fine but during backflow the crown members cave in significantly, causing very inefficient valve leaflet movement. The caving in of the members are most likely allowing significant amounts of back flow which will be confirmed with the Backflow tester. This confirms the finding during crimping that the crown-like members need to be fastened to the lower stent to avoid bowing out and now, caving in.

Pressure Drop

The Pressure Drop tester submits the valve to forward pressure around 120mm Hg. It monitors the flow rate before and after the valve and uses its imbedded algorithm to calculate the pressure drop. It is mostly used to monitor the stiffness of the valve leaflet and does not really evaluate the performance of the stent.

The stents were tested and the Crown Stent 1's saw a smaller pressure drop than the Half Diamond 1's. While the difference is not significant, it may be due to the partial deformation of the valve leaflets during thermoforming.

Backflow

The Backflow tester applies a backward pressure of 85mm Hg on the valve and monitors how much time is required for the water level to fall below two pre-determined marks. This time is equated to a flow rate.

All stent iterations saw values below the target surgical valve values. However, the Half Diamond 1 stents performed reasonably. The bottom of the skirt was not sutured at enough points and allowed a leak path to form. The leak path for the thermoformed Half Diamond 1 has not been identified yet.

The Crown Stent 1 stents performed terribly. The same behavior as on the Dynamics Tester was observed and confirmed that the commissure posts are too flexible and that the crown-like member needs to be fixed to the bottom stent.

Mock Circulatory Loop and Placement

The Mock Circulatory Loop and Placement Tester evaluates the delivery capabilities of the system but the design team did not have the resources to develop a delivery system. The poor performance results of the valve meant that more time was to be devoted on developing new stent iterations that would address the faults observed.

Cycle test

The cycle tester simulates aging of the stent, valve leaflet and attachment by vibrating the stents at 120Hz in a saline solution at 37^{o}C and 120mm Hg. The target is to reach 380M cycles which would occur after roughly 366 days if the tester was run continuously.

Only one stent was placed in the cycle tester as the mount modification was complex and not enough time was left to create a new one. After suturing the valve leaflet to the Generic Crown stent, the latter was placed in the cycle tester. Valve rupture was observed about a month into the test, that is, 31M cycles, see Figure 4.. Since only one failure was observed, no conclusion could be drawn.

Figure 4.14: Valve rupture in cycle tester

Discussion & Future Works

Discussion

After analysis of the data provided by the test results, the design team generated a list of action items that should be completed in the next phase of the project. To put the list of future work action items in perspective, a brief outline of what has been accomplished so far is presented.

- Understand the unique properties of Nitinol
- Get acquainted with the design considerations involved in modeling a Nitinol stent
- Learn about the manufacturing processes involved in making a Nitinol stent
- Using the generic stents available, recognize the most suitable attachment techniques for this application
- Analyze the attachment techniques to generate stent features that would increase quality of attachment
- Learn how and create 3D models of stent iterations in SolidWorks
- Incorporate features into stent models to meet design specifications
- Evaluate stents, valve and attachment methods via bench-top testing equipment
- Analyze and present findings

It is only after the careful execution of these steps that a coherent action plan may be developed for the next phase of this project.

Future Works

Crown Stent 1

The Crown Stent 1 seemed promising when the valve leaflet was sutured. While it did fail the bench-top tests, it is a reasonable first iteration that can be a robust prototype once its current flaws are addressed.

1. The lowest inflexion point on the crown-like member needs to be attached to the bottom stent. A flex connector could be used to join to inflexion point to the antinode on the stent directly below it. The flex connector should have a zigzag feature that will account for changes in height as the stent expands and gets crimped down.
2. The connection point between the crown-like member and the vertical strut is too high. The next iteration should see that point lowered by 5mm.
3. This iteration of the stent sees the crown-like member too steep. On top of lowering the connecting point by 5mm the lowest inflection point should be moved vertically up by 2mm and the members should experience more of a curve to better support the valve leaflet contour.
4. The vertical struts seem very prone to failing in torsion. This fault should be dealt with before the next stent generation is ordered.

Half Diamond 1

The Half Diamond 1 stent was the most promising of the two iterations. However, it is also the most difficult one to improve as the failure modes are still not understood.

1. The addition of flex connectors at every other apex on the top and bottom row would add radial stiffness to the system.
2. Testing with colored water at lower pressures should be performed. This would enable the leak path to be identified and steps taken to address it.

Finite Element Analysis

As the project gets closer to a final stent design that will have to meet all design specifications, Finite Element Modeling becomes a crucial skill. For this project, more ways to create a 1 part stent could not be explored further but the team identified some potentials ways.

1. After making the SolidWorks assembly model, save it as a part and create a Parasolid format file from the part file.
2. After creating the one-third part of the stent, instead of making an assembly, use the circular pattern feature of SolidWorks to reproduce the part into a full stent.

Cycle Tester

With a new round of stents being ordered after the current issues have been addressed, it is reasonable to assume that they will meet the test criteria. The next step will be to test the stents under fatigue loading. Ordering new mounts for the cycle tester is imperative to the smooth execution of the next step.

