

# Design and Evaluation of Coronary Artery Stent Geometry Based on Finite Element Analysis

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## Abstract

The implantation of stents in coronary arteries is a common procedure for patients diagnosed with stenosis, a narrowing of the arteries. Numerous studies have reported a significant relationship between the growth of stenosis and the configuration of stent struts. Different stent geometries result in varying peak stress, residual stress, and recoil percentage within the stented coronary artery. This study aims to determine the static structural behaviour near stent strut configurations based on different parameters. To achieve this, three-dimensional models of stents and simplified coronary arteries with balloons were created using computer-aided design (CAD) software. ANSYS was then used to simulate three different stent shapes. A parametric study was conducted to predict stent performance based on the variations in stent strut geometry. The results showed that all stent models calculated the mentioned parameters. The graphs indicated that the D1 stent model, with a particular stent strut shape, exhibited the lowest residual stress of 120.46 MPa. On the other hand, the D2 stent model demonstrated the lowest peak stress of 299.41 MPa. However, considering all the performance indicators, the D1 stent model exhibited the best overall stent performance compared to the others. In conclusion, the D1 stent model demonstrated favourable stent performance by predicting a lower percentage of thrombosis formation and reducing the growth of re-stenosis.

## 1. Introduction

A coronary artery stent is a type of medical device used to maintain or restore the patency of an individual's coronary artery. Atherosclerosis, another name for coronary artery disease (CAD), happens when an excessive amount of cholesterol accumulates in the blood vessel walls [1]. A stent is a tiny mesh tube that is placed inside the narrowed section of a coronary artery to hold the blood vessels open and prevent plaque from blocking blood flow to the heart as well as reduce the risk of a heart attack [2].

Despite the various stent designs and manufacturing methods that have been proposed, there have been reports of complications such as stent thrombosis, restenosis, and myocardial infarction in patients [3]. Since then, researchers have been working on developing a number of different coronary stents. To establish a competitive advantage in the market, stent designs have been introduced with a wide range of shapes, sizes, and strut diameters [4].

To optimize the geometry and performance of the stent, FEA is an efficient way to study its mechanical characteristics. This study examines the relationship between the stent geometry and its strength and flexibility

in the coronary artery. To achieve the result, it requires analysis on existing stent geometry design as well as simulation by using the FEA software. This is required to find any weakness behaviour to the design itself.

This part includes the modelling of stent, balloon, and vessel with plaque. There will be the design optimization for the stent geometry to counter any deficiency. Following the new coronary stent geometry design, another simulation is essential to compare the performance between the existing and newer generation of stent geometry. Therefore, the stent designs in this research are studied by design and simulation software by comparing the designs with different geometry of shape, size and structure.

## 2. Methodology

### 2.1 Materials

Table 1 presents a compilation of commercially available stents that have been extensively utilized in medical treatments for coronary artery. These designs are continuously being improved to provide better treatment options for patients. The different types of commercially available stents have unique designs that are suitable for specific cases.

**Table 1** Specification of commercial stent

No	Type Of Stent	Type	Linked Cell	Size Range		Strut Dimension
				Length	Diameter	
1	Bx Velocity	Slotted Tube	Closed Cell	8–33 mm	8–33 mm	0.13 mm wide x 0.14 mm thick
2	Driver	Tubular mesh	Closed Cell	9–30 mm	2.8–4.0 mm	Diameter, 0.091 mm
3	Gianturco-Roubin II	Coil	Open Cell	12–60 mm	2.5–5.0 mm	0.172 mm wide x 0.076 mm thick
4	Nirflex	Slotted Tube	Closed Cell	9–32 mm	2.5–4.0 mm	0.1 mm thick
5	Multi-Link RX	Slotted Tube	Closed Cell	8–28 mm	2.0–2.5 mm	0.096 mm wide x 0.099 mm thick
6	Palmaz-Schatz	Slotted Tube	Closed Cell	8–18 mm	3.0–5.0 mm	0.09 mm thick

For the geometric modelling, SolidWorks 2021 is a computer-aided design (CAD) software utilized for sketching, designing, and creating technical drawings. It offers various features such as parts, assembly, and drawing, enabling the creation of detailed models. The part feature allows for the creation of individual components, while the assembly feature brings these components together to form a 3-dimensional (3D) product.

