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Flexibility Analysis Unexpanded Balloon-Expandable Stent with Finite Element Method

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Abstract

A stent is a mesh of micro metal tube commonly used to provide support to an enlarged blood vessels that are narrowed due to plaque growth. To function correctly, a stent must have specific characteristics, which includes good flexibility. The flexibility of the stent can be predicted using the finite element method simulation. The type of stent studied are the sinusoidal and spiral type balloon-expandable stent. The 3D model is created in Solidworks 2016, while the structural analysis is performed with ANSYS Workbench Student R18. The simulation carried out is a four-point bending test. The analyzed parameters are the von Mises stress and the flexibility value of the stent. The material model for the stent is isotropic multilinear hardening SS 316 L, while the balloon was polyurethane rubber which is modeled as hyper-elastic material. The results obtained from this study are sinusoidal type stents can be deflected up to 0.221 mm to remain in the elastic area, while spiral type stents can be deflected up to 0.109 mm. The maximum flexibility value of the sinusoidal type stent is 0.003526 $N^{-1}\cdot mm^{-2}$ while the spiral type stent is 0.002478 $N^{-1}\cdot mm^{-2}$.

Keywords: Balloon-expandable stent, FEM, flexibility, four-point bending test

1. Introduction

Coronary heart disease is a disease that caused by a blockage or narrowing of the heart's coronary arteries. The blockage occurs due to the plaque formation in the heart's blood vessels, thus blocking the blood flow through the heart. The blockage results in a reduced oxygen and blood supply throughout the body.

Consideration of doctors and engineer's point of views are essential to produce good stents. As an example, the material of a stent must be compliant to a certain standard in regards to human body's susceptibility to foreign objects. Some of examples of good stents criterions are flexibility, biocompatibility, radial stiffness, trackability, conformability, recoil, and others [1].

Flexibility are generally defined as the ability of the stent and its attachment system to adapt to the anatomy of the blood vessel without compromising its implanting function. The flexibility of a stent is assessed by two criterions, whether the stent can pass through the vessel curvature, and whether the deployed stent can adapt to the vessel wall [2]. The flexibility of a stent is an important parameter to prevent restenosis.

Flexible stents are easy to expand and better adapt to vascular anatomy than rigid stents. However, overly flexible stents are found to be unsuited for treatment. A study found that overly flexible stents fail after being installed in the coronary vessels. The probability of failure due to overly flexible stents might reach 5% [3].

Due to the importance of flexibility criterion stated above, this paper studies the stent flexibility of various stent designs. The authors proposes using finite element method to conduct the stent flexibility study due to its better cost effectiveness and study flexibility compared to a clinical or other experimental study [4]. Several past researches regarding stent flexibility using finite element method has been conducted [5–7] on various stent designs. This paper studies the flexibility of sinusoidal and spiral stents design.

2. Research Method

The research was carried out numerically using Solidworks 2016 as the geometry modeling software and ANSYS R18 as the simulation software.

2.1. Stent Modelling

The model creation is begun by creating a 2D sketch of sinusoidal and spiral stents. The 2D sketch is laid out as a rectangle with length of 24.96 mm and height of 3.15 mm. The sketch would be formed into a stent model of diameter of 1 mm and length of 25 mm which corresponds to the original model. The 2D sketch design of each stent models are shown in Figure 1.

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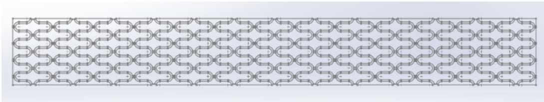
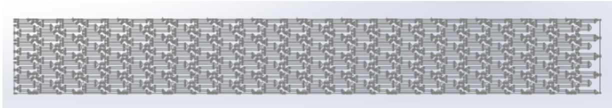
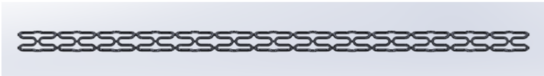


(a) Sinusoidal Stent.



(b) Spiral Stent.

Figure 1. Stent mesh design.



(a) Sinusoidal Stent.

(b) Spiral Stent.