Delivery System

At the beginning of the project, it was believed than an off-the-shelf delivery system could be adapted for use by the team. However, with the intrinsic designs being developed, a delivery device suited to the stents need to be developed. At the same time, the stents need features that will allow them to latch on to the introducer during the crimp down process.

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Appendices

Appendix A: Most Popular Stents

Table 5.1: Popular NiTi self-expanding stents (Stoeckel, Bonsignore, & Duda, 2002)

Company Name	Product Name	Fabrication Method	Comments
Bard	Memotherm	Laser cut tube	
Bard	Memotherm-Flexx	Laser cut tube	
Bard	Luminexx	Laser cut tube	Welded Ta markers
BBraun	Vascuflex SE	Laser cut tube	
Biotronik	Philon	Laser cut tube	SiC coated
BSC	Radius	Laser cut tube	
BSC	Symphony	Welded wire	Sleeve PtIr markers
BSC	Ultraflex	Knitted wire	
Bolton Medical	Sprinter	Braided wire	
Campus	Campus	Laser cut tube	
Cook	ZA	Knitted wire	Sleeve Au markers
Cook	Zilver	Laser cut tube	Coined Au markers
Cordis	SMART	Laser cut tube	
Cordis	SMARTeR	Laser cut tube	Coined Ta markers
Cordis	SMARTControl	Laser cut tube	Coined Ta markers
Cordis	Precise	Laser cut tube	
EndoCare	Horizon	Flat wire coil	
EndoTex	NexStent	Laser cut tube	
Engineers&Doctors	Memokath	Wire Coil	
FlexStent Medical	FlexStent	Braided wire	Au coated
Guidant	Dynalink	Laser cut tube	
Intratherapeutics	IntraCoil	Wire coil	
Intratherapeutics	Prot g	Laser cut tube	
Intratherapeutics	Prot g GPS	Laser cut tube	Coined Ta markers
Intratherapeutics	EndoCoil	Flat wire coil	
Intratherapeutics	EsophaCoil-SR	Flat wire coil	
Jomed	Jostent SelfX	Laser cut tube	
Jotec	FlowStent Diamond	Laser cut tube	DLC coated
Medicorp	Expander	Braided wire	
Medtronik AVE	Bridge SE	Laser cut tube	
Optimed	Sinus	Laser cut tube	
Optimed	Sinus-Aorta	Laser cut tube	
Optimed	Sinus-Flex	Laser cut tube	DLC coated (opt)
Optimed	Sinus-TIPPS	Laser cut tube	Pre-shaped
Optimed	Sinus-REPO	Laser cut tube	DLC coated (opt)
Vascular Architects	Aspire	dual rail ladder coil	ePTFE covered

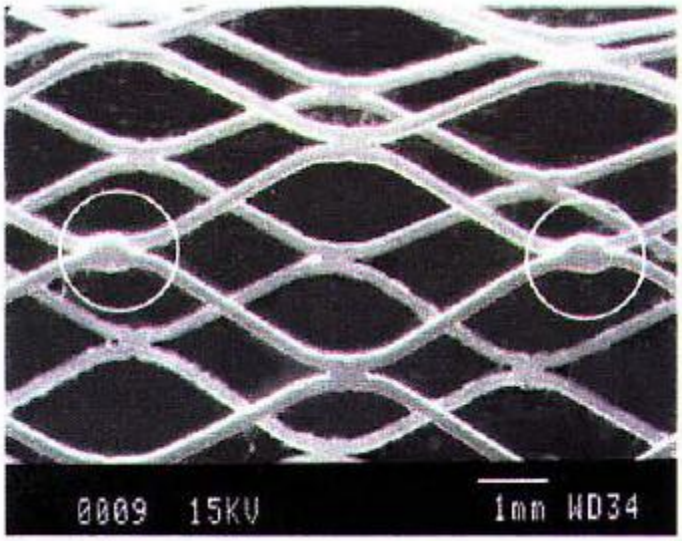


Figure 5.1: Sheet-based Memotherm Stent with lap welded struts

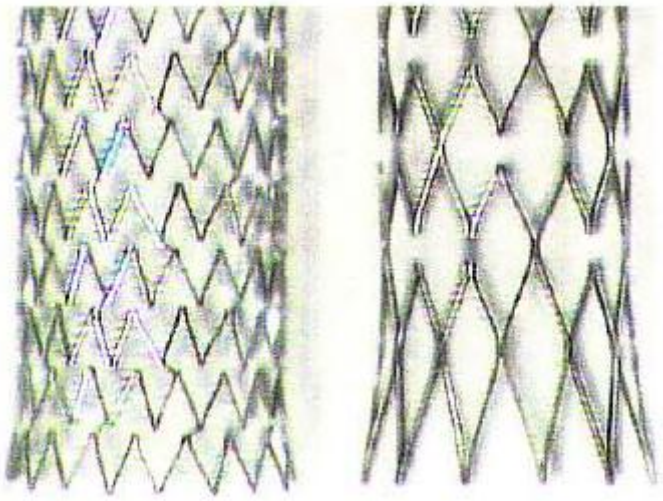


Figure 5.2: left - SMART Stent (Cordis), right - Memotherm Stent (Bard)

