Design and modeling balloon-expandable coronary stent for manufacturability

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Abstract. Coronary artery disease (CAD) is a disease that caused by narrowing of the coronary artery. The narrowing coronary artery is usually caused by cholesterol-containing deposit (plaque) which can cause a heart attack. CAD is the most common cause mortality in Indonesia. The commonly CAD treatment use the stent to opens or alleviate the narrowing coronary artery. In this study, the stent design is optimized for the manufacturability. Modeling is used to determine the free stent expansion due to applied pressure in the inner surface of the stent. The stress distribution, outer diameter change, and dogboning phenomena are investigated in the simulation. The result of modeling and simulating was analyzed and used to optimize the stent design before it is manufactured using EDM (Electric Discharge Machine) in the next research.

1. Introduction
Coronary artery disease (CAD) is a disease that caused by a plaque of cholesterol and lead the coronary artery to become narrow. CAD is the most deadly disease in Indonesia. More than 2 million people are indicated and diagnosed with CAD in 2013 [1]. The most common treatment to open or restore the narrowing coronary artery is stent implantation. A stent is a small tube that collapsed to a catheter balloon and then delivered and deployed in the narrowed coronary. The deployed stent will open the narrowing coronary and restore the blood flow.

Modeling is very important to provide research tools before a product designs are manufactured. It can be an alternative method to scenarios a various geometries or material and predict the failing of the design. In stent modeling, there are some strategies that used to simulate the deployment process of the stent. Negligible balloon, folded balloon, and hyper-elastic balloon are the most used strategy in stent modeling.

Several studies about stent deployment modeling are found in the literature. The negligible balloon is the most simple in stent deployment strategy. The pressure is applied directly to the inner surface of the stent and neglect the impact of balloon expansion [2-4]. The negligible balloon strategy needs a loading scenario to keep the expansion force equal as the accounted balloon strategy. This paper
presents a stent modeling with the negligible balloon to analyze and evaluate the deformation and stress distribution of the stent prior manufacturing.

2. Material and methods
The investigation about design and modeling of this research are based on 3D modeling and analyzing using a finite element method. A finite element model needs a design geometry, material properties, and numerical aspect.

2.1. Model Geometry
The model of the stent is designed for EDM manufacturability. The inner diameter and outer diameter of the stent are 2 mm and 2.6 mm. That dimension is obtained based on the availability the material and the turning machine capability to provide a raw material of the stent. The stent length of 10 mm with the cell length and width are 2 mm and 0.32 mm. The cell rounded to the stent with space between the other cells of 22.5°. The stent design is shown in Figure 1.

2.2. Material Properties
The stent material is 316L stainless steel. The specification of the material is the young modulus of 196000 N/mm², the poison ratio of 0.3, the yield strength of 375 N/mm² and the ultimate tensile strength (UTS) of 750 N/mm² [8].

2.3. Numerical Aspect
The modeling and simulation use ABAQUS with a dynamic explicit procedure. The stent is modeled with three-dimensional 8-node linear brick with are integration (C3D8R). The finite element mesh consists 23520 elements.

The four-step scenario is performed to simulate the stent deployment. The step scenario consists of initial step, crimping step, expansion step, and pressure release step. The crimping step is performed to simulate the crimping process or to fix the stent into the catheter. After crimped, a pressure applied directly to the inner surface of the stent until the stent deploy. Then the pressure is released. Loading scenarios are used to keep the expansion force equivalent to the balloon pressure. The loading scenarios are presented in Table 1. The contact interactions of the stent are defined as a self-contact.

2.4. Loading Scenario
The negligible balloon scenario causes a different expansion force to the stent. This expansion force definitely smaller than expansion force with the balloon. It happens because the inner stent surface

Figure 1. Stent Design
with the hole of the cell is much smaller than the surface area of the balloon. The loading scenarios are created to keep the expansion force equal when the balloon is negligible. The loading scenario equation is derived from the Pascal law. Therefore, the equation is:

\[ P_{wb} = \frac{A_{balloon}}{A_{stent}} P_{balloon} \]

Where \( P_{wb} \) is the pressure that applied in without balloon scenario, \( P_{balloon} \) is the pressure when the balloon is determined. \( A_{balloon} \) is the surface area of the balloon and \( A_{stent} \) is the surface area of the stent.

The surface areas of the balloon are assumed as a stent inner surface without a cell. Therefore, the following surface area of the stent and the balloon respectively 11.62 mm\(^2\) and 62.83 mm\(^2\). Table 1 summarized the loading scenarios that applied to the inner surface of the stent. It shows a comparison between the pressure of the balloon and the negligible balloon scenario.

**Table 1. Loading Scenario.**

| With Balloon (MPa) | Without balloon (MPa) |
|--------------------|-----------------------|
| 0.3                | 1.62                  |
| 0.4                | 2.16                  |
| 0.5                | 2.70                  |
| 0.6                | 3.24                  |
| 0.7                | 3.78                  |
| 0.8                | 4.32                  |
| 0.9                | 4.86                  |
| 1                  | 5.40                  |

3. **Results and Discussion**

This section presents the result of finite element analysis of the stent design and modeling. The result includes the stress distribution and the outer diameter change.

3.1. **Deployment Result**

The deployment process is depicted in figure 2. It shows the deployment process when a 5.40 MPa (1 MPa with balloon equivalent) pressure is applied.
3.2. Stress Distribution and Deformation

The deformations and the stress distributions when a 5.40 MPa (1MPa with balloon equivalent scenario) of pressure is applied is depicted in Figure 3. The stent deployment is designed in plastic deformation. So, the stress definitely higher than the yield strength of the material but it must under the ultimate tensile strength (UTS). The result shows that the maximum stress of crimping step and deployment process still below the UTS.

Two reference point (A and B) are used to measure the outer diameter change of the stent. The result of outer diameter change is depicted in figure 4.

**Figure 2.** Deployment Process
3.3. Outer Diameter Changes

The stent diameter changes against the pressure are shown in figure 4. The result shows that the diameter between middle and edge of the stent are different. The edge diameter often larger than the middle of the stent. This phenomenon is called dogbone.

Dogbone phenomena must be minimized because it can cause a vessel injuries. The dogbone phenomena are measured by comparing the ratio of the maximal displacement and the minimal displacement. The following equation is:

\[
DB = \frac{R_{\text{max}(\text{edge})} - R_{\text{middle}}}{R_{\text{max}(\text{edge})}}
\]

Where \(R_{\text{max}(\text{edge})}\) is the maximum radius of the stent edge after deployment and \(R_{\text{middle}}\) is the middle stent radius after deployment. The percentage of dogbone against the pressure show in figure 5. The diameter reaches the initial diameter when the pressure is 2.16 MPa (0.4 with balloon equivalent) and the percentage of dogbone is 0.4%.

Figure 3. Stress Distribution
4. Conclusion
This research is the preliminary step to investigate the stress distribution of stent expansion. The negligible balloon method is relative less accurate than included balloon method because it neglects the impact and contact of the balloon to the stent. However, this method can provide useful information about the stress distribution and deformation of the stent to evaluate the design. The result of the simulation shows that stent can deploy uniformly. The stent can reach the initial diameter with a small percentage of dogbone. The von misses stress also under the UTS of the material. It concludes that the stent design ready to be manufactured as a prototype.
5. References
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