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Effect of Link Design of Thin Cardiovascular Stent to Its Flexibility

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Abstract

Until recently, stent has been used effectively to open a cardiovascular blockage due to the plaque. Various designs of stent are available commercially in the marketplace. Thus, it was difficult to select the suitable stent that meets to the varying needs of the patient beyond the material, such as flexibility, inflated diameter, and radial strength. The present study would focus on finding the effect of link design to its flexibility, while the strut design was remained and the material was the same. The study was carried out by finite element modeling and software ABAQUS 6.13 was employed to perform the simulation. The metal alloy of Cobalt has been selected to be material of the stent model. A thin stent model consists of a pair of the strut which was connected by three links (L1, L2, L3) with a thickness of 60µm and 80µm frame wide. The model has a size of 1.237mm in outer diameter and 2mm long. The flexibility was expressed by the curvature index as the ratio of bending angle to stent length. The flexibility was performed at the bending moment concerning x-axis (Mxx) and y-axis (Myy). Results indicated that link design L1 performed the highest flexibility compared to other link designs which was indicated by the highest curvature index at the same value of bending moment (Mxx and Myy).

Keywords: Design, Link, Model, Flexibility, Stent.

1. Introduction

Cardiovascular diseases (CVD) are the leading cause of death in the world, which caused by vascular blockage [1]. Stent, both types of the bare metal stent (BMS) and drug-eluting stent (DES), have been applied effectively as a medical device to open the cardiovascular blockage due to the plaque. In the commercial marketplace, various designs of stent (strut and link) using various materials are available. A common metal alloy as a raw material could be found in the form of mini-tube including metal alloys (Stainless steel 316L, and CoCr L605) and bio-absorbable polymers such as Poly (L-lactic) Acid or PLLA. The other promising materials, even though these, were not commercial yet such as degradable metals including Mg and Zn based metal. The fabrication technology of stent based on the cutting of mini-tube, has been also established. However, the issues of biocompatibility, restenosis, and thrombosis, as well as flexibility, are remained open for the improvements. Issue on this biocompatibility has been solved by applying better biocompatibility and finding new biomaterials which have better biology properties. Meanwhile, the restenosis and thrombosis which exist as the biological responses of protection due to the existence of metal have been addressed by applying bio-absorbable polymer, such as PLLA. The consequence of using polymer for the stent was a higher thickness to achieve the same radial strength. Thus, it may cause the turbulent flow of the blood which lead to thrombosis. Beyond the biological responses, restenosis [2]–[5] and thrombosis [6]–[14] might also be affected by stent design, both design of strut and link, as well its thickness, and frame structure wide. For these reasons, the efforts have been taken place by reducing the outer circumstance surface area of the stent, and thickness, but still considering the need of the radial strength. Another effort has also been carried out by smoothing design of strut and link to enable the blood flow in a laminar state, instead of turbulence state. The last issue is still open for the improvement especially for the flexibility either in crimped or inflated conditions. The flexibility in the crimped condition is required to accommodate the needs of a cardiologist on ease of stent placement, although, it was rather subjective matter. During the process of placement, the stent was pushed through an artery in wrist hand following catheter guide wire. The pushing of the stent was continued via a complex passage of artery till the blockage location. While flexibility of inflated condition was important in order to accommodate the heart beating that could be million bpm (systole and diastole) during the rest of patient life. The stent placed was in the cardiovascular artery in which the heart beating and corrosive environment, this may potentially cause the stent fatigue [15]. Thus, a good stent should adaptive to this condition, such as it should be flexible enough. However, there was no definite number representing the lowest limit of good flexibility that satisfying the cardiologists. Previous studies on the flexibility have been concerned to find a correlation of design to the mechanical behaviour of the stent, such as the design of strut and link, open and closed cell [16]. Here it is noticed that the flexibility is affected by the ease of stent placement through the complex passages of the artery, flexibility of stent in the condition of developed and non-developed. Furthermore, the flexibility can be determined by the curvature index as a ratio

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of bending angle $\Delta\phi$ to the length of the stent L[17]. The present work is a numerical study of flexibility of stent link designs. The aims of the study is to determine its flexibility which leads to decide the highest flexibility as the best stent link design.

