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Effect of Asymmetric Geometry on the Flexibility of Stent

Achmad Syaifudin[1*], Ryo Takeda [2], and Katsuhiko Sasaki[2]

[1]Department of Mechanical Engineering, Institut Teknologi Sepuluh Nopember, Surabaya, Indonesia
[2]Division of Human Mechanical Systems and Design, Faculty of Engineering, Hokkaido University, Japan

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Abstract

Mechanical characteristic assessment of the new stent design is important to improve the performance during the stenting process. Stent with good performance in geometric assessment should pass several tests in the unexpanded and expanded condition. The FEM assessment is expected to replace the actual mechanical assessment to save the cost and time of the manufacturing. In this study, the FEM assessment is conducted using the structural nonlinear analyses in ANSYS R15.0. The stent type used in the simulation is the Asymmetric stent and the Sinusoidal stent. The assessments included in this study are the flexibility test on the unexpanded condition (single-load and multi-load) and that on the expanded condition under single point loading. The three-point bending test is chosen as the flexibility test, either for unexpanded or expanded condition, due to its simplicity. To restrain angular deformation and more save the computation process, a symmetry model (due to longitudinal and angular plane) of each stent type is constructed. By utilizing Multi Point Constraint (MPC) element, the loading is subjected over pilot node at the center line of the stent. The analysis results showed that Asymmetric stent has lower flexibility comparing with Sinusoidal stent in the unexpanded configurations. In the case of Asymmetric stent, its inflated-side is more flexible than the fixed-side.

Keywords: Balloon Expandable Stent; Asymmetric; Flexibility; FEM

1. Introduction

A stent is inserted through tortoise artery, which is often aggravated by the plaque obstruction; produce the track to be passed becomes more complex. Stent with good performance in geometric assessment should pass the flexibility, trackability, and conformability tests. The flexibility itself is an essential property in the stent delivery and long term results of stenting. Flexible stents are easily inflated and show great adaptability to vasculature compared with a rigid stent. Colombo et al. [3], reported the hinge effect of the NIR stent on a tortuous vessel. Another studies found that the longitudinal straightening effect of stents contributed on the occurrence major adverse cardiac events and angiographic restenosis [5]. On the other hand, the flexibility is the one of the most important parameters allowing the restenosis to be prevented. The stent collapse incidence can achieve 5% of the implantation due to very flexible configuration

A number of flexibility assessment have been conducted, either using in vitro evaluation or using FEM analysis. A comparative analysis on coronary stent assessment has been started by Rieu et al.[10], by conducting in vitro evaluation on the trackability, flexibility, and conformability. It was indicated that their developed tools could be used by clinicians to evaluate mechanical characteristics of various coronary stents. Mori and Saito [8] suggested the four-point bending test to measure the stent flexibility because it restrains the radial stent deformation and generates the uniform moment conditions. Following the study of Mori and Saito [8], Szabadits et al.[13] built an in vitro coronary vessel model with one-point and four-point bending tests for the flexibility assessment. They found that the flexibility of stents depends on the stent design more than raw materials.

First flexibility assessment through FEM was carried out by Petrini et al.[9] on three-point bending test method. Two sets of simulations were performed: i.e. bending test in the unexpanded configuration and bending test in the expanded configuration. Results expressed that the flexibility depends on the contact condition between the different parts of the struts. In contrast to this, Mori and Saito [8] built a simplified 2D FEM simulation corresponded with their in vitro experiment to investigate the deformation mode and resistance under the longitudinal compressive load. The results indicated that the simplified FEM model was suitable to characterize the various stent structures. Wu et al. [14] introduced the multipoint constraint elements (MPC) to apply uniform bending moment on a unit model of an expanded coronary tubular stent. It was concluded that this method can be used to compare the flexibility of different stents and provides a convenient

*Email:saifudin@me.its.ac.id
Phone/Fax:+62(31)5922941

tool for designers to pretest and improve bending characteristics of new stents. In other hand, more actual FEM study on unexpanded stent flexibility was performed by Kim et al. [7]. It was three solid half-ring which used as the bending load and bending support.