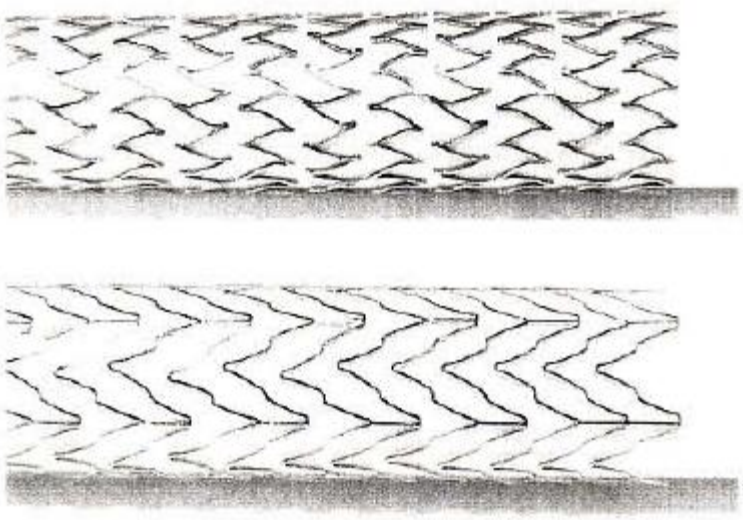


Figure 5.3: top - Jostent SelfX Stent (Jomed), bottom - Dynalink Stent (Guidant)

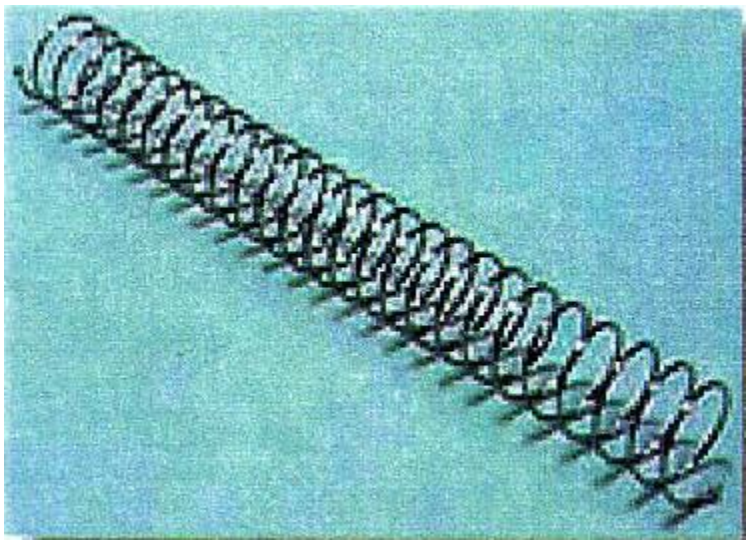


Figure 5.4: Intracoil stent (IntraTherapeutics)

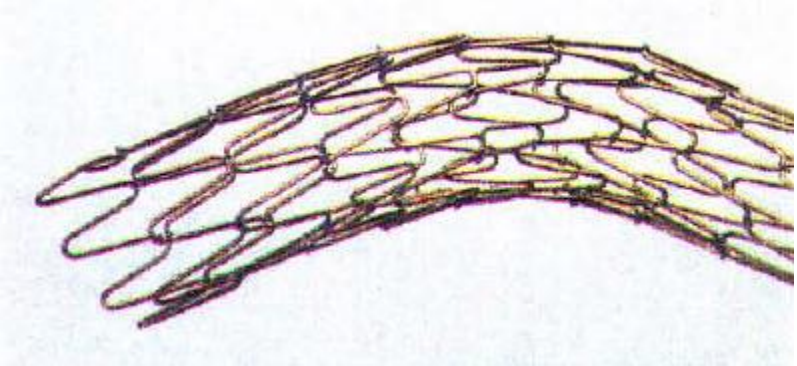


Figure 5.5: Cragg Stent

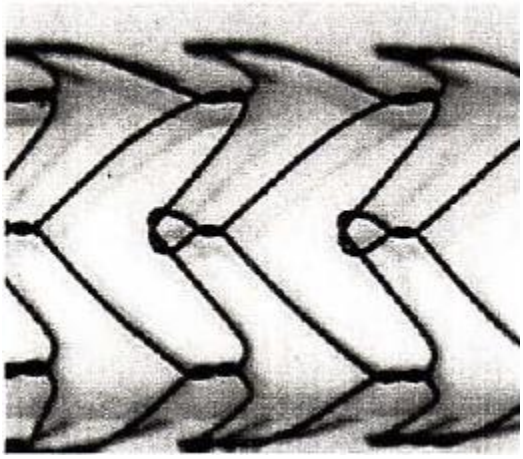


Figure 5.6: Cook ZA knitted stent

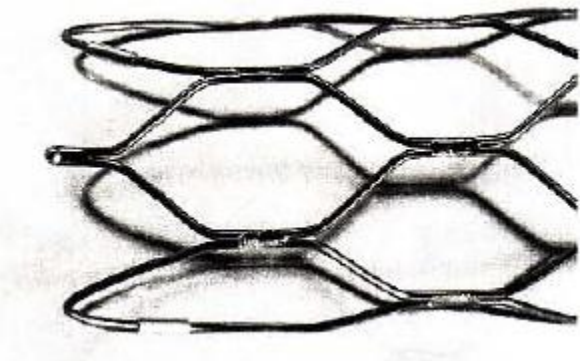


Figure 5.7: Welded Symphony Stent (BSC)