In this research, ANSYS 2023 software is employed for simulating the mechanical behavior of a stent within an artery. It facilitates the creation of a numerical model representing the stent and its surrounding environment. ANSYS is also capable of predicting the long-term performance of a stent, including its ability to maintain open vessel patency and prevent restenosis.

### 2.2 Methods

The purpose of this study is to gain essential understanding about recoil percentage, peak stress, and residual stress, as well as their impact on stent implantation in coronary arteries with three different geometries. The diameter (D) of the coronary artery is 4 mm, and its length (L) is 10 mm. Previous researchers have simplified the model by using a cylindrical shape without any narrowing and keeping it straight. The model consists of a simplified balloon and a stent.

**Table 2** Stent Strut Configuration

No	Stent	Types Of Links Structural	Types Of Unit Cell	Shape Pattern	Number Of Slot (Per Unit Cell)
1	D1	No connector	Closed	Repeated pattern	32
2	D2	Bridging	Open	Wavy S	9
3	D3	Bend shapelink	Closed	Hexagon	20

The stent strut configuration is derived from the geometry of a commercial stent (referred to Palmaz Schatz). Three stents are considered, assuming a straight cylindrical tube shape, as depicted in Figure 1. The stent models share a closed cell structure. The stents have a length (L) of 9 mm, an outer diameter (OD) of 2.5 mm, and an inner diameter (ID) of 2.35 mm.

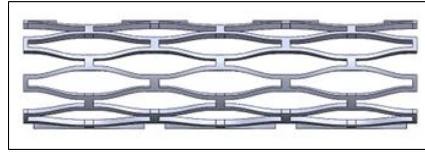


Fig. 1 Illustration of stent D1

Material properties define the mechanical behavior of the materials used in the analysis. This data includes parameters such as density, Young's modulus, Poisson's ratio, thermal conductivity, and specific heat. The balloon material is modelled using the Hyper elastic Mooney-Rivlin 2 parameter material model. The stent material which assigned to structural steel is modelled using the Plasticity Bilinear isotropic hardening material model. This model is suitable for simulating the behavior of structural steel, which is commonly used in stent manufacturing.

Table 3 Properties of Hyper elastic and Plasticity

Properties	Hyper Elastic	Plasticity
	Mooney-Rivlin 2 Parameter	Bilinear Isotropic Hardening
Density (Kgm <sup>-3</sup> )	7850	-
Young's Modulus (Pa)	2E+11	-
Poisson's Ratio	0.3	-
Bulk Modulus (Pa)	1.67E+11	-
Shear Modulus (Pa)	7.62E+11	-
Yield Strength (Pa)	2.07E+08	-
Tangent Modulus (Pa)	6.92E+08	-
Material Constant C10 (Mpa)	-	-
Material Constant C01 (Mpa)	-	0.114
Incompressibility Parameter D1 (Pa <sup>-1</sup> )	-	0

Geometric data in ANSYS provides crucial dimensional information about the components or structures under analysis, including their shapes and orientations. In the case of stent design D2 it is imported from SolidWorks 2019 into ANSYS for performance evaluation and behavior analysis under different operating conditions. Additionally, the "balloon" geometry, which is essential to the analysis, is created using ANSYS's DesignModeler, an integrated modelling tool. This allows to gain valuable insights into the behavior and response of the designs through ANSYS's simulation capabilities.

Meshing refers to the process of dividing the geometry of a model into smaller discrete elements, such as nodes and elements, to create a mesh. The mesh forms the numerical representation of the model and serves as the basis for solving the governing equations during simulation.

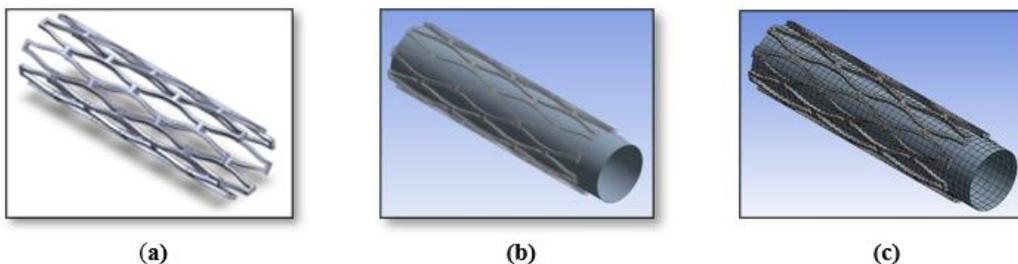


Fig. 2 (a) Stent design (b) Simplified Geometry (c) Meshing

To ensure mesh quality around the stent strut configuration, a tetrahedral mesh is employed for the artery model. The choice of tetrahedral elements is driven by the complexity of the stent model. To achieve the most accurate results, the finest meshing is concentrated in the vicinity of the stent strut configuration.