Figure 2. Final stent geometry.

The process above is followed by making a solid cylinder with diameter of 1 mm and length of 24.96 mm. The previously made 2D sketch is then wrapped onto the cylinder, using a deboss of 0.08 mm on the cylinder as the thickness of the stent. Then, the debossed cylinder are extrude cut by a circle with a radius of 0.42 mm to remove the cylinder's center part. The final geometry are shown in Figure 2.

2.2. Material Properties

The stent material used is SS 316L, and the balloon material used is polyurethane. The stent material is modelled as a multilinear isotropic properties to produce results that match the actual material. This value is obtained from the fitting-curve tensile test of SS 316L, whose material behavior is shown in Table 1 and plotted in Figure 3 below. The stress-strain curve obtained from the tensile test [8] is used as the material properties of the stent.

The balloon is modelled as an isotropic 2 parameters Mooney Rivlin 2 parameters hyperelastic material, which allows modelling of ballon expansion up to 300% of its original size. Balloon material properties are taken from research [9, 10]. Table 2 shows the summary of balloon and stent material properties.

2.3. Meshing

Meshing is the process of dividing the analysis objects into smaller elements which significantly affects the results of the simulation. Therefore, meshing must be done with the appropriate type and number of elements [11].

In this study, the mesh type for the balloons are modelled as solid with quadratic type mesh due to the geometric shape of the tube-shaped balloon, while the stents are modelled as curvature mesh due to shape of the stent being dominated by curves.

Table 3 below is a mesh convergence test table comparing the number of elements and the von Mises stress of the stent. By considering Table 3 below, mesh size of 0.02 mm is chosen because the higher number of elements does not show significant (less than 5%) von Mises stress difference.

2.4. Contact

Definition of contact between bodies are necessary in a multiple bodies simulation cases. Improperly defined contact between bodies leads to convergence difficulties. There are various types of contact, including bonded, no separation, rough, frictional, and frictionless. This study defines the contact between the balloon and the stent as frictional with friction coefficient of 0.125 and a normal stiffness factor of 0.1. The formulation used is Augmented Lagrange with "nodal-projected normal from the contact" detection method. Augmented lagrange detection method is chosen due to its less sensitivity to contact stiffness thus improving convergence. "Projected normal from the contact" is a contact detection method which detects overlap between contacting surfaces. This method has a better accuracy compared to other models despite of it being computationally expensive. Figure 4 shows the complete definition of contact.

2.5. Load and Boundary Conditions

The simulation case being carried out in this study is a four-point bending test simulation on a stent with a balloon inside. To simulate mentioned case, both right and left ends, and the center of the stents are given 0 degrees of freedom for X, Y, and Z translations, as well as X and Y rotations. Meanwhile, Z rotations are made free. The balloon are fixed at both of its ends. Opposing forces boundary condition of 1.5 N are given at the quarter and three-quarters of total distance from the left side of the stent. Figure 5 shows the demonstration of boundary condition application in this paper.

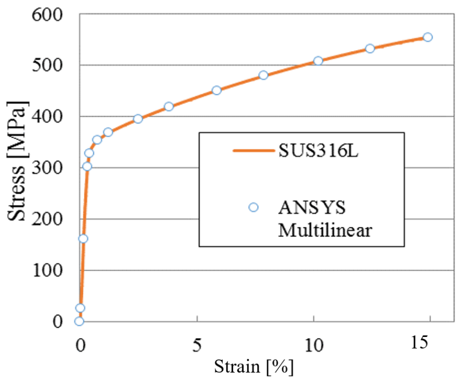


Figure 3. Fitting-test results of SS 316 L tensile test.

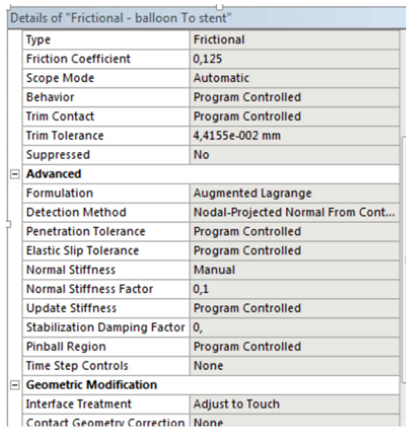


Figure 4. Contact Definition.

