

A review on fracture prevention of stent in femoropopliteal artery

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Abstract. Heavily calcific lesions, total occlusions, tortuous blood vessels, variable lengths of arteries, various dynamic loads and deformations in the femoropopliteal (FP) arterial segment make stenosis treatments are complicated. The dynamic forces in FP artery including bending, torsion and radial compression may lead to stent fracture (SF) and eventually to in-stent restenosis (ISR). Stent design specifically geometrical configurations are a major factor need to be improved to optimize stent expansion and flexibility both bending and torsion during stent deployment into the diseased FP artery. Previous studies discovered the influence of various stent geometrical designs resulted different structural behaviour. Optimizing stent design can improve stent performances: flexibility and radial strength to prevent SF in FP arterial segment.

1. Introduction

Peripheral artery disease (PAD) has affecting over 200 million individuals worldwide making PAD the third leading cause of morbidity and mortality in the world [1–3]. In fact, 60-80% of patients with PAD have coronary artery disease (CAD) in at least one vessel, and 25% have carotid stenosis [4]. Through PAD encompass a several vascular beds, it is most often occurred in the lower body limb, involving aortoiliac (AI), femoropopliteal (FP), and infrapopliteal (IP) vascular beds. The FP arterial segment composed of the superficial femoral artery (SFA) in the proximal region and popliteal artery (PA) in the distal region [5] (Figure 1), often has high atherosclerotic plaque represent a challenge for endovascular revascularization [6]. Atherosclerosis occurred when excessive cholesterol, calcium and fibrin attached to the wall of blood vessel leading to the thickening and hardening of the vessel wall. As a result, the forming fatty substances called plaques capable to narrow the arteries.

Percutaneous transluminal balloon angioplasty (PTA) followed by stenting have proven superior to prevent abrupt artery closure [7], restore blood flow and vessel patency [8] in FP vascular beds. In this process, the stent is mounted on a balloon. The stent is expanded by inflating the balloon at the blockage region to compress the plaque against the artery wall. When the balloon is deflated the stent remains in place and support the artery open [9]. However, FP arterial segment is often found to have calcific and occlusive [10] atherosclerosis due to its length, the longest in the body. Heavily calcific plaque can affect the expansion of stent leading to less luminal gain that is resulted with higher rates of restenosis, known as in-stent restenosis (ISR) [6] leading to late thrombosis and stents fractures (SF) probably due to low radial strength of the stent. From previous study, PTA through effective for



shorter (<5 cm) non-calcified lesions [11], fails when lesions are longer, calcified, and more complex. The restenosis rates vary, but are between 35% and 65% at 6-12 months for lesions more than 100 cm [12–14]. The main reason of restenosis is smooth muscle cell and intima hyperproliferation resulting adverse remodelling, caused by endothelium injury, inflammation of the persistent atherosclerosis plaque, hemodynamic factors, and mechanical stress from a permanent stent [15,16]. Indeed, the 12-month rates of ISR after implantation of modern bare metal nitinol stents in the FP segment range from 18% to 37% [11].

FP arterial segment is subjected to various dynamic forces including radial compression, bending and torsion [8] due to daily physical movements have been associated with high rates of SF [17–19]. This failure is reliable attributed by low flexibility, contributed to increased rates of restenosis [20]. The dynamic mechanical loading generated within tortuous blood vessels during deliverability of the stents to the target lesion that are going to be cured, might also lead to SF. Flexibility and radial strength of the stent in FP artery may be improved by optimizing the stent design parameter. Previous studies have reported the influence of various stent design configuration resulted different structural behaviour of the stent under numerical studies. This paper will be focused on FP arterial stenting commonly known as most anatomic locations of lower extremity atherosclerosis and discussed the effect of stent geometrical design on stent flexibility and expansion to prevent SF. Previous numerical studies of stent structural behaviour: bending, torsion and expansion will be reviewed aiming to know the influence of stent geometry design on the stent performances. These data may assist in the future modification process of stent design.

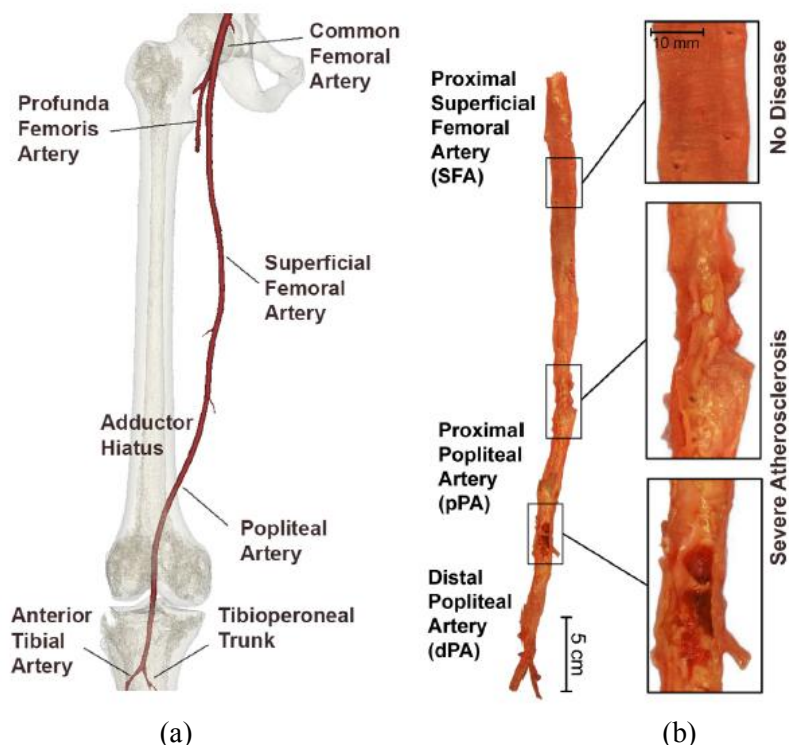


Figure 1. Anatomy of (a) FP arterial segment and (b) severe PAD in the distal SFA and PA [5].