Boundary conditions define the constraints and external influences applied to a finite element model during a simulation. They help simulate the behavior of the system within a defined environment. Boundary conditions are essential for accurate analysis and interpretation of results. Displacement boundary conditions specify the displacement or movement of a specific point or region in the model. For example, fixing a particular point to prevent any movement or applying a specific displacement to simulate a loading condition. Force boundary conditions define the external forces applied to the model. Forces can be applied in different directions and magnitudes to simulate loads such as pressure, gravity, or other external forces. Constraint boundary impose restrictions on the model's degrees of freedom. They can prevent certain displacements or rotations from occurring in a particular direction, representing fixed or constrained regions.

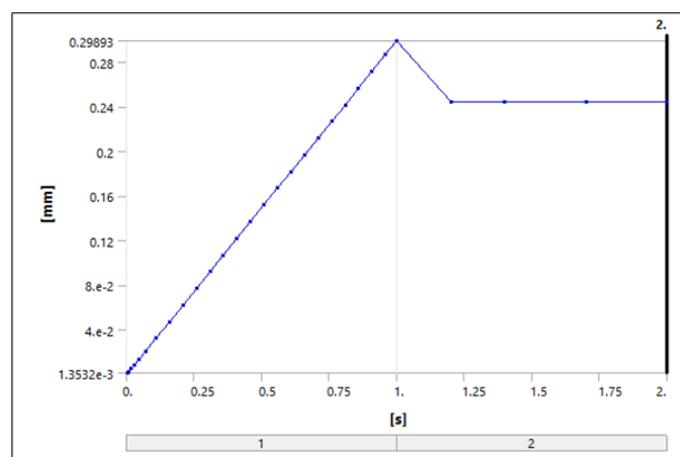
Boundary conditions are applied to different surfaces, edges, or nodes of the model, depending on the specific requirements of the analysis. They help define the model's response to external influences and provide a realistic representation of the system's behavior. It's important to carefully define and assign appropriate boundary conditions in ANSYS to ensure accurate simulation results and meaningful analysis of the model's response under different conditions.

### 3. Results and Discussion

Computational-aided design modelling was employed to evaluate the static structural performances of the stented coronary artery. The results obtained from the numerical analysis were validated against experimental data from previous studies to ensure the accuracy of the assumptions made in the simulation models.

#### 3.1 Directional Deformation

Figure 3 represents the directional deformation values at different time intervals. The x-axis represents time in seconds, while the y-axis represents the deformation value in mm. The graph shows the average directional deformation of Stent D1 over a specified period, with time measured in seconds and deformation values in millimetres. At the starting point of 0 seconds, the average deformation is recorded as  $1.3532e-003$  mm. This initial value suggests that the stent is relatively stable or in its original configuration at the beginning of the measurement. As time progresses to 1 second, the average deformation increases to  $2.8407e-003$  mm. This indicates that within the first second, the stent experiences additional deformation or displacement from its initial state. The increase in the average value at this time point suggests that the stent's shape has changed noticeably compared to its original configuration.



**Fig. 3** Directional Deformation D1

At 2 seconds, the average deformation continues to rise to  $5.073e-003$  mm. This further demonstrates a consistent trend of deformation over time, signifying continuous changes in the stent's structure. The increase in the average value from 1 second to 2 seconds implies ongoing deformation or displacement, with the stent adapting and altering its shape throughout the measurement period. Overall, the graph illustrates a clear and continuous upward trend in the average deformation of Stent D1 over the recorded time period. This trend indicates that the stent is experiencing directional deformation, and its structure is evolving or adjusting as time elapses. The observed increase in average deformation suggests a cumulative effect, with the deformation accumulating progressively over time.

### 3.2 Equivalent Stress

Von Mises stress (Equivalent Stress) analysis is performed to evaluate the structural integrity of the system.