Table 1. Stress and strain data from tensile test of SS 316 L.

Point	Stress (MPa)	Strain (mm/mm)	Point	Stress (MPa)	Strain (mm/mm)
1	0.00	0	8	394.76	0.025
2	24.67	0.000113	9	418.59	0.038
3	161.13	0.0014	10	450.90	0.058
4	301.02	0.003	11	479.28	0.078
5	328.10	0.004	12	508.05	0.10
6	352.79	0.0075	13	532.17	0.12
7	369.32	0.012	14	553.38	0.15

Table 2. Material Properties of balloon and stent in Ansys R18.

Components	Balloon	Stent
Density (kg/m^3)	1380	7990
Material	Polyurethane	SUS 316 L
Modulus Young (GPa)	0.03447	218.319
Poisson's Ratio	0.495	0.33
Material Behavior	Hyperelastic	Multilinear Isotropic Hardening
Material Constant	Mooney-Rivlin (MPa): $C_{10} = 1.032$ $C_{01} = 3.693$ d = 0.004261	Fitting stress-strain curve from the SUS 316 L tensile stress test result

Table 3. Mesh Convergence.

Size (mm)	Number of Elements	Number of Nodes	Quality	Von Mises (MPa)
0.1	39854	99141	0.466	321.88
0.09	57369	137233	0.561	359.72
0.08	62322	143487	0.542	361.22
0.07	78508	181836	0.608	404.15
0.06	93816	224856	0.705	436.51
0.05	122808	287495	0.703	472.53
0.04	275631	544633	0.719	493.79
0.03	596617	1092082	0.784	532.02
0.02	1914349	3276202	0.835	542.57
0.01	3455791	5787420	0.848	543.09

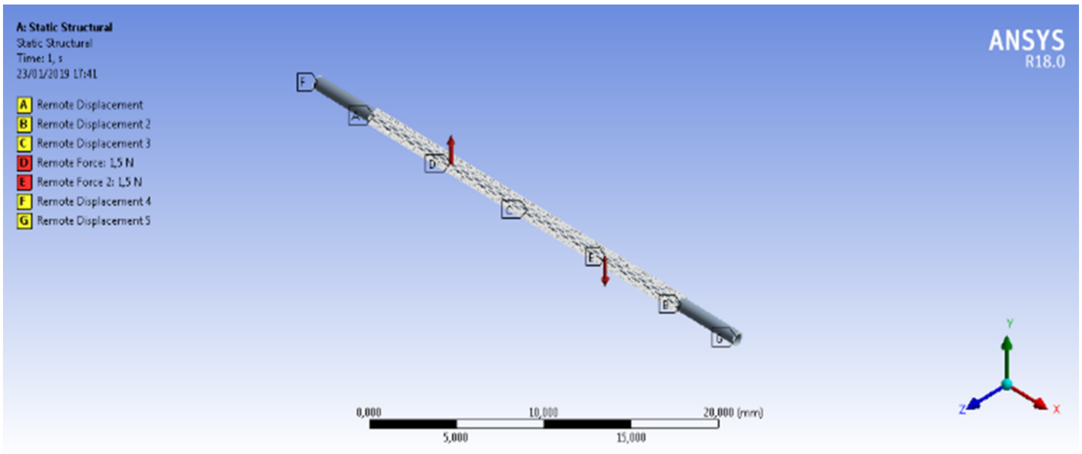


Figure 5. Load and boundary condition of stents and balloons.