Those aforementioned studies revealed the importance of flexibility assessment and how to perform the assessment. Indeed, it is necessary for each new stent design before the clinical trial. Prior to the study, Syaifudin et al. [12] developed new stend design whose nonsymmetric geometry. The influences of non-symmetric geometry on stent flexibility should be investigated through a reliable method. This study attempts to examine flexibility of Asymmetric stent, either in unexpanded or in expanded configuration, under single- and multi- point loading through finite element modelling (FEM). A simplification based on appropriate assumption should be taken into account carefully to avoid oversimplifying the physical problem, which could lead to the inaccurate solution.

2. Method

2.1. Finite Element Model

ANSYS R15.0 [1](ANSYS Inc., Pennsylvania, USA) was used as a simulation tool and CREO 2.0 (PTC Inc., Needham, USA) as a solid model generator. The balloon expandable stent model type non-symmetric geometry, called Asymmetric stent (flat view displayed in Figure 1, is built using CREO 2.0 then investigated through FEM assessment using ANSYS R15.0. This stent type is developed by Syaifudin et al.[12] to accommodate carotid artery obstructed by eccentric plaque. Sinusoidal stent with proportional length and nominal diameter, which is studied by Ju et al.[6] while representing a stent type with the flexible structural geometry, is included in the simulation as a comparison.

The stents, made from SUS316L, have multilinear isotropic properties with 218 GPa of modulus elasticity and 0.33 of Poisson ratio (Syaifudin et al., [12]). Isotropic hyperelastic PET balloon is chosen to apply uniform pressure onto stent surface, while inflating the stent to achieve the expanded configuration. The balloon used material properties defined by David Chua et al. [2]. There are two kind of assessment for stent flexibility, i.e. unexpanded and expanded stages. The flexibility in unexpanded configuration is needed to assess stent performance while delivered through tortuous vessel with catheter system. The flexibility in expanded configuration, indeed, is important information for a doctor/practitioner in choosing more appropriate stent type to be deployed in the treatment. The flexibility test simulated in this study is the three-point bending test, either unexpanded or expanded condition. This method is chosen due to more simple and saving calculation time.

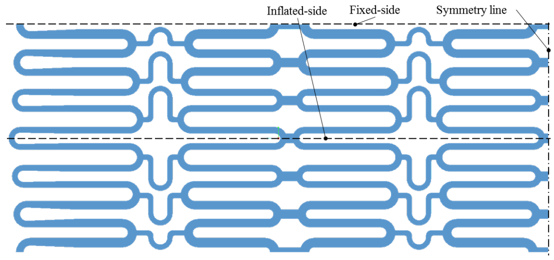

Figure 1. Flat view of Asymmetric stent, shown from central part to distal one

In order to obtain optimal asymmetric expansion, balloon type offset is used to inflate the stent[11]. To restrain angular deformation and more save the computation process, a symmetry model (due to longitudinal and angular plane) of each stent type is constructed. Boundary conditions used in the flexibility assessment under the single-point loading is shown in Figure 2 and 3 for the unexpanded and expanded configuration, respectively. Meanwhile, boundary conditions used in the flexibility assessment under the multi-point loading are shown in Figure 4 for the unexpanded configuration.

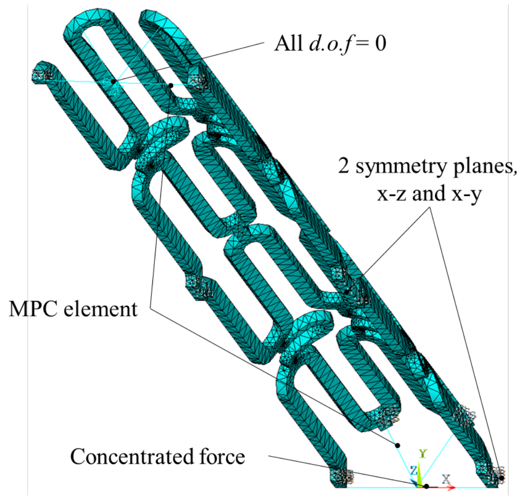

Figure 2. BC's in single-point loading of unexpanded stent

The flexibility of stents in this study, either unexpanded or expanded one, is assessed utilizing Multi Point Constraint (MPC814) elements in ANSYS R15.0. Wu et al. [14] firstly introduced MPC184 to assess the expanded coronary stent by comparing a unit cell of stent and whole stent model. MPC184 comprises a general class of multipoint constraint elements that apply kinematic constraints between nodes. The elements are loosely classified as constraint elements (rigid link, rigid beam, etc.) and joint elements (revolute, universal, etc.). All of these elements are used in situations that require some constraints to meet certain requirements. Since these elements are implemented using Lagrange multipliers, the constraint forces and moments are available for output purposes.

