Optimization of Arterial Stent Geometry to Minimize Shear Stress on Arterial Wall and Risk of Restenosis

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Abstract

This research paper explores the optimization of arterial stent geometry to minimize shear stress on the arterial wall and the risk of restenosis. The study employs computational fluid dynamics simulations and finite element analysis to investigate the impact of various stent design parameters such as the stent radius, on the flow dynamics and mechanical stress distribution within the stented artery. The findings suggest that optimizing the stent geometry to a cross-sectional area of approximately 5.2 cm^2 to 10 cm^2 can effectively reduce shear stress on the arterial wall and mitigate the risk of restenosis. This research can provide valuable insights into the design and development of more effective arterial stents that can improve clinical outcomes for patients with coronary artery disease.

1 Introduction

Cardiovascular disease is one of the leading causes of mortality and morbidity worldwide. According to the World Health Organization, an estimated 17.9 million people die from cardiovascular diseases every year, accounting for 31% of all global deaths [7]. Furthermore, a recent study from Harvard University showed that 2/3 of Americans suffer from either obesity or overweight. Roughly 1/3 of Americans suffer from obesity (36%) which may lead to other diseases such as diabetes or coronary artery disease. Coronary artery disease is a significant contributor to this burden, causing over 7 million deaths annually. One of the primary treatments for coronary artery disease is the placement of a stent in the affected artery to restore blood flow. While stenting has become a common and effective intervention, the risk of restenosis remains a significant challenge, affecting up to 30% of patients.

Restenosis is the re-narrowing of a previously treated artery, resulting in reduced blood flow and recurrent symptoms. Several factors can contribute to restenosis, including neointimal hyperplasia, inflammation, and shear stress on the arterial wall. Shear stress is the growing concern throughout this study, and it's defined as the frictional force exerted by blood flow on the endothelial cells lining the arterial wall. High shear stress can cause endothelial damage and lead to restenosis. Its implications on restenosis are crucial. By finding the optimal shear stress in healthy adults as an anchor point, the optimal geometry will be found and maintained[3].

Current treatments for coronary heart disease include drug control therapy and surgical practices. A primary goal with stent implantation is to be minimally invasive to reduce recovery duration and intensity. A clinical study compared the quality of life between two groups, one receiving conventional drug therapy only and the other undergoing stent intervention therapy. The prognosis determined that the control group, drug therapy alone, experienced a lower quality of life compared to the research patients receiving coronary surgery. While these research subjects experience more recovery trauma compared to the control group, symptoms after discharge were less intense and insufferable to live with[5].

By utilizing computational fluid dynamics simulations and finite element analysis using COMSOL, we explore the effects of various stent design parameters, such as stent thickness, stent spacing, and stent length, on blood flow and mechanical stresses within the stented artery and compare these values to the nominal values of healthy adults. Neointimal hyperplasia is the abnormal growth of cells that can form within the stent, causing it to narrow. Inflammation can also cause neointimal hyperplasia and contribute to stent failure. Recent advances in computational modeling have made it possible to study the fluid dynamics and mechanical stresses within stented arteries. These models can provide valuable insights into the impact of stent design on blood flow patterns and stress distribution, potentially leading to improved stent designs that reduce the risk of restenosis. Our findings have the potential to inform the development of more effective arterial stents, ultimately improving clinical outcomes for patients with coronary artery disease[2].

However, designing a stent using COMSOL to lower restenosis comes with plentiful dangers. For instance, the design might not correctly reflect the conditions that actually exist in the human body, which could result in incorrect results, which is one of the key hazards. Ineffective or even hazardous effects may result from the stent design's failure to effectively address the intricate physiological and mechanical aspects that contribute to restenosis. Another danger is that the stent could harm the patient or cause issues during the implantation procedure, which could result in additional health issues. To reduce the likelihood of these problems, it is crucial to carefully assess the stent's size, shape, and material composition. The choice to utilize a stent should be made in conjunction with a skilled medical expert because it may not be the best course of treatment for all people with restenosis[4].

Aim 1: Reducing shear stress using COMSOL modeling software to optimize stent geometry by altering cross-sectional area. The optimal range of aortic shear stress was determined through standardized physiological measurements under healthy conditions. This shear stress was derived from shear rate through conversion using dynamic viscosity relations; blood was assumed Newtonian to reach these solutions. A major characteristic of this model was its ability to fit within an aortic vessel. Therefore, an elliptical cross-section was utilized as restenosis prevention with circular inlet and outlet conditions. Simulations were processed by measuring the shear rate and determining the overall correlation of shear rate with various cross-sectional areas. The experiment utilized Navier-Stokes to identify the flow velocity profile with assumptions of neglecting body forces, no flow condition into or out of arterial walls, fully developed flow, axisymmetric flow, and neglect transverse pressure gradients.