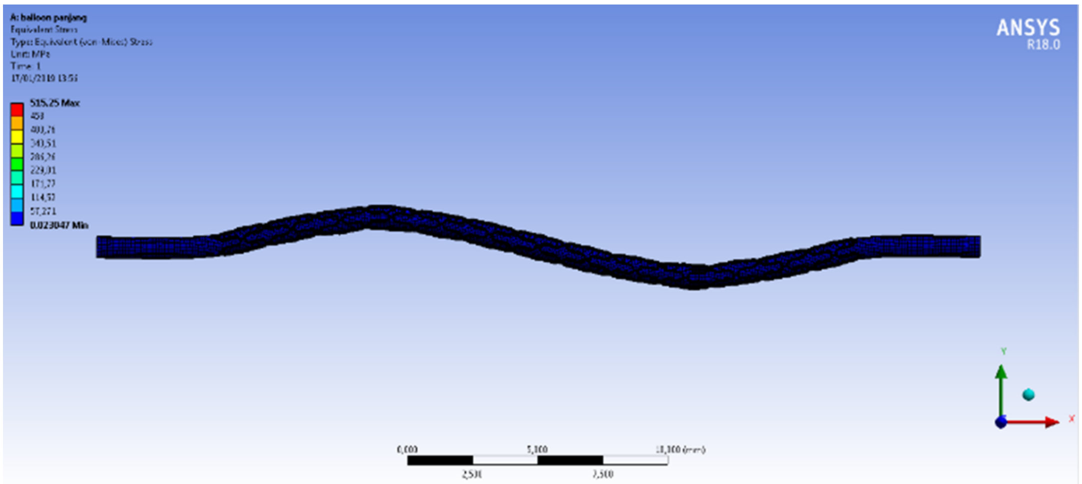


Figure 6. Stent's final geometry with the load given.

2.6. Solution Control

The last step in the simulation setup is to determine the parameters that can be retrieved and analyzed. This study analyzes the von Mises stress and Y-direction deformation of the stent. The reaction force at the support are also be taken as simulation results validation [12].

3. Results and Discussion

The results being discussed in this section are the Von Mises equivalent stress distribution and flexibility analysis, which is shown by the occurring stent deflection. In the flexibility simulation with the four-point bending test method, an opposing load of 1.5 N is given at the 1/4 of the stent length in the positive y-axis direction and the 3/4 of the stent length in the negative y-axis direction. The supports are placed at both ends of the stent. The simulation result is shown by Figure 6

3.1. Von-Mises Stress Analysis

Figure 7 below shows the largest von Mises stress of the stent. Figure 6 shows that that the largest von Mises stress occurs on the stent part which being applied force loading. For the sinusoidal stents, the largest von Mises equivalent stress is 541.58 MPa. Meanwhile, for spiral stents the largest von Mises equivalent stress is 546.59 MPa. Comparing the value to the ultimate tensile strength and yield strength of SS 316L, 554.02 MPa and 332 MPa, respectively, the loading applied to the stent causes plastic deformation.

Both sinusoidal and spiral-type stents are assumed can safely pass through curving blood vessels when the occurring von Mises stresses are in the elastic region or below the yield strength. The ultimate tensile strength of SS 316 L material is 554.02 MPa, while its yield tensile strength is 332 MPa. By comparing the results of both sinusoidal and spiral stents with the tensile strength of the SS 316 L material shown in Figure 8, the loading in the simulation results in a plastic deformation due to the exceeded the yield strength. However, the stents have not failed because the resulted values are below the ultimate strength.

