Case Study

Materials Selection and Computational Fluid Dynamics Study of a Coronary Stent

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Ansys Software Used

This case study uses Ansys Granta EduPack™, the set of teaching resources to support materials education and Ansys Fluent®, the fluid simulation software.

Summary

In this case study, we discuss the design requirements of a coronary stent that is typically used for atherosclerosis (plaque build-up in arteries causing them to narrow). We use Ansys tools such as Ansys Granta EduPack software and Ansys Fluent Software to understand and prioritize the desirable properties of a stent. In the first instance, we look at the material selection properties and propose different materials that are a good fit for the application while highlighting the mechanical performance. Stainless steel and nitinol are identified as good materials choices. In the second instance, we use computational modeling to predict the fluid dynamics of an artery with a stent. As predicted, the stent facilitates fluid flow within a diseased artery. This study highlights the importance of in silico testing with a design workflow that streamlines the process before prototyping.

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1. Introduction

According to the World Heart Report (World Heart Federation , 2023), cardiovascular diseases (CVDs) continue to impact over half a billion people worldwide, resulting in approximately 20.5 million deaths in 2021. This represents nearly one-third of all global fatalities and signifies an increase compared to the estimated 121 million CVD-related deaths.

The human body relies on vessels to transport fluids such as blood, air, and urine throughout the body, playing a crucial role in delivering essential resources to critical organs. However, these vessels can become partially or completely blocked due to various factors that individuals may encounter throughout their lives. In the case of coronary arteries, blockage typically occurs due to the build-up of plaque, also known as atherosclerosis (Xu, 2020), leading to damage in critical regions where oxygen supply is insufficient. Among the various medical advancements, coronary artery stents have emerged as a revolutionary device that greatly improves life expectancy. These stents offer a predominantly non-invasive approach, reducing both patient recovery time and costs. According to the Stents Market Analysis Report (Grand View Research, 2023), the estimated global stents market size reached USD 14.07 billion, with a projected compound annual growth rate (CAGR) of 3.8% from 2024 to 2030.

2. Stent Design Requirements

There are two main types of stents commonly used:

1. The Balloon Expandable (BX) Stent: This stent is initially manufactured in a crimped (squeezed) state and then expanded to match the vessel diameter by inflating a balloon. It was originally designed to prevent coronary restenosis after balloon angioplasty and was first applied to a human in 1987 (Abbott, 2018). To avoid permanent buckling, it needs to be resistant to buckling and undergoes plastic deformation. It possesses high stiffness to resist cyclic deformation and fatigue, as well as offers precise placement accuracy.
2. The Self-Expanding (SX) Stent: The SX stent is manufactured slightly larger than the vessel diameter, crimped, and constrained to a smaller diameter for delivery. Once delivered, the constraint is removed, allowing the stent to recover its original shape. The first SX stent was implanted in a human in 1986 (Benedetta Tomberli, 2018). Compared to balloon-expandable stents, the SX stent exhibits greater compliance in radial, axial, and bending directions. It is considered softer than balloon-expandable stents and exhibits "breathing" with the pulse, making fatigue an important consideration. The focus of this case-study is on the self-expanding stent.

2.1 Desirable properties

Stents possess distinctive characteristics (Pan, 2021) that render them suitable for their intended application. These notable attributes are outlined below:

- Crimpability: Stents should be capable of being crimped to fit into a small catheter during delivery.
- Expandability: They need to expand to large diameters without failure, effectively opening up the vessel.
- Sufficient Stiffness: Stents must possess enough stiffness to hold the vessel open against the closure force.
- Buckling and Fatigue Resistance: It is important for stents to exhibit resistance against buckling and fatigue.

- Visibility: Good visibility through modern technologies is essential for proper placement and monitoring.
- Biocompatibility: Stents should be biocompatible to minimize platelet adhesion and deposition, reducing the risk of complications.
- MRI Compatibility: Whenever possible, stents should be made of materials that are compatible with magnetic resonance imaging (MRI).

2,2 Geometries

Another crucial aspect is stent geometry design (Kapoor, 2024), which aims to achieve strength, flexibility, and a small diameter.

- Open cell structures dominate the stent designs due to their flexibility.
- Stent cell connectors can be categorized into flex and non-flex connectors.
- Woven designs are commonly used for SX stents, offering excellent coverage. The radial strength heavily relies on the axial fixation of its ends.
- Helical spiral designs are flexible but lack longitudinal support.