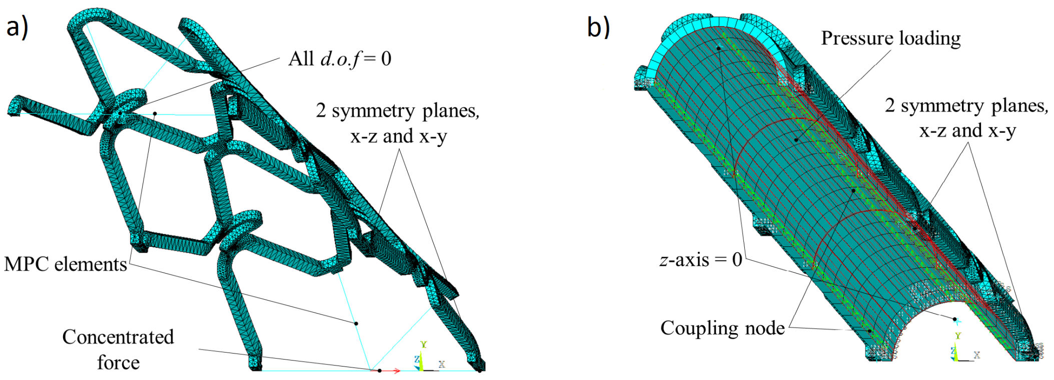

Figure 3. BC's in single-point loading of expanded stent: (a) Before expansion, (b) After expansion.

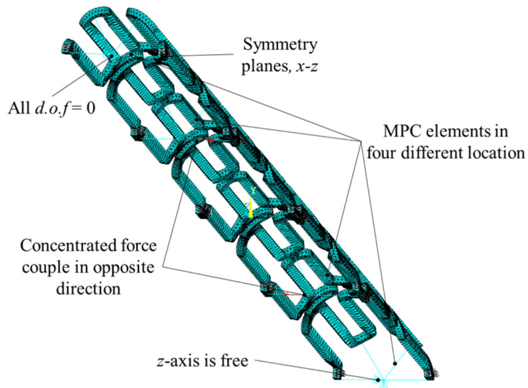

Figure 4. BC's in multi-point loading of unexpanded stent

The constraint may be as simple as that of identical displacements between nodes. To utilize MPC184 elements, several nodes in a planar surface of stent cross section should be assigned sequentially. Those nodes classified as constraint elements (rigid beam) in which direct elimination method is activated in the element key option. For the direct elimination method, the degrees of freedom of a dependent node in the equations are eliminated in favor of an independent node. As replacement, the dependent degrees of freedom are eliminated. Therefore, the constraint forces and moments are not available from the element output table for output purposes. However, the global constraint reaction forces are available at independent nodes in the results file.

For expanded stent simulation, particularly, using feature UPGEOM (update geometry) in ANSYS is necessity. This is useful to subject moment loading after balloon removal and stent deformed. MPC184 elements could also be built after executing UPGEOM. This command updates the geometry of the finite element model according to the displacement results of the previous analysis and creates a revised geometry at the deformed configuration. This command works on all nodes (default) or on a selected set of nodes. However, the solid model geometry is not updated by this command.

2.2. Flexibility Measurements

According to the simply supported beam theory (as denoted in Figure 5), the deflection caused by imposing concentrated force P (for single-point loading) on a stent can be obtained by 1

$$def = \frac{P \cdot L^3}{48 \cdot E \cdot I} \qquad (mm) \tag{1}$$

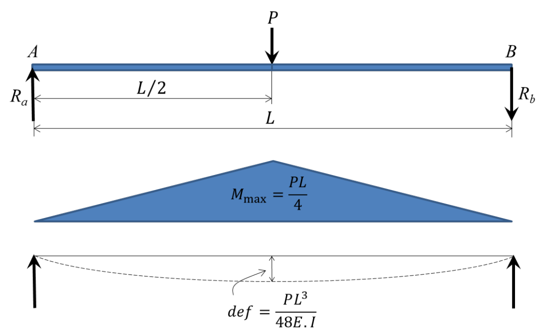

Figure 5. Flexibility for one-point bending test

In this case, the deflection is the maximum displacement of the stent along x-axis direction and is easy to be obtained from FEM simulation. As a result, the bending stiffness E·I of the stent under the single-point loading can be determined by Equation 2. That shows the relationship between the moment of inertia I, the Young modulus E, free bending length L, and the bending deflection def and the concentrated force P.