Appendix B: French Catheter Scale

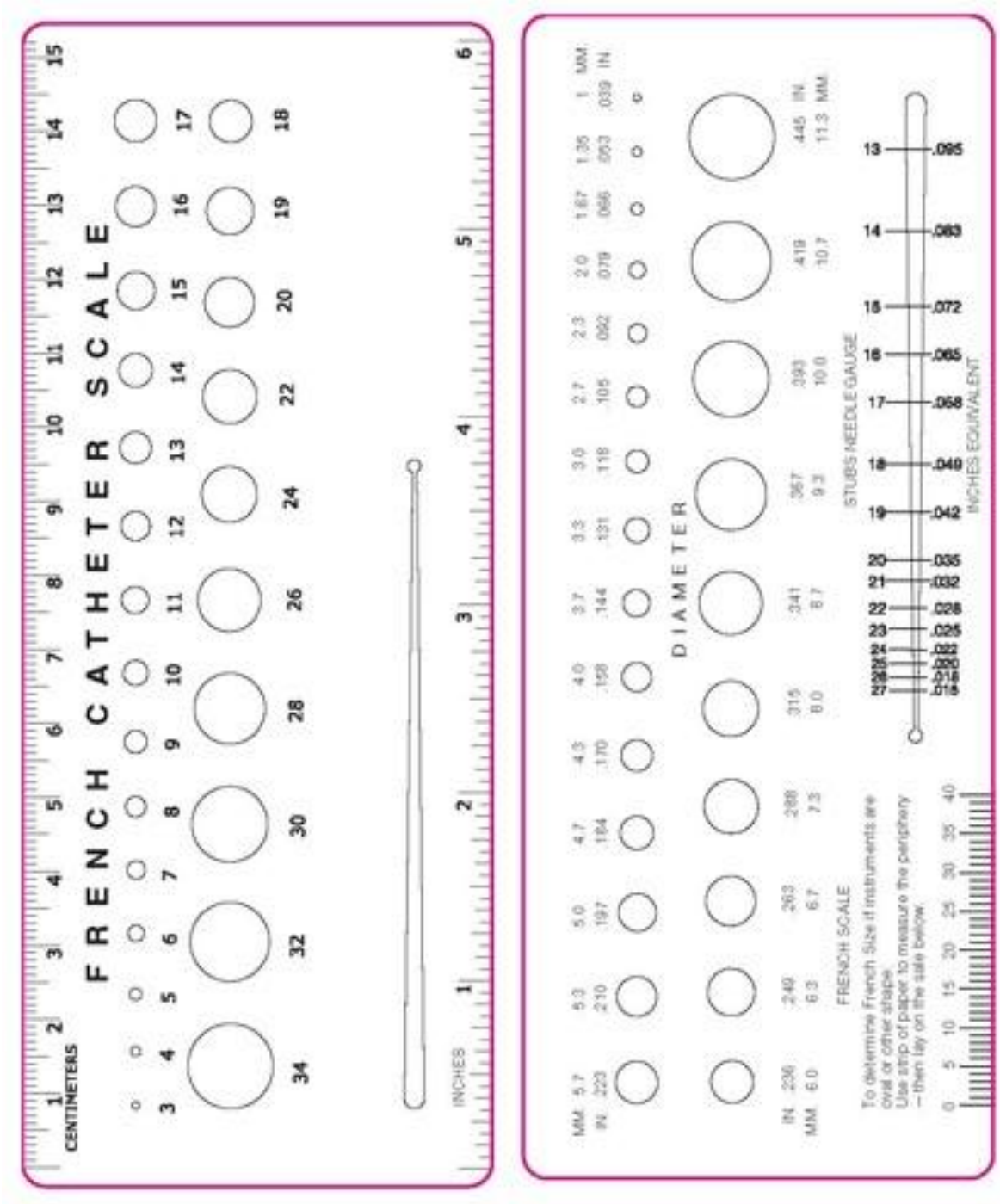


Figure 5.8: French catheter scale (not to scale)

Appendix C: Strut Measurements

Strut Thickness

Table 5.2: Generic stents thickness measurement

Reading Number	Generic Straight (mm)	Generic Curved (mm)	Generic Crown (mm)
1	0.623	0.470	0.561
2	0.631	0.468	0.560
3	0.632	0.468	0.559
4	0.629	0.472	0.559
5	0.627	0.469	0.56
6	0.629	0.471	0.562
7	0.630	0.470	0.558
8	0.630	0.467	0.56
9	0.628	0.471	0.561
10	0.628	0.470	0.56
Exact Average	0.6289	0.4696	0.56
Rounded up Average	**0.63**	**0.47**	**0.56**