2.3 Coatings

Additionally, studies (Udriște, 2024) have shown that coating stents with a slow-release medication can help prevent blood clots and potential blockages (also known as restenosis). Stent coatings can be divided into two categories: biocompatible coatings and drug-eluting coatings. Biocompatible coatings consist of inert materials like carbon, gold, and silicon carbide, which are considered less thrombogenic and inflammatory. Drug-eluting coatings can contain anticoagulants, corticosteroids, or antimitotic agents.

3. Materials Selection of a Coronary Stent

Material selection is a critical step that involves considering the desired properties of the stent. Professor Michael Ashby's materials selection methodology (Ashby, 1992) can be employed to systematically break down design requirements into functions, limits, and objectives, aiding in the identification of the most suitable materials candidates. This process requires evaluating different materials, including metal alloys, biostable polymers, and bioresorbable materials, and weighing their advantages and limitations. It is important to note that no single material meets all the desirable properties of stents.
Ansys Granta EduPack 2024 R1 software was used to carry out the material selection of the coronary stent. Level 3 Bioengineering has a healthcare and food section where we can use the limit stage to filter out stents from the list of healthcare applications. A Youngs' Modulus vs. Yield Strength chart, as shown in Figure 1, highlights materials typically used for stent design.

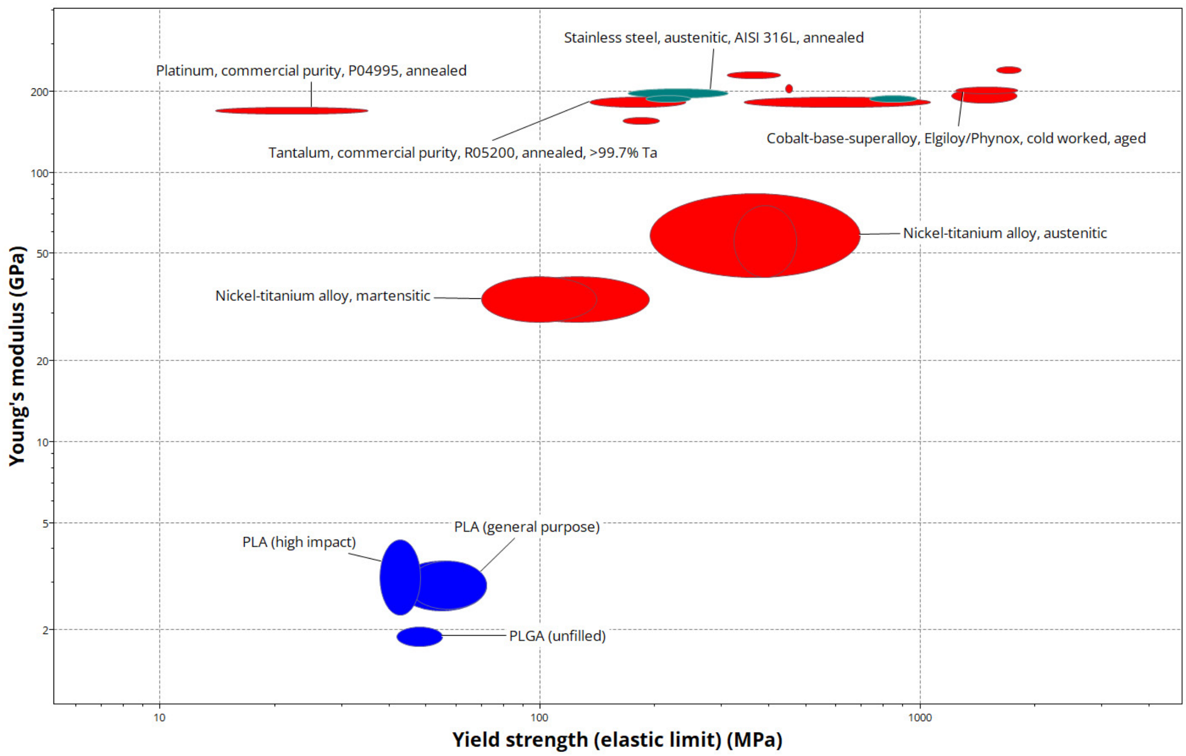

Figure 1: Mechanical properties of stents.