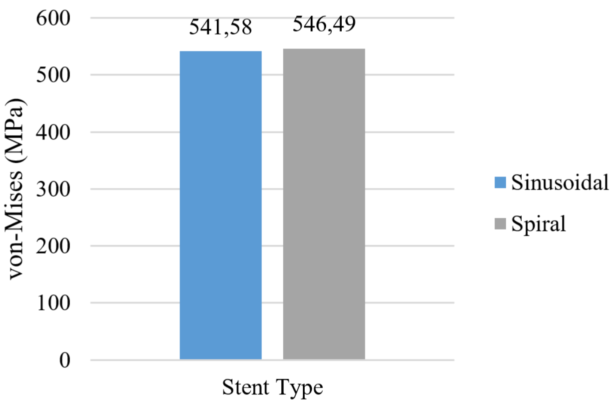
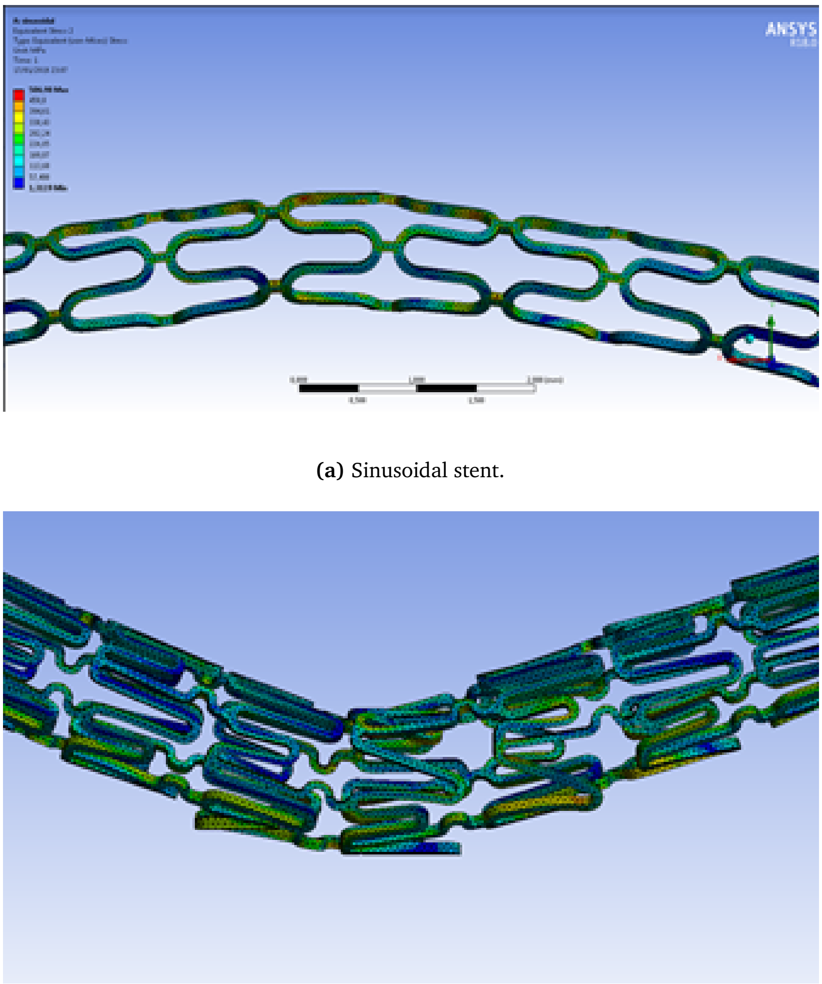


Figure 7. Maximum von-Mises stress.

Another stent design criterion to be considered is the elastic limit of the stent loading during installation. When a stent is in an undeployed state and passes through a bend or curvature of the blood vessel, the stent must able return to its original geometry before deployment. If the von Mises stress in the stent has exceeded the yield strength limit, the stent has permanently deformed. The permanenly deformed stent before deployment should be avoided. For sinusoidal stents, the elastic loading limit is found to be 0.204 N with a resulting deflection of 0.221 mm. Meanwhile, for spiral-type stents the elastic loading limit is found to be 0.141 N with resulting deflection of 0.109 mm.

3.2. Flexibility Analysis by Calculation

The stent loaded by a force will deform in both negative and positive Y-axis direction. Deformation in Y direction is called deflection. Flexibility of a stent can be analyzed from the deflection value, the magnitude of the loading force, the length of the stent, the Young's modulus, and the moment of inertia of the stent. Figure 9 shows the loading diagram and the formulas used in the flexibility analysis [13].



(a) Sinusoidal stent.

(b) Spiral Stent.

Figure 8. Von-Mises stress distribution.