Strut Diameter

Table 5.3: Generic stents diameter measurement

Reading Number	Generic Straight (mm)	Generic Curved (mm)	Generic Crown (mm)
1	23.12	23.22	23.08
2	23.09	23.19	23.10
3	23.10	23.20	23.11
4	23.09	23.18	23.11
5	23.11	23.22	23.10
Exact Average	23.102	23.202	23.1
Rounded up Average	**23.1**	**23.2**	**23.1**

Appendix D: Machine Solution Crimper

Product Specifications

HV200 Specifications:

- Hard anodized aluminum base.
- Stainless steel crimp handle and gear pin.
- Polysulfone activation ring.
- Hard anodized aluminum removable face plate.
- Eight hand machined Delrin segments.
- Diameter range 2mm to 34.0mm.
- Maximum specimen length 40mm (including elongation).
- Easily disassembled and reassembled for cleaning.
- Equipment supplied bulk non sterile.

HV500 Specifications:

- Injection molded disposable unit.
- Polycarbonate base and housing.
- Integrated stop with customizable fixed diameter settings.
- Ten injection molded polycarbonate segments.
- Diameter range 1mm to 50mm.
- Maximum specimen length 90mm (including elongation).
- Equipment supplied bulk non sterile.

HV950 Specifications:

- Hard anodized aluminum base.
- Hard anodized aluminum handle with Delrin grip.
- Integrated spring-loaded worm drive for diameter lock and fine adjustments.
- Stainless steel quill with a levered arm to advance device out of crimp head.
- Ten hand machined Ertalyte TX or Stainless Steel segments.
- Diameter range 6mm to 60mm.
- Maximum specimen length 90mm (including elongation).
- Engraved visual diameter indicator.
- Easily disassembled and reassembled for cleaning.
- Equipment supplied bulk non sterile.

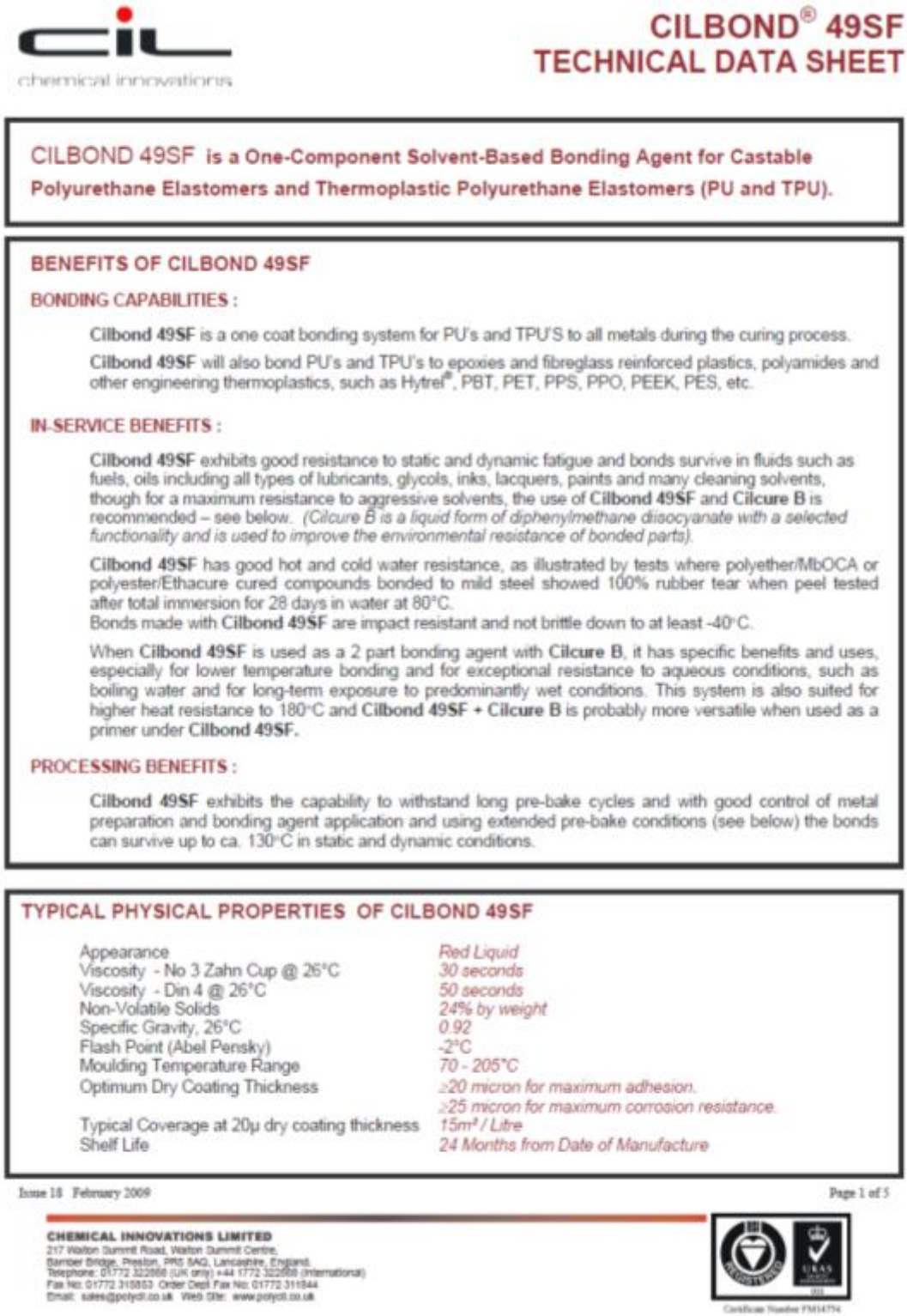
Figure 5.9: Machine solutions product specifications (Equipment Specifications)