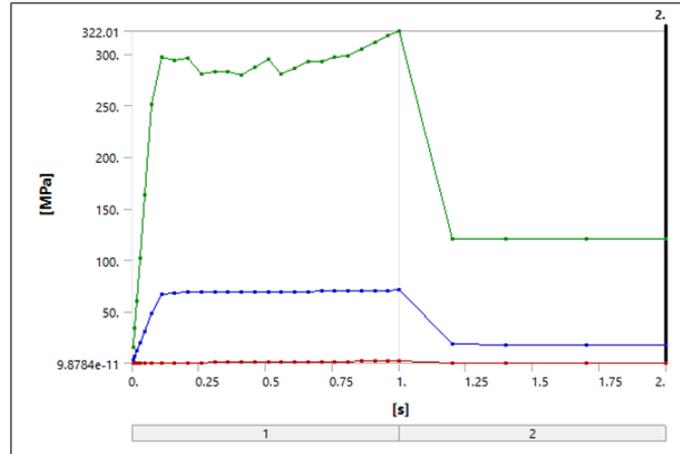


Fig. 4 Equivalent Stress D2

The dataset presents the equivalent stress values for stent D1 at various time intervals from the beginning to the end of its deployment. Equivalent stress is a critical mechanical parameter used to assess the stent's structural integrity and mechanical performance under different loading conditions. At the start of deployment (5.e-003 seconds), the minimum equivalent stress is 1.065e-002 MPa, indicating relatively low mechanical loading on the stent. As time progresses, the minimum stress gradually increases, reaching 1.976 MPa at the end of deployment (1 second). This suggests that even during less demanding phases, the stent experiences appreciable mechanical forces.

Conversely, the maximum equivalent stress for stent D1 starts at 15.437 MPa and increases significantly as the deployment progresses. At the end of the deployment (1 second), the maximum stress reaches 322.01 MPa, signifying critical moments of intense mechanical challenge. These peak stress levels are crucial to consider when evaluating the stent's mechanical performance and its ability to withstand extreme loading conditions. The average equivalent stress demonstrates a steady increase from 3.077 MPa to 70.79 MPa at 1 second, indicating the overall mechanical behaviour of the stent during its deployment. The rising trend in average stress reflects the cumulative mechanical loading experienced by the stent throughout the deployment process.

### 3.3 Total Deformation

Total deformation is a critical mechanical parameter used to assess the stent's ability to expand and conform within the surrounding anatomical environment.

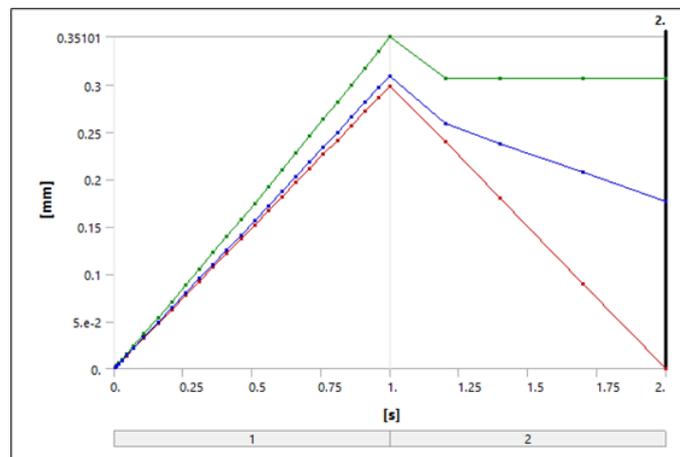


Fig. 5 Total Deformation D2

At the beginning of deployment (5.e-003 seconds), the minimum total deformation is 1.3136e-003 mm, indicating the initial expansion of the stent. As time progresses, the minimum deformation gradually increases, reaching 0.29889 mm at the end of the deployment (1 second). This signifies that the stent undergoes more significant expansion as it adapts to the surrounding anatomical conditions. Similarly, the maximum total

deformation for stent D1 starts at  $1.5916e-003$  mm and increases steadily as the deployment proceeds. At the end of the deployment (1 second), the maximum deformation reaches 0.35101 mm, indicating the maximum expansion or deformation the stent experiences during deployment. This reflects the stent's capacity to adapt and accommodate different anatomical variations. The average total deformation demonstrates a consistent increase from  $1.4321e-003$  mm to 0.30977 mm at 1 second. This average value represents the overall deformation behaviour of the stent during its deployment process.