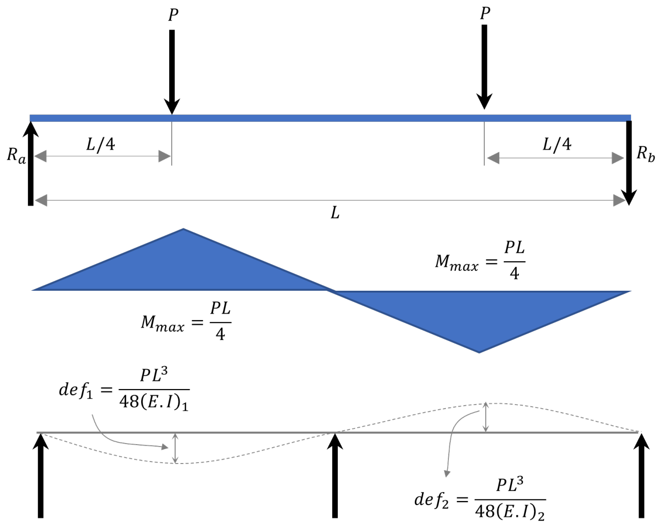


Figure 9. Load and deflection diagram.

Table 4. Mass, Moment of Inertia, and Flexibility Value of the stents.

Cross Section	Mass (gr)	Inertia of Area (Software-calculated) (mm^4)	Flexibility ($N^{-1}.mm^{-2}$)
Sinusoidal 1	0.010315	0.0005036	0.001064
Sinusoidal 2	0.010315	0.0002510	0.002134
Spiral 1	0.016936	0.010094	0.000531
Spiral 2	0.016936	0.006226	0.000860
Spiral 3	0.016936	0.009038	0.000593
Spiral 4	0.016936	0.001644	0.003259

The flexibility of a stent can be calculated by Equation (1).

$$F = \frac{1}{E \cdot I} = \frac{48def}{PL^3}(N^{-1}mm^{-2}) \qquad (1)$$

which:

- def is the deflection value
- P is the magnitude of loading force
- L is the stent length
- E is Young's modulus
- I is the stent inertia

Table 4 shows the stent's mass and moment of inertia data obtained from Solidworks 2016. The data are calculated from the half section of both sinusoidal stents and spiral stents. The sinusoidal stent is sectioned in two areas—the middle of the stent connector and the middle of the stent strut. In the first cross-section, the area moment of inertia is 0.005036 mm^4 with a flexibility of 0.001064 $N^{-1}{\cdot}mm^{-2}$. In the second cross-section, the moment of inertia area is 0.002510 mm^4 with a flexibility value of 0.002134 $N^{-1}{\cdot}mm^{-2}$.

The spiral stent, however, is sectioned into 4 cross-sections due to the more complex spiral stent pattern. In the first cross-section, the area moment of inertia value is 0.10094 mm^4 with a flexibility value of 0.000531 $N^{-1}{\cdot}mm^{-2}$, in the second cross-section, the area moment of inertia value is 0.006226 mm^4 with a flexibility value of 0.000860 $N^{-1}{\cdot}mm^{-2}$, in the third cross-section the area moment of inertia value is 0.009038 mm^4 with a flexibility value of 0.000593 $N^{-1}{\cdot}mm^{-2}$, and in the fourth cross-section the area moment of inertia is 0.001644 mm^4 with a value of flexibility 0.003259 $N^{-1}{\cdot}mm^{-2}$.

The sinusoidal stent shows that the difference in the moment of inertia and flexibility between the first cross-section and second is 0.002526 mm^4 and 0.001070 $N^{-1}{\cdot}mm^{-2}$. Meanwhile, the difference in the moment of inertia area and flexibility in the spiral stent is greater, namely 0.00845 mm^4 and 0.002399 $N^{-1}{\cdot}mm^{-2}$.

From the data shown in Table 4, it is shown that both sinusoidal and spiral stents have different moments of inertia depending on the location of the cross-section. For the sinusoidal stent, only 2 cross-sections is taken due to relatively simple geometry. In contrast, the spiral stent requires 4 cross-sections to obtain an overview of stent's flexibility from the area moment of inertia. Differences in value are found in value of the area moment of inertia and flexibility between the first and second cross-sections in sinusoidal stents. Likewise, the spiral stents also show differences in the value of the area moment of inertia and flexibility in cross-sections 1, 2, 3, and 4.