2. Material and Method

2.1 Material

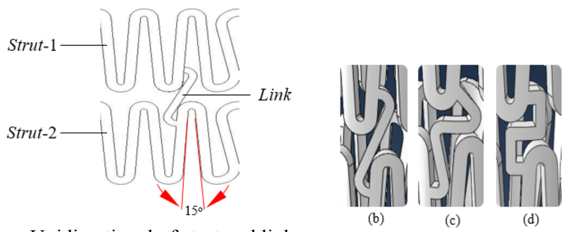
In the present numerical study, the Cobalt Alloy was used as tested material, and the mechanical properties of this metal alloy are depicted in Table 1. It includes the yield stress (MPa), ultimate tensile strength (MPa), modulus young (GPa), poisson's ratio and density (g/cm^3). For the simulation purposes, the stent model was only a pair of two struts connected by three links. Each pair has an outer diameter of 1.237mm, 60µm of thick and 2mm in length.

Table 1. Mechanical properties of Cobalt Alloy [18]

Mechanical Properties	Material: Cobalt Alloy
Yield Strength (σ_y), MPa	485
Ultimate Tensile Strength (σ_u), MPa	1,012
Modulus Young (E), GPa	243
Poisson's Ratio (υ)	0.29
Density (ρ), g/cm^3	8,414

2.2 Design of Link

The design process of the stent model was carried out by using the commercial software of Inventor 16.1. There were three designs of strut link as depicted in Fig. 1, i.e. L1, L2, and L3link models. All the models were applied to the same design of strut. Here, it was only a pair of the strut, instead of the whole length, to be made for reducing computation time. Thus, the length of the stent model was determined according to the length of the pair model (strut-link-strut). The stent model has outer diameter 1.237mm (crimped condition), 60µm of thick and 80µm frame wide.



(a) Unidirectional of strut and link in 2D view

Fig. 1. Design stent S>> (a). A pair of strut and link and 3 Link model designs: (b). L1, (c). L2, and (d). L3.

2.3 Simulation

The simulation to determine the curvature index of the crimped condition was performed by using the commercial software of ABAQUS 6.13. The stent model was composed by 30,230 elements type of Quadratic Tetrahedral C3D10. In this simulation, it was also assumed that the balloon catheter which located underneath of the crimped stent was not considered. Therefore, the flexibility of the stent model is only presented beyond the flexibility of the balloon catheter. Before the simulation, the coupling constraints were fixed alongside the longitudinal axis as depicted in Fig. 2a and the radial pressures were applied to the inner surface of the stent as seen clearly in Fig. 2b, while Fig. 3 illustrated bending moments applied at x and y-axes.

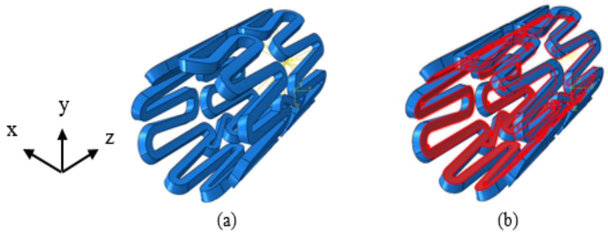


Fig. 2. (a) Multi-Point Constraints (MPC), and (b) Radial pressure.

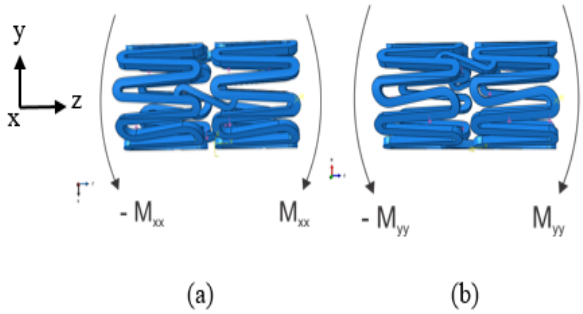


Fig. 3. Bending moment applied in respect to (a) Axis-x (Mxx), and (b) Axis-y (Myy).

In the present study, the flexibility was indicated by the curvature index (X) and is calculated by using Eq. (1) as suggested by [17].

$$X = \frac{\Delta\varphi}{L} \tag{1}$$

where $\Delta\varphi$ is angle formed due to bending moment in x-axis (Mxx) or equal with $UR1_{max}$and y-axis (Myy) or equal with $UR2_{max}$, and L is the ength of a pair of strut which connected by 3 links (mm).