These can be grouped according to:

- Metal and Metal Alloys: Stainless steel, cobalt-chromium, and shape memory alloys like nitinol are prevalent choices (Ahadi, 2023). Stainless steel is often employed in balloon-expandable stents due to its low yield strength, enabling the stent to maintain its deformed shape after balloon removal. Nitinol, a nickel titanium alloy, exhibits remarkable properties such as shape memory effect and super-elasticity, allowing for substantial elastic strain. It possesses excellent biocompatibility, remaining non-toxic and non-allergenic, with no inflammatory response during its functional period within the human body. Consequently, nitinol is widely utilized in self-expanding stents. However, cobalt-chromium alloys have been associated with allergic reactions in certain cases (Grosgogeat, 2022).
- Biodegradable Polymers: Polylactic acid (PLA) and polylactic-glycolic acid (PLGA) are also employed as stent materials (Mani, 2006).

Combining materials with appropriate geometry design, coatings, and drug elution is necessary to achieve the desired stent performance. The design workflow of a stent, as shown in Figure 2, encompasses various stages, with material selection and simulation playing vital roles. Stainless steel was selected as the material of choice over nitinol, although the latter showed better material attributes, since it tends to be the most common material generally simulated. The mechanical behavior of a stent, and its relationship to a particular material, was previously studied and presented here: Material Selection and Modeling of a Bio Stent. In this case study, we will take the previous work a step further by incorporating the fluid dynamics aspects of a stent.

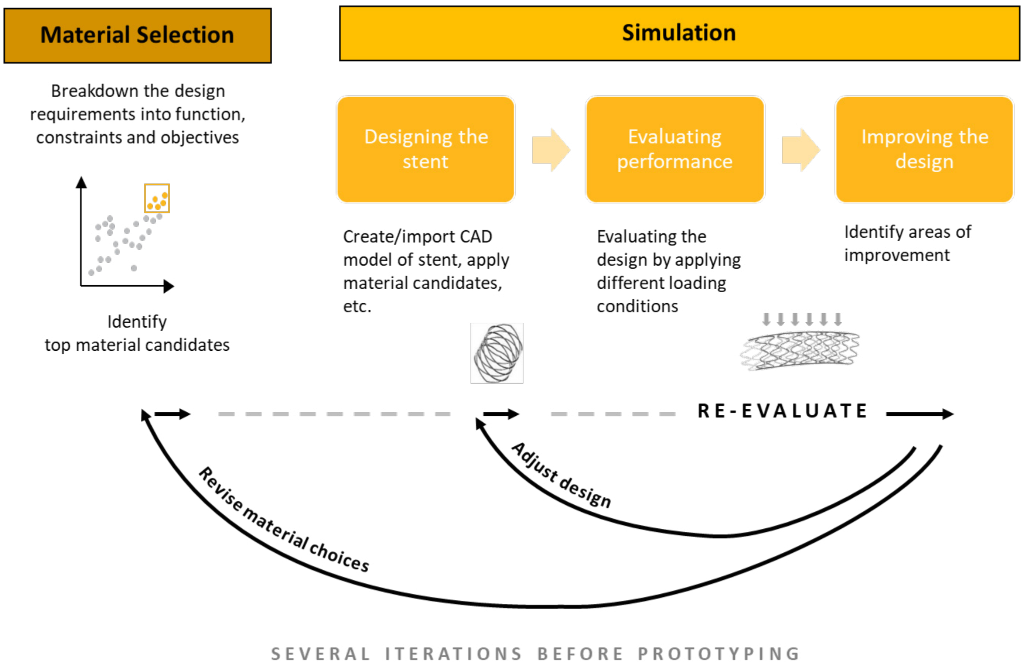

Figure 2: Design Workflow of a Stent

4. Fluid Dynamics Simulation

The fluid dynamics analysis was carried out using Ansys Fluent 2024 R1 software with stainless steel as the chosen material. The same process can be repeated with nitinol, or any other material identified earlier.

4.1 Boundary Conditions Setup

To mimic a simple blood flow, with a stent and a constrained artery, two different simulations were set up. The areas of the simulation domains are as shown in Figure 3 below.