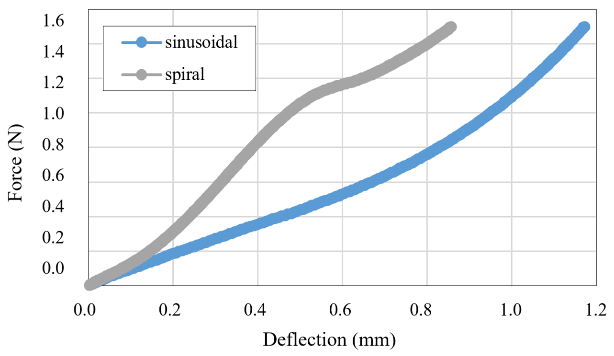


Figure 10. Correlation between force against deflection.

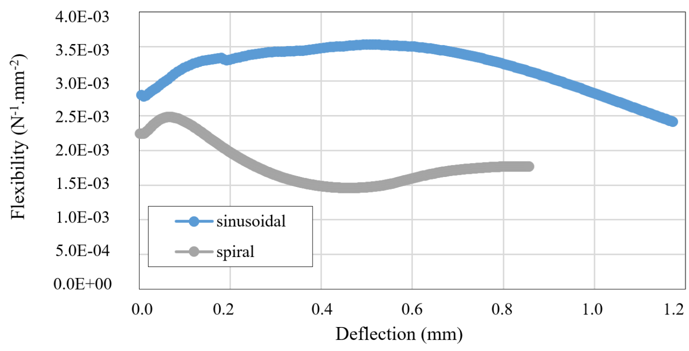


Figure 11. Correlation between flexibility against deflection.

It is difficult to predict the value of the stent flexibility by manual calculation due to the changing cross-section along the longitudinal of the stent, depending on the shape of the pattern. The values obtained by manual calculations only represent the stent flexibility in certain cross-sections. In fact, the flexibility of the stent should not only be analyzed in the cross-section area but also along the stent length. Therefore, a numerical study is necessary to predict the overall stent flexibility.

3.3. Flexibility Analysis by Simulation

Figure 10 above shows that the force versus deflection graph of the spiral stent type stent is located above the force versus deflection graph of the sinusoidal type stent. Both cases are given load starting from 0. However, the resulted deflection occurred in the two stents are different. In the spiral type stent, maximum deflection that occurred is 0.857 mm, while in the sinusoidal stent, the deflection reaches a maximum value of 1.173 mm.

For the spiral stent, the graph has a constantly changing slope that changes from 0 mm deflection to 0.0485 mm deflection. The spiral stent graph has a steep slope. As the force is increased, the deflection change also increases, which is shown by the graph slope. Meanwhile, in sinusoidal type stents, the slope is relatively stable starting from zero deflection until the end of loading which deflection value was 1.173 mm.

The graphs shows that both sinusoidal stents and spiral stents show their conformity to the existing theory. When the force given is greater, the resulting deformation will become more significant. However, the difference of occurring deformation might be caused by various things, such as dimensions, geometry, the magnitude of the loading force, forming materials. Because both types of stents have the same material, the dimensions of both length and radius are the same.

The factors that influence the deformation characteristics that occur are the geometry of stent shape. Sinusoidal type stents have a relatively simpler shape than spirals. The mass of sinusoidal stents is relatively smaller compared to spiral type stents. The average cross-sectional area is also relatively smaller compared to spiral stents. Those differences resulted in difference of deformation characteristics between the two stents.

Figure 11 shows the flexibility versus stent deflection graph. Flexibility is the inverse of the stiffness of an object. The higher the stiffness of an object, the lower its flexibility. According to the data obtained in the study, the maximum flexibility of the sinusoidal type stent at a deflection of 0.507 mm is 0.003526 $N^{-1}{\cdot}mm^{-2}$. This flexibility value yielded when the force reaches 0.444 Newton. In comparison, the minimum deflection is 0.002413 $N^{-1}{\cdot}mm^{-2}$ at a deflection of 1.173 mm. This value occurrs when the force is 1 Newton.