3. Results and Discussion

The calculated results of flexibility as expressed by the curvature index are presented in Fig. 4 to Fig. 6. In general, the curvature index (X) which respects to the bending moment Mxx and Myy (bending moment of 0 to 0.8 N.mm) shows a similar trend for all link models. In Fig. 5, and 6 correspond to the cases of link models L1, L2, and L3 respectively. However, due to the stent design was not symmetric, there was different responding of curvature index in respect to x and y-axes. Thus, the flexibility of the stent was also resulting in different values. Bending moment needed for the stent at all range of curvature index (0.0-0.03 rad/mm) in respect to y-axis was less than that of x-axis. As seen in Fig. 4, the curvature index of L1 link model indicated the highest value compared to that of the links of L2, and L3 models. The lowest curvature index value was L3 link model and followed by and L2 link models. In addition, the curvature index was obtained from Eq. (1) namely dividing UR_{max} value with length of the pair model stent (2mm). URmax value was resulted from the ABAQUS 6.13.simulation as seen in Fig. 5, for example UR_{max} of Mxx=0.1 N-mm namely 1.248e-02. L1 has "S" geometry which possible to spring effect in x axes, so that give higher flexibility than another link models.

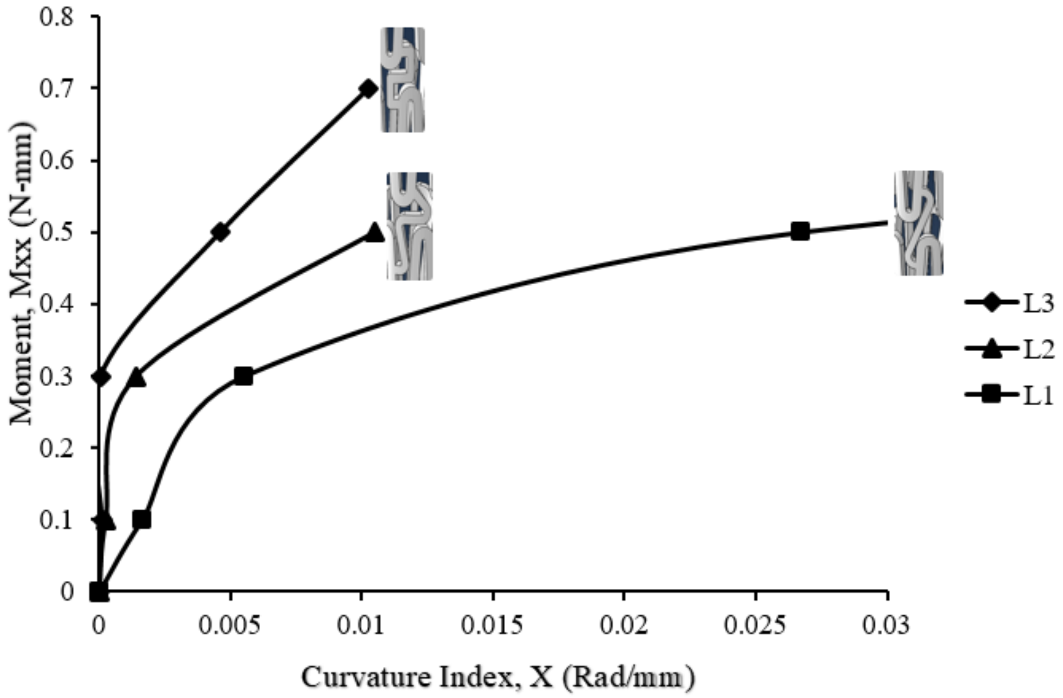


Fig. 4. Curvature index of stent for various Link design in respect to moment Mxx.