$$E \cdot I = \frac{P \cdot L^3}{48 \cdot def} \qquad (N \cdot mm^2) \tag{2}$$

The flexibility of a stent F can be easily expressed as follows (Mori and Saito[8],; Petrini et al.[9], as expressed in 3,

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

In term of the multi-point loading, because of similar value of the point forces couple P, the generated reaction moment couple will also be similar each other. However, the deflections caused by the point forces couple is deferent each other. For the symmetric stent geometry, the deflection and is equal. Therefore, the bending stiffness, which is caused by a couple point forces P acted on the different surface of the stent with opposite directions in Figure 6, can be determined in following Equation 4a-b, which is affected by the deflection itself.

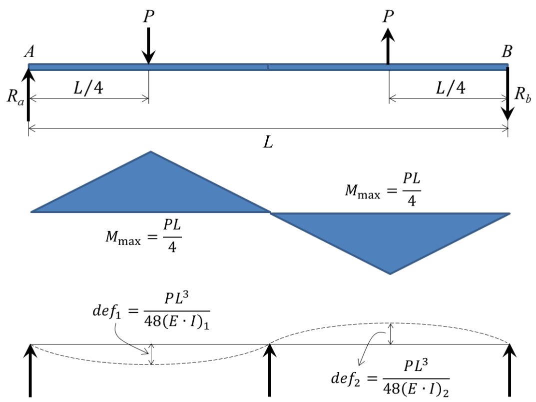

Figure 6. Flexibility for multi-point bending test

$$(E \cdot I)_1 = \frac{P \cdot L^3}{48 \cdot (def)_1} \qquad (N \cdot mm^2) \tag{4a}$$

$$(E \cdot I)_2 = \frac{P \cdot L^3}{48 \cdot (def)_2} \qquad (N \cdot mm^2) \tag{4b}$$

While the flexibility form can be expressed in Equation 5a-5b, as follows:

$$F_1 = \frac{1}{(E \cdot I)_1} = \frac{48 \cdot (def)_1}{P \cdot L^3} \qquad (N^{-1} \cdot mm^{-2}) \tag{5a}$$

$$(F_2 = \frac{1}{(E \cdot I)_1} = \frac{48 \cdot (def)_2}{P \cdot L^3} \qquad (N^{-1} \cdot mm^{-2}) \tag{5b}$$

The flexibility and will be similar for the stents with symmetric geometry.

3. Results

Figure 7 shows the reaction moment versus the deflection for the unexpanded configuration under the single-point loading and its corresponding bending stiffness. Figure 7a denotes that for the similar point force, Sinusoidal stent yielded larger reaction moment than Asymmetric stent, with a mean slope difference of 2.91 0.67. In term of Asymmetric stent, its inflated-side produced lower reaction moment than the fixed-side, by a slope margin of 1.36. In the meanwhile, the correlation of bending stiffness and deflection in Figure 7b describes a similar phenomenon with that of reaction moment and deflection. Namely, Sinusoidal stent has higher bending stiffness than Asymmetric stent with a mean difference of 345.14 14.68 N.mm2. In term of Asymmetric stent, its inflated-side generated lower bending stiffness than the fixed-side by a margin of 29.35 N.mm2.

Figure 8 represents the reaction moment versus the deflection for the unexpanded configuration under the multi-point loading denoted by the bending moment number (1) and (2). From Figure 8a and b, it is obviously seen that a couple of the opposite bending moment produced the similar reaction moment on the stent with symmetric geometry. For Asymmetric stent, the reaction moment of the inflated-side is equal to that of the fixed-side though those have different deflection values. Because of the different deflection value, the bending stiffness of both side of Asymmetric stent is not similar each other. This result suggests that the flexibility assessment using the multi-point loading is useful to identify the difference in the stent deflection with non-symmetric geometry.