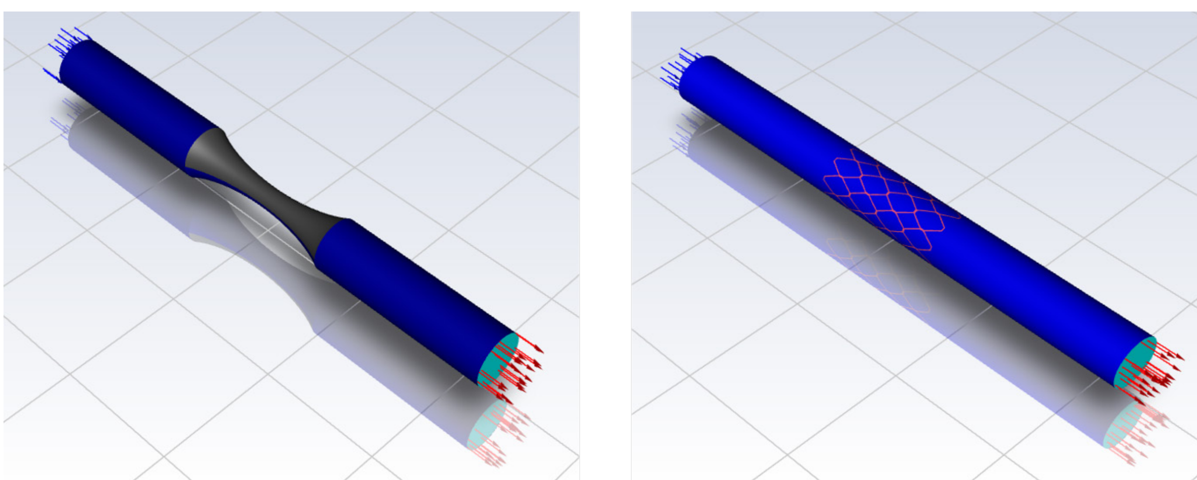

Figure 3: Two cases of (a) constrained artery and (b) an artery with the stent included.

Two different simulations were run in transient condition (here the simulation is carried out for time step) for both cases. We decided to run transient condition, because the input that we are considering is a time dependent pulsating velocity. This suggests that a time dependent simulation needs to be carried out which would capture this pulsating inlet velocity for the time. We have implemented a similar inlet condition as described in the Model 3D Bloodflow in a Bifurcating Artery | Ansys Innovation Courses resource. We chose this condition for mimicking the blood as a viscous liquid. To represent the pumping of the heart, a UDF (User Defined Function) was utilized. This function was taken directly from previously mentioned resource. The outlet pressure was taken as, and the simulation run for 2 sec with a time step of 0.01 s. More details on setup and initial and boundary conditions can be found by reading through the case file included.

4.2 Meshing

The meshing of the simulation is one of the most important parts of setting up a fluid dynamics simulation. A good mesh leads to efficient and accurate simulation results which are important for analyzing the results. A good mesh sensitivity study should always be carried out to understand the effect of the mesh on the simulation results. 421343 cells were meshed for the vessel with the stent and 29405 for the no stent simulation. The meshes are as shown in the Figure 4; it can be seen that the vessel is well captured using the mesh generated. More about the Watertight Geometry Workflow in Ansys Fluent software and the best practices can be found by following the Learning Path.

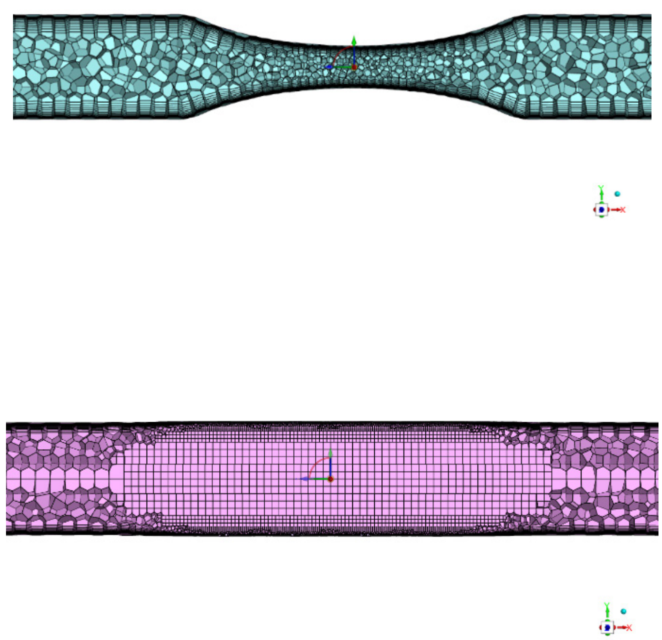

Figure 4: Mesh generated using Ansys Meshing

4.3 Results

An important thing to be kept in mind while simulating blood as a viscous fluid is, although blood is considered as a liquid for the sake of computational modeling, in reality, it contains particles such as red blood cells, white blood cells and platelets. This unique property of blood makes it quite difficult to simulate. Thus, it is attributed the following properties instead:

- Density ρ=1060 kg/m^3
- Viscosity = Carreau viscosity model is utilized. This is a model where the viscosity varies with

shear rate. The Carreau model attempts to describe a wide range of fluids by the establishment of a curve-fit to piece together functions for both Newtonian and shear-thinning (η<1) non-

$$\eta = H(T)\left(\eta_\infty + (\eta_0 - \eta_\infty)[1+\gamma^2\lambda^2]^{\frac{n-1}{2}}\right)$$

Newtonian laws. In the Carreau model, the viscosity is given by:
And the parameters *n*, λ, T_α, η_0, and η_∞ are dependents upon the fluid. λ is the time constant, *n* is the power- law index (as describe above for the non-Newtonian power law), η_0 and η_∞ at low and high shear rates. Finally, *H(T)* is the temperate dependence known as the Arrhenius law.

The analysis is carried out at transient, and the following results were obtained for the two cases.

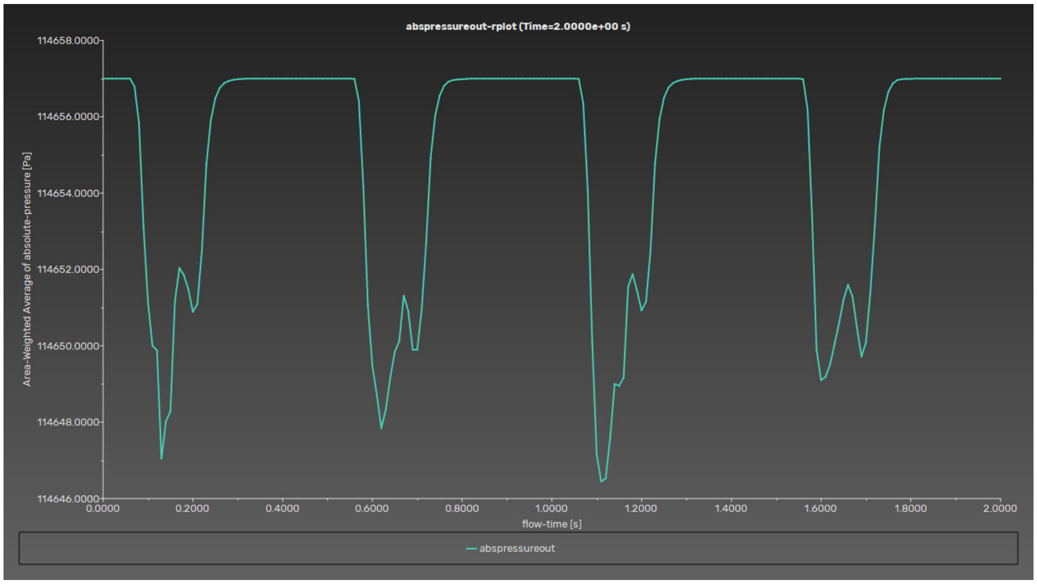

Figure 5: Pressure drop at the outlet for collapsed artery.

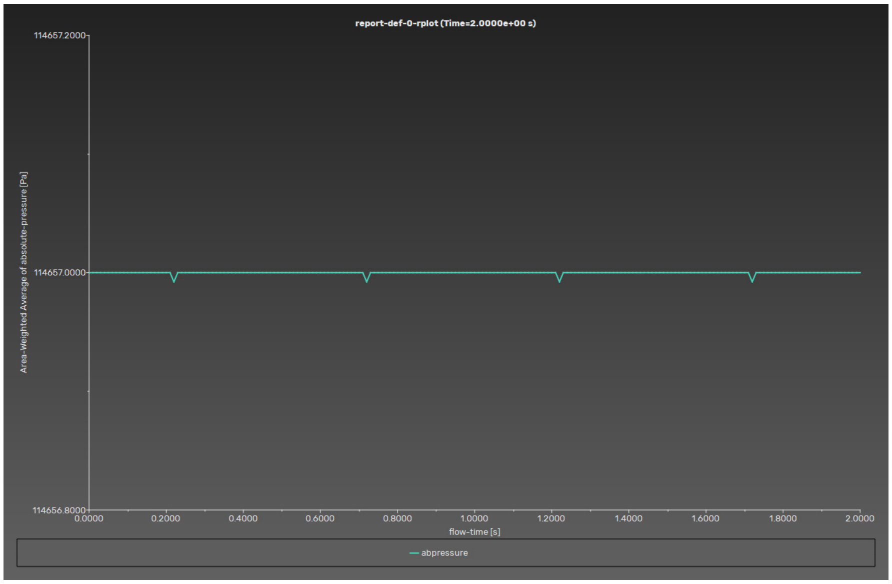

Figure 6: Pressure drop at the outlet for artery with stent installed.