2 Results

2.1 Physics

The governing equation for this model is Navier Stokes in cylindrical coordinates.

$$\rho(\frac{\partial u_z}{\partial t} + u_r\frac{\partial u_z}{\partial r} + \frac{u_\theta}{r}\frac{\partial u_z}{\partial \theta} + u_z\frac{\partial u_z}{\partial z}) = -\frac{\partial P}{\partial t} + \rho g_z + \mu(\frac{1}{r}\frac{\partial}{\partial r}(r\frac{\partial u_z}{\partial r}) + \frac{1}{r^2}\frac{\partial^2 u_z}{\partial \theta^2} + \frac{\partial^2 u_z}{\partial z^2}) \tag{1}$$

The continuity equation is as follows.

$$\frac{1}{r}\frac{\partial u_r}{\partial r} + \frac{1}{r}\frac{\partial u_\theta}{\partial \theta} + \frac{\partial u_z}{\partial z} = 0 \tag{2}$$

From the continuity equation, we can determine that the flow is fully formed and that $\frac{\partial u_z}{\partial z} = 0$. We can assume that the velocity component only acts along the z axis, the pressure is constant, body forces are negligible, and we must also apply the no-slip condition. From the continuity equation, we apply that $\frac{\partial u_z}{\partial z} = 0$. This yields a simplified equation.

$$\rho(\frac{\partial u_z}{\partial t}) = \mu(\frac{1}{r}\frac{\partial}{\partial r}(r\frac{\partial u_z}{\partial r}) + \frac{1}{r^2}\frac{\partial^2 u_z}{\partial \theta^2}) \tag{3}$$

An analytical solution cannot be derived from this point onward yielding Eqn. 2 as our final result

2.2 Simulation

The processing of the simulation yielded shear rate, shear stress, and flow profile data.

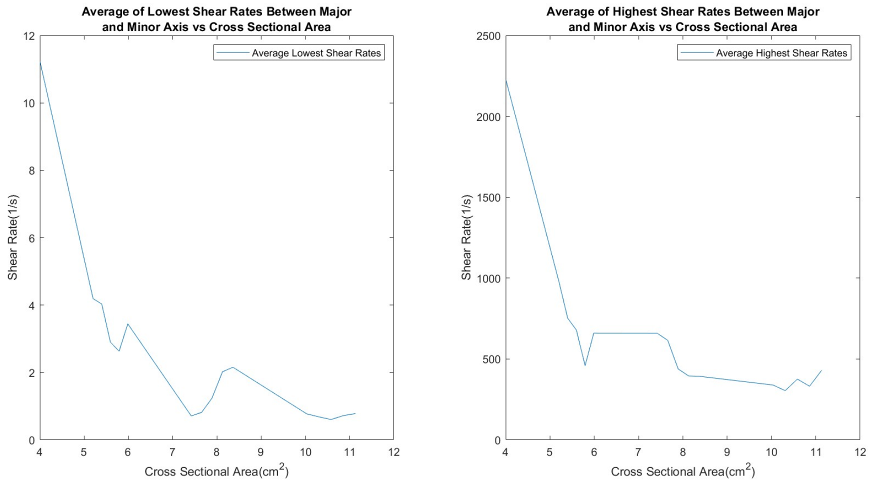
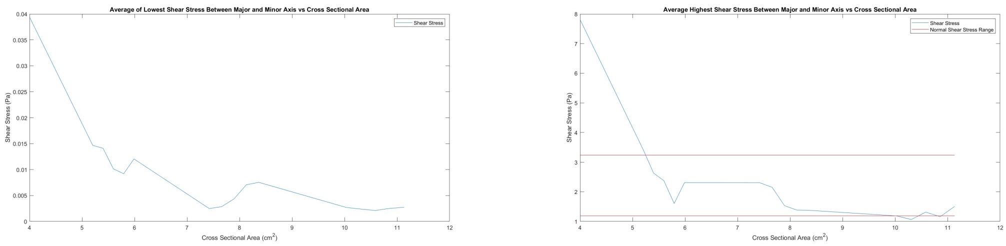
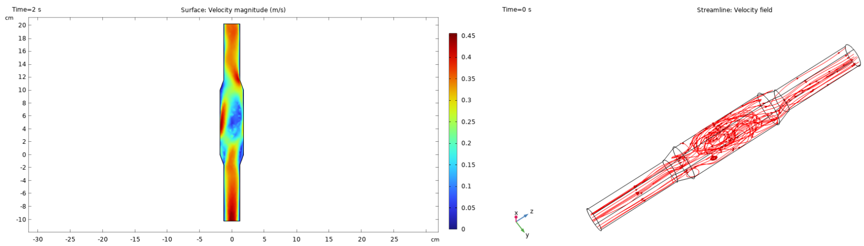