Catalogue Pages

Figure 5.10: Page 1 of Crimper Catalogue (Crimper Catalogue)

Figure 5.11: Page 2 of Crimper Catalogue (Crimper Catalogue)

Appendix E: Cilbond® 49SF Data Sheet (Vita, 2011)



chemical innovations

CILBOND® 49SF TECHNICAL DATA SHEET

CILBOND 49SF is a One-Component Solvent-Based Bonding Agent for Castable Polyurethane Elastomers and Thermoplastic Polyurethane Elastomers (PU and TPU).

BENEFITS OF CILBOND 49SF

BONDING CAPABILITIES :

Cilbond 49SF is a one coat bonding system for PU's and TPU'S to all metals during the curing process.

Cilbond 49SF will also bond PU's and TPU's to epoxies and fibreglass reinforced plastics, polyamides and other engineering thermoplastics, such as Hytrel®, PBT, PET, PPS, PPO, PEEK, PES, etc.

IN-SERVICE BENEFITS :

Cilbond 49SF exhibits good resistance to static and dynamic fatigue and bonds survive in fluids such as fuels, oils including all types of lubricants, glycols, inks, lacquers, paints and many cleaning solvents, though for a maximum resistance to aggressive solvents, the use of **Cilbond 49SF** and **Cilcure B** is recommended – see below. *(Cilcure B is a liquid form of diphenylmethane diisocyanate with a selected functionality and is used to improve the environmental resistance of bonded parts).*

Cilbond 49SF has good hot and cold water resistance, as illustrated by tests where polyether/MbOCA or polyester/Ethacure cured compounds bonded to mild steel showed 100% rubber tear when peel tested after total immersion for 28 days in water at 80°C.
Bonds made with **Cilbond 49SF** are impact resistant and not brittle down to at least -40°C.

When **Cilbond 49SF** is used as a 2 part bonding agent with **Cilcure B**, it has specific benefits and uses, especially for lower temperature bonding and for exceptional resistance to aqueous conditions, such as boiling water and for long-term exposure to predominantly wet conditions. This system is also suited for higher heat resistance to 180°C and **Cilbond 49SF + Cilcure B** is probably more versatile when used as a primer under **Cilbond 49SF.**

PROCESSING BENEFITS :

Cilbond 49SF exhibits the capability to withstand long pre-bake cycles and with good control of metal preparation and bonding agent application and using extended pre-bake conditions (see below) the bonds can survive up to ca. 130°C in static and dynamic conditions.

TYPICAL PHYSICAL PROPERTIES OF CILBOND 49SF

Appearance	*Red Liquid*
Viscosity - No 3 Zahn Cup @ 26°C	*30 seconds*
Viscosity - Din 4 @ 26°C	*50 seconds*
Non-Volatile Solids	*24% by weight*
Specific Gravity, 26°C	*0.92*
Flash Point (Abel Pensky)	*-2°C*
Moulding Temperature Range	*70 - 205°C*
Optimum Dry Coating Thickness	*≥20 micron for maximum adhesion.* *≥25 micron for maximum corrosion resistance.*
Typical Coverage at 20µ dry coating thickness	*15m² / Litre*
Shelf Life	*24 Months from Date of Manufacture*

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Figure 5.12: Page 1 of Cilbond 49SF data sheet

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CILBOND® 49SF TECHNICAL DATA SHEET

WHERE TO USE CILBOND 49SF

Cilbond 49SF will bond castable and thermoplastic polyurethanes to metals and plastics at temperatures of 70°C or above, though best results are achieved at ≥85°C, particularly if the component is going to be subjected to a severe environment. It is especially suitable for use in dynamic conditions where hydrolytic stability is important.

When bonding MDI Quasi Prepolymer Systems and where the cast PU bond line may not reach much above 70°C, it is recommended that after applying the **Cilbond 49SF**, the coated metal parts are dried thoroughly and then pre-baked for an absolute minimum of 1 hr at 85°C - 100°C to ensure a good cement to metal bond.

For the bonding of PU to polyamides (Nylon), using **Cilbond 49SF**, refer to CIL Information Sheet B10.

END-USE APPLICATIONS OF CILBOND 49SF

End applications for products using Cilbond 49SF include :

- Rollers for the paper and textile industries
- Solid tyres
- Carriage wheels
- Dunnage
- Pipe linings and pipe coatings
- Reinforced screen decks
- Any product with an engineering bond between a PU elastomer and a metal or plastic substrate.