Figure 9 shows reaction moment versus deflection for expanded configuration under single-point loading and its corresponding bending stiffness. It is denotes that for the similar deflection value, Sinusoidal stent yielded larger reaction moment than Asymmetric stent. Besides, the maximum deflection of Sinusoidal stent (0.548 N.mm) is quite small comparing with that of Asymmetric stent (1.309 N.mm). Meanwhile, the correlation of bending stiffness and deflection in Figure 9b describes that Sinusoidal stent has only a few remaining bending stiffness to resist bending deformation. In the contrary, Asymmetric stent still could withstand more bending deformation, with a difference deflection of 0.1916 mm. These results lead to an important note that flexibility assessment of expanded stent is very useful to reveal potential-configuration of stent. Adding the U-type bridges between strut rows seems to give major impact to the potential-configuration of Asymmetric stent. This result supports the studies mentioned that the bridges or connecting links make a stent more flexible in the radial and axial direction (Mori and Saito [8]; Szabadits et al.[13]; Kim et al.[7]). In the modern design of stents, the bridges are almost provided in the geometry design of stents in order to increase the stent flexibility.

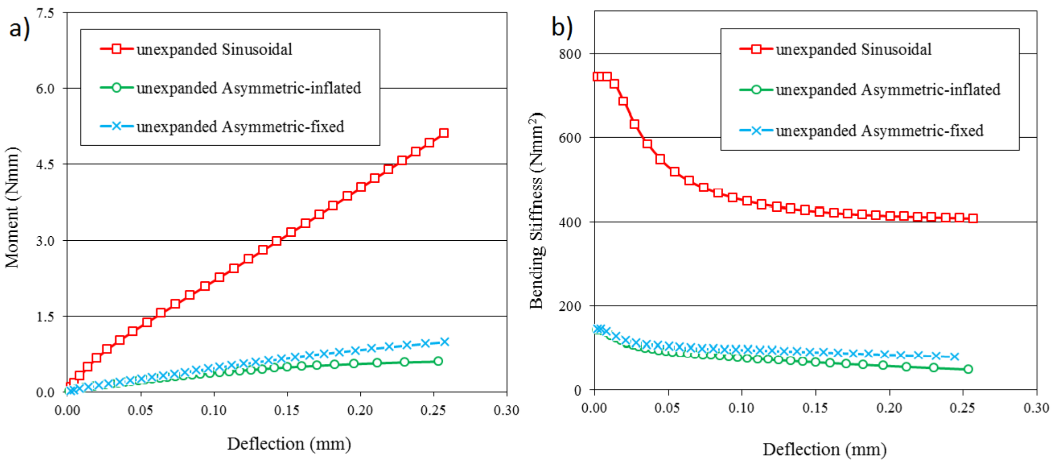

Figure 7. Unexpanded configuration under single-load: (a) Reaction moment, (b) Bending stiffness.

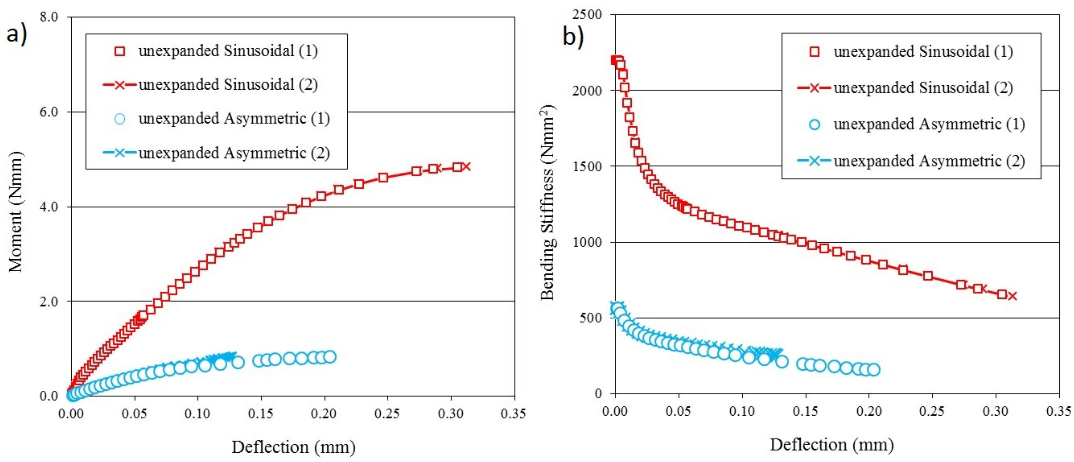

Figure 8. Unexpanded configuration under multi-load: (a) Reaction moment, (b) Bending stiffness.