Fig. 1: Average shear rates values taken at all cross sections. Minimum shear rates range from 0.6039 1/s to 11.22 1/s. Maximum shear rates range from 304.367 to 2225.667



(a) (b)

Fig. 2: (a)Average minimum shear stress values taken at all cross sections. (b)Average maximum shear stress values taken at all cross sections with healthy aorta shear stress ranges overlaid. This plot indicates that cross sections ranging from 5.2 to 10 cm^2 allow for the development of shear stress within a healthy range of values.



(a) (b)

Fig. 3: (a) Velocity profile of a cut place. Regions of high and low velocities are seen where velocities at the wall are generally higher than velocities at the center. (b) Streamline plot of the stent at 2 seconds with vortices and eddies.

3 Discussion

The data presented in Fig. 1 and Fig. 2 indicate a trend where shear rate and subsequently shear-stress tend to decrease with increasing cross-sectional area. One limitation to the accuracy of our data is the curves of the data is jagged for both the minimum and maximum. The irregularity of these curves can likely be attributed to several factors. The strongest factor that is likely contributing to the irregularities in the data is that Coarser mesh setting was used for the COMSOL model. Other mesh settings such as "Fine or "Extra Fine" contain more elements and can subsequently account for more complex data input than the Coarser setting. Had a finer mesh been used to run our simulations, the data recovered would have been most certainly more consistent than what Fig.1 portrays. However, mesh settings that contain more elements also increase the computational power to run the simulation, and the choice to use the coarser mesh setting for the COMSOL model over the finer mesh settings in our simulations was due to a limit on the computational power of the resources available to us. The coarser mesh setting, as we leanred from our simulations was the most complex mesh we could use, and still have the model converge.

Additionally, Fig.3b represents the streamline diagram of our model. Fig.3a showed areas of turbulent flow and recirculation within the elliptical stent. The turbulence is partially accounted for by the fact that flow is unsteady (pulsatile) by design, as we thought the addition of pulsatile flow more accurately mimics the in vivo conditions of the descending aorta. Turbulence naturally occurs in the descending Aorta which has a mean Reynold's number of 4500. When comparing the results obtained throughout the study to nominal results from healthy adults, it is clear to see that turbulence in the descending aorta is completely expected. Shear stress and turbulent flow are closely related. Turbulent flow is characterized by chaotic and irregular fluid motion with high levels of fluctuation in velocity and pressure. This results in a large amount of energy dissipation and mixing within the fluid. Shear stress is the force per unit area that is exerted on the fluid as it flows past a surface, and in turbulent flow, the shear stress is highly fluctuating and irregular, similar to the velocity and pressure fluctuations. In fact, the irregularities in the fluid motion that cause turbulence are often a result of the shear stress on the fluid. Therefore, in systems with turbulent flow, the magnitude and distribution of the shear stress can be highly variable and difficult to predict, making it an important consideration in the analysis and design of fluid systems [6]. Therefore, it can be said that based on the streamlined plots, the results are acceptable.

4 Conclusion

In conclusion, this research paper highlights the potential benefits of optimizing arterial stent geometry to reduce shear stress on the arterial wall and mitigate the risk of restenosis. By utilizing computational fluid dynamics simulations and finite element analysis, the study investigated the impact of various stent design parameters on blood flow and mechanical stress distribution within the stented artery. The findings suggest that optimizing the stent geometry to a cross-sectional area of approximately 5.2 to 10 cm^2 can effectively reduce shear stress, to an optimal range that the human body can sustain (a range of 2.3 ± 1.04 Pa), on the arterial wall and improve clinical outcomes for patients with coronary artery disease. However, there are several hazards associated with stent design and implantation, and the choice to use a stent as a treatment should be made in conjunction with a skilled medical expert. Furthermore, it should also be noted that each individual may require different needs, and optimization to the needs of individual patients should be considered on a one-by-one basis.