METAL SURFACE PREPARATION

Cilbond 49SF must be applied to carefully prepared surfaces for it to be effective. Surfaces should ideally be grit blasted with clean, filtered sharp alumina or steel grit (200-400µ), and solvent degreased. For cast PU's it is vital that when dealing with hard surfaces, such as case hardened steel, stainless steel and some grades of high carbon cast iron, that the grit is capable of giving a sharp surface.

Alternatively, surfaces may be phosphated using well-established proprietary procedures.

Good metal preparation is vital if the environment is continually wet such as sub sea situations and/or involves severe dynamic fatigue.

For detailed recommendations on substrate preparation refer to **Information Sheet A1**.

Figure 5.13: Page 2 of Cilbond 49SF data sheet

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APPLYING CILBOND 49SF

BRUSHING

Application by brushing is normally undertaken without further dilution, but for coating large areas, dilution with MEK or the diluent blend shown below, improves flow and speed of application.

DIPPING

Dilute to a viscosity of 16-24 seconds using a Zahn No.2 cup at 25°C or 13-20 seconds using a Din 4 or Ford 4 Cup at 25°C using the diluent blend given below, or use MEK if a fast drying coating is required.

SPRAYING

We recommend an HVLP gun using 1.5 Bar air-pressure and a nozzle size of 1 - 1.5mm.

Dilute to 16-24 seconds on a Zahn No 2 cup or 13-20 seconds on a DIN 4 or Ford 4 cup at 25°C, using the diluent shown below. If fibrillation (cob webbing) occurs, use diluent containing more higher boiling solvent, such as MPA. **Cilbond Diluent 4000** is a suitable diluent for **Cilbond 49SF**.

Typically, dilute ca. 100 parts of **CILBOND 49SF** with 40-70 parts **Cilbond Diluent 4000**, by weight or volume, depending on the gun type, the nozzle size and pressures used.
If MEK is used as the main diluent, beware of chilling of the sprayed metal parts (due to rapid MEK evaporation) and subsequent condensation of water, which may lead to a micro porous film.

ROLLER COATING

Dilute to 35-45 seconds on a DIN 4 or Ford 4 cup at 25°C for most roller application processes. Dilution with a high boiling solvent like MPA may be necessary to achieve the best finish and to reduce the skinning of the bonding agent in the applicator.

DRYING

Dry each coat for at least 45 minutes and the final coat for at least 1 hour at room temperature (25°C). At temperatures below 20°C extend the drying time accordingly.
Forced drying may be used provided care is taken to prevent blistering of the films so we recommend temperatures below 60°C in the early stages of drying. Pre-warming the parts *before* coating will also aid drying (60°C is recommended).

PRE-BAKING

Pre-baking is required to develop good bonding to the substrate, especially to metals. The minimum pre-bake is 1 hour at 100°C and a **typical recommended pre bake is 2 hours at 100-110°C**, though it is well established that longer pre-bakes (4-8 hrs at 100°C) do maximise bond strengths, percentage bond retention and especially the heat resistance of the bond and environmental resistance. The **Cilbond 49SF** coating should not be pre-baked for more than 48 hours at temperatures of ca. 100°C, 24 hours at 110°C or 16 hours at 130°C.

Pre-bakes at >130°C should be fully validated and very carefully controlled and especially with porous and hardened metals (particularly cast iron and cast aluminium) as de-gassing may affect the cement to metal bond.
As an alternative to extended pre-bakes, consider using **Cilbond 49SF+ Cilcure B** as a primer under **Cilbond 49SF – See separate section on page 5.**
Pre-bakes prior to TPU injection moulding are less sensitive to this problem, partly due to the high injection pressures and temperatures involved, which will re-bond the **Cilbond 49SF** to the metal.

COATING THICKNESS

For general-purpose applications use a dry coating thickness of **15 microns**.
For dynamic fatigue applications use a dry coating thickness of **≥20 microns**.
For severe environments use a dry coating thickness of **≥25 microns**.
Under these conditions it is possible to achieve bonds, which exhibit no sign of edge failure after 480 hours salt spray tests, especially with **Cilbond 49SF + Cilcure B**.

STORAGE

Coated parts may be stored for long periods of time (several weeks) provided they are protected from dust and moisture.

DILUENTS

The best diluent is the following blend, where parts are by weight:

86 parts Methyl ethyl ketone (MEK)
7 parts Methyl proxitol acetate (MPA)
7 parts Ektapro (EEP), ethoxy ethyl propionate.

This solvent blend is available from CIL as **Cilbond Diluent 4000**. For many applications it is possible to dilute with low moisture content MEK, provided that the **Cilbond 49SF** is agitated whilst adding the MEK. If cob webbing occurs on spraying, additions of **Cilbond Diluent 4000,** or mixtures of MEK and high boiling ethers and/or esters, such as MPA will reduce it.

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ADDITIONAL INFORMATION

With certain polyurethane systems, especially those plasticised by polar plasticisers, there is the possibility of the plasticiser in the polyurethane solvating the **Cilbond 49SF** prior to gelation of the PU. This may exhibit itself as an observation of staining of the PU by the red dye in the **Cilbond 49SF** or at worst some failure at the PU to cement bond.