To understand the trends of the constrained vs the stented artery, we looked at the absolute pressure values at the outlet. It can be clearly seen from Figure 5 that there is a significant pressure drop at the exit of the artery when there is restricted flow access due to plaque buildup within the artery walls. This obstruction can lead to a heart attack if left untreated. However, placing a stent in this region (Figure 6) helps keep the artery open by pushing the plaque against the artery walls, allowing blood to flow more freely. Further analysis on the velocity profiles validates these trends, as shown in Figure 7.

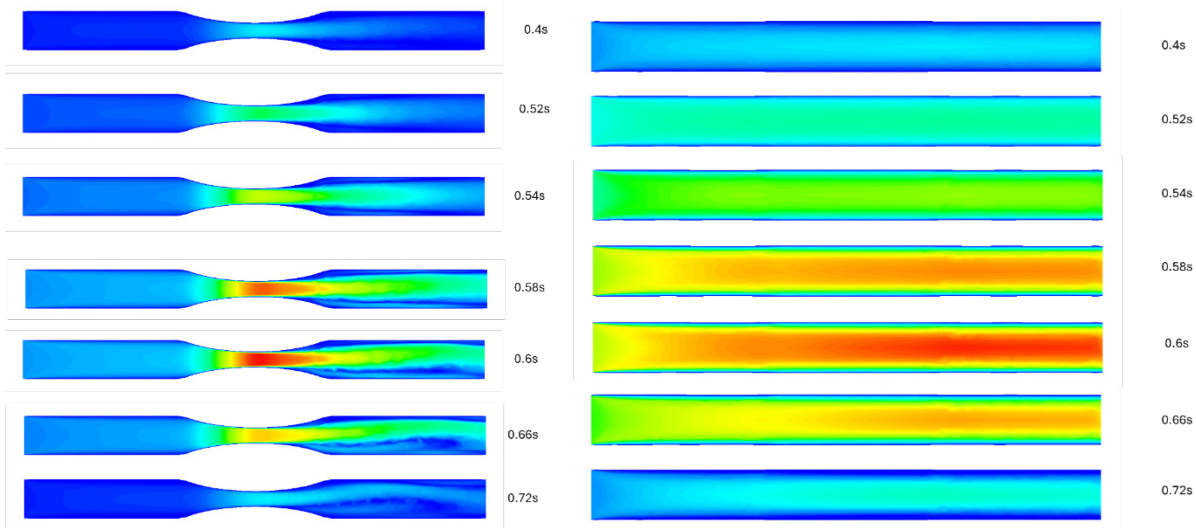

Figure 7: The blood flow in an artery without a stent installed (left) and with the stent installed (right) at various times. Here, we have not given exact numbers, but this is to understand how the blood flow effects the velocity profile. Here the blue color depicts lower value and red the highest.

The design of a stent is a complex process where elements of materials selection, mechanical performance and fluid dynamics come into play. Simulation can be used to understand the relationships between materials selection, mechanical behavior and fluid flow through an artery with or without a stent. By iterating this workflow, as highlighted in Figure 2, we are able to identify the stent with the best performance enabling to build a prototype in a cost-effective and timely manner.

5. Conclusion

In this case study, we have explored the design of stents, from a materials selection and computational fluid dynamics modeling perspective. Metal alloys and biodegradable polymers were deemed as good choices for stents based on their mechanical properties and other attributes. Fluid dynamics through a diseased artery pre- and post-stent placement was studied whereby it was observed that stents facilitated fluid flow, hence preventing potential heart attacks and minimizing the need of invasive surgeries. The study also concludes that simulation design cycles could be used to save both time and money, and efficiently create prototypes with good performance.

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Document Information

This case study is part of a set of teaching resources to help introduce students to topics around materials selection and fluid dynamics.

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