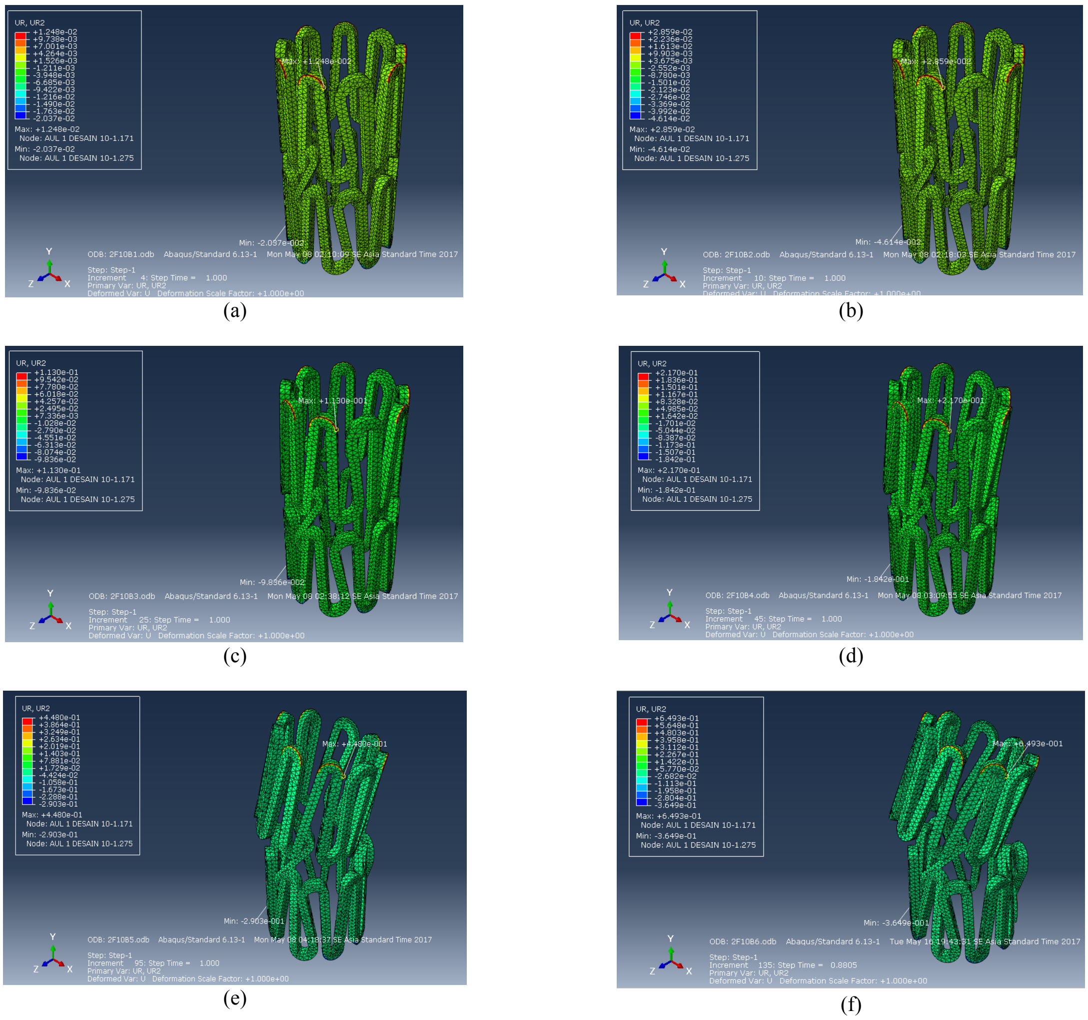


Fig. 5. A sample of stent condition with model Link L1 at (a) Mxx=0.1 N-mm, (b) Mxx=0.2 N-mm, (c) Mxx=0.3 N-mm, (d) Mxx=0.4 N-mm, (e) Mxx=0.5 N-mm, and (f) Mxx=0.6 N-mm.

In responding to the bending moment of Myy, a similar trend of curvature index was also occur for all links model. Here, L1 link model showed the highest value of its curvature index at the same bending moment for less than 0.1 N.mm. It was then followed by L3, and L2 link models. The worst flexibility of the stent here was L2 link model.