For such systems, we strongly recommend the maximum pre-bake prior to casting. If this fails to give good bonding, use **Cilbond 49SF+ Cilcure B**

WHEN TO USE CILBOND 49SF + CILCURE B

If bond line temperatures are likely to be below 70°C, or if a pre-bake of the coated substrates is not feasible, or if the in-service environment is extreme, then consider the use of **Cilbond 48** (see separate Technical Data Sheet) or **Cilbond® 49SF + Cilcure B**.

Applications for **Cilbond 49SF+ Cilcure B** include low-temperature casting or spraying of PU's, the rotational casting of small and medium sized rollers and applications involving dynamic fatigue at temperatures of ≥140°C.

CIL strongly recommend **Cilbond 49SF+ Cilcure B** for applications that involve continuous use in aqueous environments. The resistance of PU to metal bonds made with **Cilbond 49SF+ Cilcure B** at a ratio of 100:10 and subjected to water at <50°C is predicted to be ≥ 20 years and the use of Cilbond 49SF as a cover coat is covered below.

Cilbond 49SF+ Cilcure B yields bonds capable of withstanding boiling water for up to 105°C for ≥200 hours.

Cilbond 49SF+ Cilcure B gives improved adhesion to many substrates; especially epoxy resins, such as FBE, GRP/FRP, glass, ceramics, etc.

Cilbond 49SF+ Cilcure B is recommended for highly plasticised PU systems and for systems where the curing agent could potentially solvate the bonding agent layer, such as trans CHDI/CHDM PU systems.

Cilbond 49SF+ Cilcure B or **Cilbond 49SF+ Cilcure B** as a primer under **Cilbond 49SF** produce bonds capable of withstanding temperature of up to 180°C

HOW TO USE CILBOND 49SF WITH CILCURE B

The standard mix ratio of **Cilbond 49SF + Cilcure B** is **100:10** by weight, but for some applications, it may be possible to use a mix ratio down to 100:5, especially for very fast cure 2 component PU's.

Cilbond 49SF (100 parts by weight) should be mixed with **Cilcure B** (10 parts by weight), preferably by adding the **Cilcure B** to the **Cilbond 49SF**, whilst stirring. Stir well until homogeneous. Allow to stand for a few minutes, stir again and it is then ready for use.

Ideally make up sufficient mix to last ca. 8 hours, which is the recommended pot life. Dispose of any material after this, especially if it has a gelatinous nature.

Apply this mixture following the same procedure as for **Cilbond 49SF**, except that a pre-bake is now not a definite requirement, though the dried parts must be brought up to the moulding temperature or to ≥50°C prior to casting the PU. If parts are dried at ≥70°C, then best bonding is achieved, even if the metals are at ≥50°C when the PU is cast.

A high temperature pre-bake is possible, but it must be stressed that long pre-bakes must be avoided, though the system will tolerate up to ca. 4 hours pre-bake at 100-110°C without any adverse effect on bonding.

Longer and higher temperature pre-bakes may be possible, depending on PU type, i.e. Vulkollan®. However this must be fully validated to ascertain reproducible results.

Figure 5.15: Page 4 of Cilbond 49SF data sheet

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END USE APPLICATIONS OF CILBOND 49SF + CILCURE B

Applications benefiting from **Cilbond 49SF** + **Cilcure B** include:

- Low temperature applied spray coatings and any difficult to bond very fast curing PU.
- Low temperature casting of PU's, especially rotational casting of small and medium sized rollers and pipe, where some limited heat input is possible
- Applications required to withstand boiling water, hot water, where bonded items are continually in aqueous environments or where the bonds must survive up to 180°C.
- Applications where aggressive solvents are employed.

CILBOND 49SF + CILCURE B AS A PRIMER UNDER CILBOND 49SF

This combination is used for those applications where the benefits of **Cilbond 49SF** + **Cilcure B** as a primer can be combined with the long open time and pre-bake resistance of **Cilbond 49SF**, with the added advantage that this system gives bonds with the same heat resistance as **Cilbond 49SF**+ **Cilcure B** on its own.

A primer coat of **Cilbond 49SF** + **Cilcure B** is **100:10** by weight is applied to well prepared metals to give a minimum of 15µ dry coating thickness and dried for 1-2 hrs at ambient temperature or with gentle applied heat. A second coat of **Cilbond 49SF** is applied to give a total coating thickness of ≥25µ and dried thoroughly.

This system is now treated as though it was a dried coating of **Cilbond 49SF** to produce the bonded component and bond performance is equal to using **Cilbond 49SF** + **Cilcure B** at **100:10** by weight.

PACKAGING

Cilbond 49SF is supplied in 10L, 25L and 200L containers. 250ml trial samples are also available upon request.

FURTHER INFORMATION

For more information on **Cilbond 49SF** or for details of our other products please visit www.cilbond.co.uk or e-mail sales@polycil.co.uk

Figure 5.16: Page 5 of Cilbond 49SF data sheet