Meanwhile, for the spiral stent, the maximum flexibility occurs at 0.067445 mm deflection with the value of 0.002478 $N^{-1}{\cdot}mm^{-2}$. This value occurs when the force is 0.084 Newton. While the minimum flexibility value is 0.001456 $N^{-1}{\cdot}mm^{-2}$ at 0.4614 mm deflection. The value occurrs when the simulation is carried out with a force of 0.978 Newton.

As shown in Figure 11, the entire portion of flexibility graph of the sinusoidal type stent is above the graph of the spiral stent. The graph yielded by a sinusoidal stent is a curve with a relatively smooth shape. This indicates that the change in flexibility of the sinusoidal stent to deflection and loading is relatively smaller and stable.

As of the graph yielded by the spiral stent, the curve rises to a maximum point and then decreases to a minimum point, then rises again with a relatively gentle slope. This indicates that the change in flexibility of the spiral type stent is more unstable compared to the sinusoidal type stent.

3.4. Comparison of Flexibility by Calculation and Simulation

Spiral type stents were chosen because, in previous studies, spiral stents showed good deformation characteristics. The deformation characteristics reviewed by Pau in 2014 shows that the spiral type stent has a foreshortening characteristic of 8% from the initial length of 25 mm to 23 mm at the final length of the stent after being expanded. Meanwhile, the recoil characteristic is 6.25% from the maximum deformation of 1.6 mm to 1.5 mm at the final deformation as seen from the diameter of the spiral stent.

The values of the deformation characteristics of the spiral stent are considered as good parameters. However, there are other parameters that needs to be assessed for the stent to function properly, which one of them is flexibility. Therefore, this study predicts the flexibility of the spiral stent and compare it with other stent models, namely sinusoidal stents. Sinusoidal type stent is chosen for comparison to the spiral stent due to the sinusoidal stent is one of the stent models used at the beginning stent's usage as a method of treating coronary artery narrowing disease.

The results obtained in this study, both by manually-calculated flexibility results and the simulation flexibility results, show that the spiral stent has a lower flexibility value than the sinusoidal type stent model. While the results of manually-calculated flexibility shows that spiral stents in the fourth cross-section has better flexibility than sinusoidal stents, however the flexibility characteristics can not only be assessed from one cross-section, but the overall length of the stent.

On average, the results show the sinusoidal stents have higher flexibility than spiral stents. In fact, considering the dimensions of the diameter and length of the stent, the two models are built on the same dimensions, 1 mm in diameter and 25 mm in length. However, when viewed in larger picture, the spiral stent has a larger mesh area. It means that the spiral type stent is much denser than the sinusoidal type stent. The higher density of these mesh makes the spiral stent mass higher up to 65.87%. With a higher mass, the material used to make spiral stents is also 65.87% more. This makes spiral stents stiffer than sinusoidal stents.

If we wish to compare the flexibility values of two types of stents, it is recommended that all dimensions, including stent length, stent outer diameter, stent inner diameter, and stent mass, must be made equal or close to the same value with small differences. In such that the difference in the flexibility value obtained is only influenced by the mesh pattern of the stent itself. If there are different parameters, such as the mass of the stent, with a significant difference, the result of the difference in the flexibility value is not only caused by differences in the pattern of the stent nets but also the mass.

4. Conclusion

From the study of the flexibility simulation of sinusoidal stents and spiral stents using the four-point bending test method, it is obtained that the von Mises equivalent stress value on the sinusoidal type stent is 541.48 MPa, while the spiral type stent is 546.49 MPa. Both are still below the ultimate tensile strength material value, therefore the stents are considered as safe. The sinusoidal type stent model can accept deflection up to 0.221 mm to remain in the elastic region, while the spiral-type stent model can accept a deflection of up to 0.109 mm to remain in the elastic region. Sinusoidal stents are more flexible than spiral stents, which shown by the flexibility value of the sinusoidal type stent, which reaches 0.003526 $N^{-1}\cdot mm^{-2}$, is higher than the spiral type stent, which only reaches a value of 0.002478 $N^{-1}\cdot mm^{-2}$. Stents with the same diameter and length dimensions but having more mass has lower flexibility.

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