The study provides valuable insights into the impact of stent design on blood flow patterns and stress distribution, which can inform the development of more effective arterial stents. While the use of COMSOL modeling software may have some limitations, this research showcases the potential benefits of utilizing computational modeling to study the fluid dynamics and mechanical stresses within stented arteries. Looking into the future it would be most efficient to utilize finer meshes within the COMSOL simulations as they would yield the most accurate results. Therefore, to increase accuracy we would ideally need to modify the geometry to properly replicate human stent model. This is most efficiently achieved by analyzing the aorta geometry and creating a model based off of those criteria.With ongoing advancements in computational modeling, it is likely that future studies will continue to shed light on the optimal design and development of arterial stents, ultimately improving clinical outcomes for patients with coronary artery disease Finally, it is essential to emphasize the importance of continuing research in this area to minimize the risk of restenosis and improve overall patient outcomes.

Biomedical engineering ethics are an essential structure to the moral obligations of innovation and research. Specific characteristics of bioethics are integrity, responsibility, and self-discipline. The main moral principles are autonomy, justice, beneficence, nonmaleficence, and fidelity. Current research hasn't provided insight into animal and human testing. The next step for our research would be to create more prototypes to garner more accurate data and a safer model. In vitro testing would need to follow data acquisition to create a model that more accurately represents the human aorta. At this time, there are no ethical issues during our computational modeling. In future research, specifically involving in vivo testing, human subjects have the right to be informed about our research and the liabilities they may experience from it. Liabilities may include thrombosis, arterial wall deformation, and other adverse effects. It is our responsibility to supplement treatment for symptoms experienced as a result of our in vivo testing. Finally, we will respect cultural and individual differences, ensuring that choices are consistent with each person's beliefs and values. When developing a stent designed to reduce restenosis, we recognize the importance of considering the ethical implications of its utility. Ensuring the stent's safety, effectiveness, and accessibility is our primary responsibility, along with considering the cost and long-term impact on patient health and well-being. Taking a utility-based approach to ethics allows for the development of a stent that can have a significant positive impact on patient health while minimizing any potential harm. By committing to these principles, we will ensure that testing is conducted in a manner that is fair, equitable, and ultimately beneficial to all.

5 Suplemental Materials

The COMSOL model was created in a 3D format with laminar flow and time dependent. An ellipse built in a work plane was extruded 10 cm. The dimensions of the cross-sections were altered after every simulation in order to recreate different cross-sections. The minor axis dimensions were organized in cohorts of 5 and each cohort increased by 0.25 cm starting from 1 cm to 1.75 cm. The major axis dimensions started at 1.075 cm and increased by 0.05 cm after each run where the largest dimension was 2.025 cm. A total of 20 cross-sections were tested. An elliptical cone was then added to the elliptical cylinder with a base of the same size as the elliptical cylinder. A circular cylinder with a radius of 1.25 cm and a height of 10 cm was positioned so that it would overlap the elliptical cone. The ratio of the elliptical cone was adjusted so the top of the cone and the top of the circular cylinder were not visible as they were hidden within each other. The entire geometry was mirrored across the center point of the elliptical cylinder. After mirroring, the geometry was unioned.

Initial values, a wall, an inlet, an outlet, and fluid properties were selected based on actual, average aorta values. The inlet value was defined as a flow rate based on a pulsatile flow file updated. The outlet was defined as a pressure value that was the same as the initial pressure value. The pressure values were changed three times for each trial; the values were specifically 14665 Pa, 15332 Pa, and 16000 Pa. The wall was defined as the exterior of the entire geometry except for the inlet and outlet. The density of the fluid was set to 1060 kg/m^2 and the viscosity was set to $4e^{-3}$. A coarser mesh was selected in order to reduce computational strain. The simulation was set to run for two seconds and two 3D cutpoints were

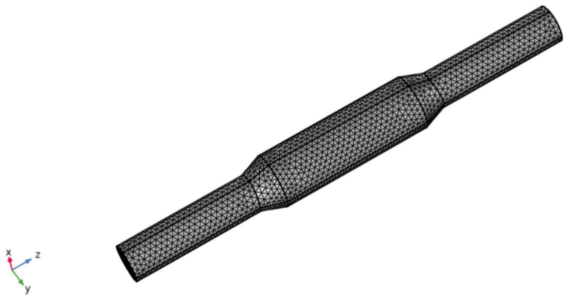


Fig. 4: An example mesh taken from a model with an elliptical cross-section of 11.13302 cm^2

added to the results section in order to determine the shear rate. Streamlines and velocity profiles were determined from the velocity output of results and a cut plane respectively.

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