After reaching the peak deformation, the values start to decrease gradually. From 0.1 seconds to 1 second, the deformation values fluctuate but remain relatively high compared to the initial stages of the simulation. The average deformation during this period ranges from 0.10251 mm to 0.18663 mm, indicating a sustained level of deformation in the system. Towards the end of the simulation (around 1 second), the deformation values stabilize, with the minimum, maximum, and average deformation values converging to a relatively steady state. The system has reached a new shape or structure, and the deformation remains within a certain range.

### 3.4 Data Summary

As per the FDA's recommended submission guidelines for stents, the stent model should be configured to provide outputs for three essential parameters: recoil percentage, peak stresses, and residual stresses resulting from deflation and contact separation. The recoil percentage is determined by examining the deformation of a specific point on the stent and subtracting the maximum displacement value after relaxation from the maximum displacement value. During previous clinical trials involving the implantation of Palmaz Schatz stents in humans, the occurrence of acute stent recoil ranged from 3% to 15% [5]. Peak stress is determined by evaluating the Von-Mises equivalent stress criterion at the point of maximum displacement of the stent. Similarly, level of the tensile residual stresses in a coronary artery stent scatters usually between 100 MPa until 420 MPa according to [6], which can vary based on the specific stent design and the intended application. This measurement helps determine the total stress resulting from plastic deformation.

**Table 4** Final Data Collected from Graphs

	Stent D1	Stent D2	Stent D3
Directional Deformation (mm)	0.29893	0.22858	0.32333
Equivalent Stress (MPa)	120.46	235.71	192.29
Total Deformation (mm)	0.30633	0.30633	2.1485
Recoil Percentage (%)	9.34%	4.14%	5.40%
Peak Stress (MPa)	302.02	299.41	330.97
Residual Stress (MPa)	120.46	235.71	192.29

After a thorough analysis of the provided data in Table 4, we can determine the most suitable stent by comparing several crucial parameters. The residual stress values play a vital role in assessing the stent's ability to withstand plastic deformation and relaxation. In this context, Stent D1 stands out as it demonstrates the lowest residual stress value, indicating excellent resistance to deformation. Furthermore, while Stent D1 exhibits a slightly higher recoil percentage compared to Stent D3, it still maintains a relatively low value, implying favourable performance in maintaining its shape after relaxation. Moreover, Stent D1's peak stress value, though slightly higher than that of Stent D2, remains well within an acceptable range for desirable stent characteristics. Thus, all things considered, Stent D1 emerges as the most promising option overall, striking a balance between key parameters and offering superior performance potential.

### 4. Conclusions

The project successfully achieved its objective of simulating the static structural behavior of the stent against the balloon using SolidWorks for design and ANSYS Workbench for analysis. The study examined the deformation and failure characteristics of different stent designs, focusing on the peak stress, recoil percentage, and residual stress in the polar direction of the stent. A comparison was made between the results obtained from the previous design model, the Palmaz Schatz stent.

The analysis revealed that the stent deformation increased with stents D1, D2, and D3, suggesting that the material properties and shape of the stent can influence deformation. The geometry of the stent plays a crucial role in determining the level of deformation, with variations in size, shape, strut thickness, spacing, cell design, and stent materials affecting stress distribution and concentrations. It was also noted that a low recoil percentage indicates better stent performance, as it indicates that the stent maintains its shape after relaxation, while a high recoil percentage suggests significant deformation.

Furthermore, lower peak stress values were found to be desirable for stents, as they indicate lower stress levels at the point of maximum displacement. Based on the provided data, stent D1 exhibited the best overall performance, as it had the lowest values for, equivalent stress, total deformation, and residual stress. However, it is important to consider additional factors and requirements when selecting the most suitable stent for a specific application.

This research generated numerous results and offered various possibilities for analysis based on the provided data. However, there is room for improvement to enhance the accuracy of the study. It is recommended to ensure proper implementation of the research methodology and minimize errors. Several aspects of the study require improvement to obtain more precise results:

- i. Tetrahedral meshing is recommended for this case study because it allows for a more focused mesh resolution in the stent area, leading to improved results, particularly in capturing directional deformation accurately.
- ii. It is advisable to use the original license of Ansys software instead of the academic license in this case, as the academic license restricts the number of simulation nodes to a maximum of 512k since this will limit the probability of best result.
- iii. Create three distinct cross-sectional configurations for stent struts to explore in future research.
- iv. Include a simplified coronary artery design to enable accurate real-time comparisons between the stent and the coronary artery in future studies.

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