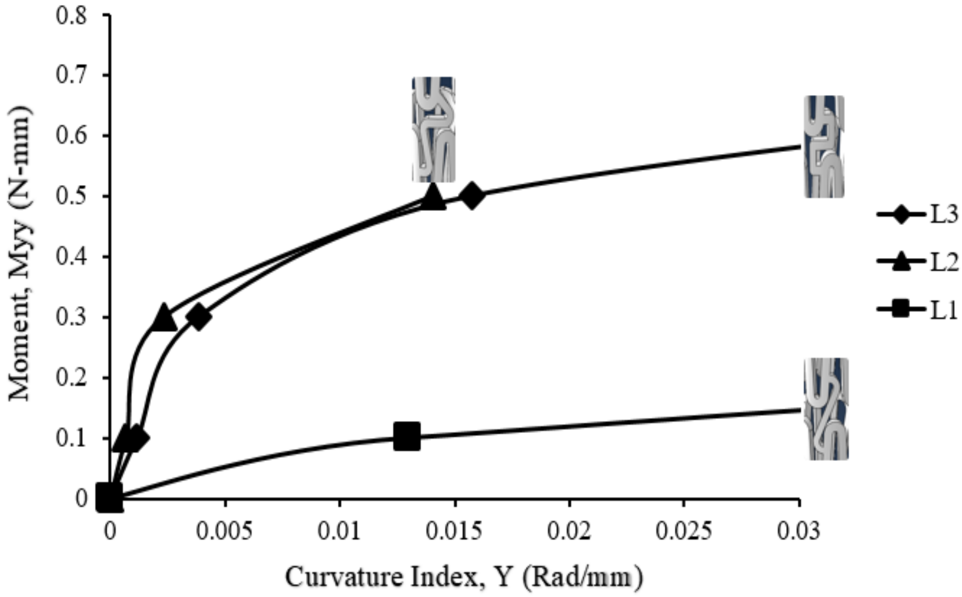
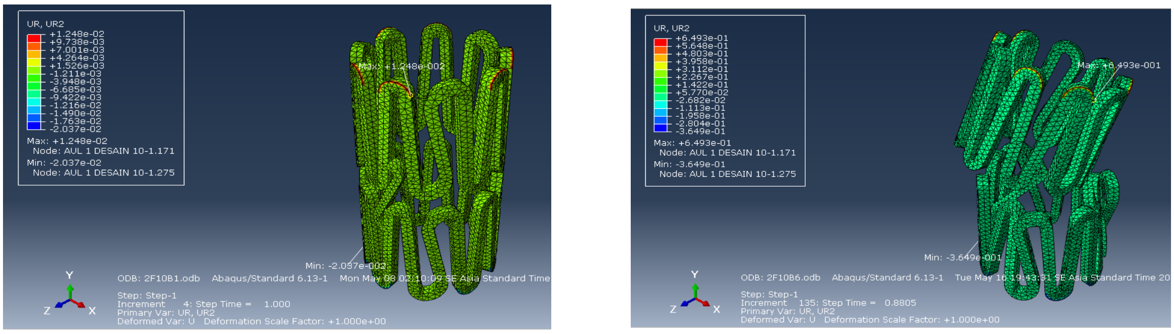


Fig. 6. Curvature index of stent for various Link design in respect to moment Myy.

Similar to the Fig. 7, when the bending moment Myy was applied to the same model link of L1, the stent experienced the same bending moment to bend as indicated in Fig. 7. However, the von mises stress of the link model of L1passed over the ultimate stress of 1,012 MPa at the bending moment of 0.6 N.mm as seen in Fig. 7. Thus, it was clear that different link design gave the different response of flexibility.



(a) (b)

Fig. 7. A sample of stent condition with model Link L1 at (a) Myy=0.1 N-mm and (b) Myy=0.6 N-mm.

It was well known that a good flexibility of stent was indicated by both the lowest bending moment and the highest curvature index value. In case of stent with L1 link model that already known as the best model, it has highest curvature index value (>0.03 rad/mm) and lowest bending moment Myy of about less than 0.1 N.mm. The flexibility of this stent could be improved by making a symmetric of design and the lower thickness. However, carrying a lower thickness should the considered because the radial strength requirement, and it depends on the strength of the plaque blockage the artery.

4. Conclusion

The flexibility of three links models has been simulated numerically using ABAQUS 6.13. Among thus models link, the model link of L1 showed the highest flexibility compared to other model links. At the same bending moment, curvature index (X) of L1 link model indicated the highest value in responding to the bending moment of Mxx and Myy. Increasing curvature index of stent with L1 link implies to its flexibility that needed by stent manufacturers to improve their stent product and by doctors during stent placement.

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