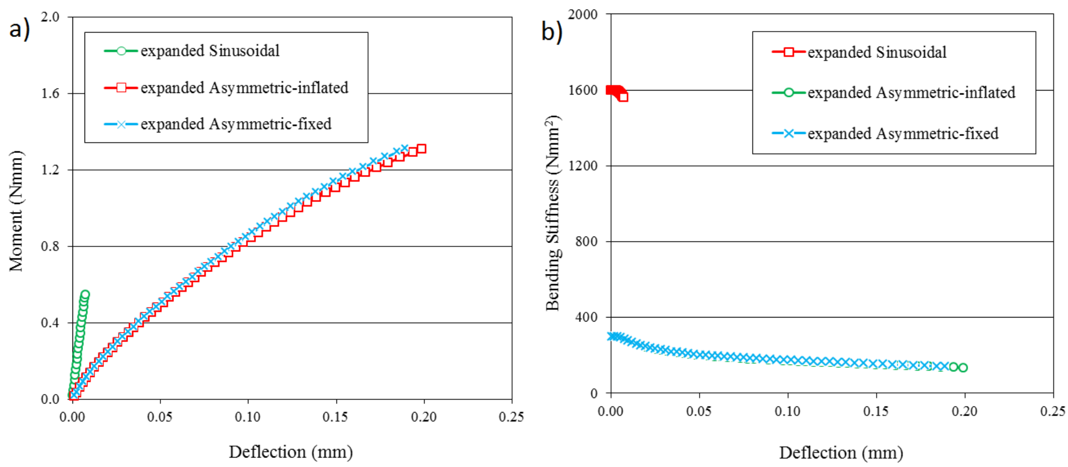

Figure 9. Expanded configuration under single-load: (a) Reaction moment, (b) Bending stiffness.

However, it should be constructed carefully to avoid the less axial rigidity. For the treatment of the carotid artery, the less axial rigidity could cause the concertina effect, which is defined as the longitudinal deformation of the proximal segments of a deployed stent (Foin et al.[4].

The flexibility of both stents for the unexpanded configuration, which can be calculated using Equation 3 for single-point loading and using 5a-5b for multi-point loading, is listed in Table 1. These results demonstrate that the geometry modification could change the stent flexibility significantly. The flexibility of Asymmetric stent is higher than Sinusoidal stent for both loading types, i.e. the single-load and multi-load. It also can be noted that the stent is more flexible in the case of the single-point loading test. Since all stents tested in this study have similar length, the effect of the stent length on the flexibility cannot be observed.

Table 1. Flexibility of Sinusoidal and Asymmetric stents

Configuration		Sinusoidal stent ($N^{-1}m^{-2}$)	Asymmetric stent ($N^{-1}m^{-2}$)	
			Inflated-side	Fixed-side
Single-load	Unexpanded	0.0025	0.0209	0.0129
	Expanded	0.00064	0.0075	0.0071
Multi-load	Unexpanded	0.0016	0.006	0.004

4. Conclusion and Outlook

This paper demonstrated the geometry assessment on Asymmetric stent through FEM. The assessment on Sinusoidal stent as the comparative analysis is figured out as well. This study indicated that the geometry modifications such as varying the struts length and width, adding the bridges, and varying the curvature width of struts affect the stent flexibility. Particularly, adding the bridges/connector between stent segments yields the largest effect on the stent flexibility and affects the potential-configuration after expansion. The FEM protocol used in this assessment is also useful to identify the geometry characteristics of stent. Then, the FEM protocol might be adopted for stent assessment widely.

The geometry assessment conducted in this study considers only the radial deflection under the unexpanded configuration. The flexibility in the expanded configuration, indeed, is the important information for a doctor / practitioner in choosing an appropriate stent type to be deployed in the treatment. Besides, as for stent with the bridges such as Asymmetric stent type, it is necessary to be assessed its axial rigidity. Adding the bridges increases the stent flexibility. The flexibility of a stent may be also achieved by reducing the number of bridges and using a helical arrangement of the connecting links. Then, each stent segment has high abilities to change its length longitudinally when the stent is bended in the curved segment. As a side effect, a more flexible stent may also have a greater susceptibility to deformations when force is applied in its longitudinal axis (Foin et al., 2013). Therefore, future studies should develop the axial rigidity assessment to identify the minimum number of bridges/connecting links.

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