2. The influence of stent design on fracture

Heavily calcific lesions, total occlusions, tortuous blood vessels and numerous dynamic loads on FP artery may lead to SF and eventually to severe ISR and thrombosis. The mechanical forces involved are radial compression, bending and torsion due to limbs movements. SF can result unwanted event and life threatening [21–23]. Failure may potentially occur when the stress is locally high at certain locations [24]. High radial strength and flexibility is characterized as significant properties during the

implementation of FP stent. Radial strength and flexibility can be improved by optimizing the stent strut and stent geometry configurations. An ideal stent should be considered to have the following design requirements: high radial strength, good flexibility, good fatigue properties, low elastic radial and longitudinal recoil and optimum scaffolding. Stent geometry dictates many of the delivery system and contributes to the performance of the stent [25,26]. The optimization of stent geometry and stent strut design will enhance stent structural behaviour: bending, torsion and radial strength, thereby reduce the possibility of SF and eventually ISR in FP arterial segment.

2.1. Flexibility

Flexibility of FP stent is often associated with the capacity of an expanded stent to assume the natural curve of a vessel specifically during the movements of the lower extremity without unnatural straightening. Flexibility also signifies deliverability or the capacity of the unexpanded stent to navigate tortuous passage to the stenosed region [24]. Torsion and bending ability of the stent are important characteristics to withstand the dynamic mechanical forces in the FP artery as the knee will flexes and twists and during delivery of the stent into tortuous blood vessels. Improving flexibility demands the ability for expandable stent to pull apart from each other on the outer radius of a curved vessel and push together on the inner radius. Optimizing of stent geometrical design has led to improvements of stent performance subsequently minimize the frequency of SF. The structural behavior of stent has been examined by previous studies such as Azaouzi et al. [24], Petrini et al. [27], Mori and Saito [28] and Junlei et al. [29]. These findings may be discussed in the following paragraphs.

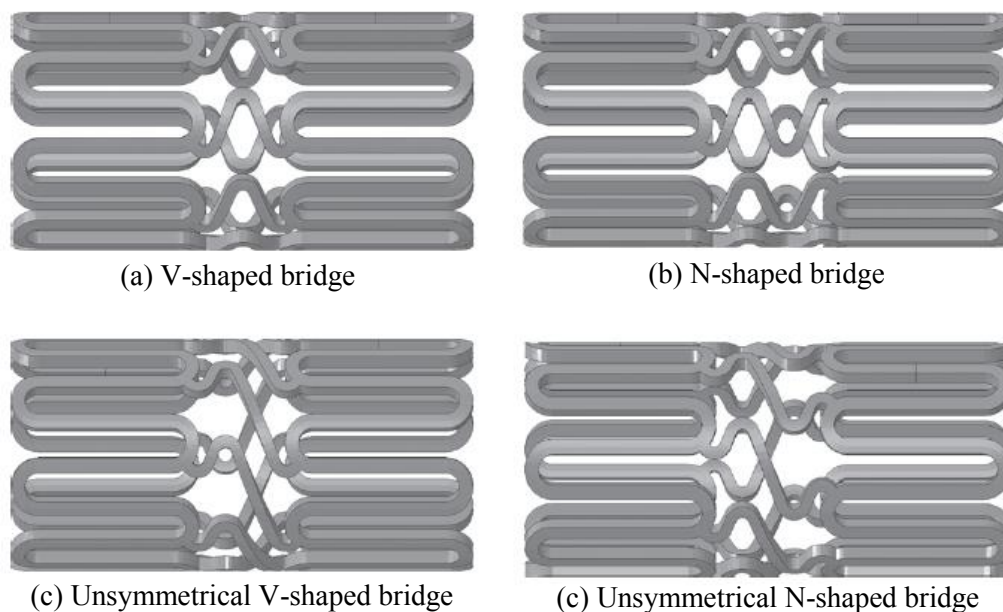


Figure 2. Geometries of the bridges [24].

2.1.1. Bending

The structural behavior of a stent in terms of bending can be demonstrated by constraining one of the extremities of the stent unit cell, and moment of bending is applied on the other extremity in stent simulation tests. Azaouzi et al. [24] has investigated the effect of the different connecting element geometry known as ‘bridge’ depicted in Figure 2 on the structural behaviour of balloon expandable (BE) stent including bending, torsion and expansion demonstrated using FEA. Basically, most of BE stents have two fundamental elements: expandable ring elements and connecting elements (bridge) [24]. Expandable rings consist of some number of struts in a zigzag pattern arrangement and offer

excellent combination of flexibility and strength during in service. Petrini et al. [27] stated that the expandable ring element is mainly function to scaffold the wall of the artery.

Various bridge geometry configurations aim to upgrade stent flexibility however influence foreshortening characteristics of the stent. During stent expansion, a peak-to-peak bridge connection will tend to pull adjacent expanding rings apart from each other as strut angles increase resulting in reduction in length (foreshortening). Based on Azaouzi et al. [24] simulation result, the location and magnitude of the maximum stress within the bridge is different for each bridge geometry design. As a result, at the beginning of bending, unsymmetrical bridges are remarkably more flexible than symmetrical bridges. The unsymmetrical V-shaped bridge is more flexible than the unsymmetrical N-shaped bridge. This study indicates the geometry modification of bridge elements using numerical analysis is crucial to enhance the flexibility of the stent.

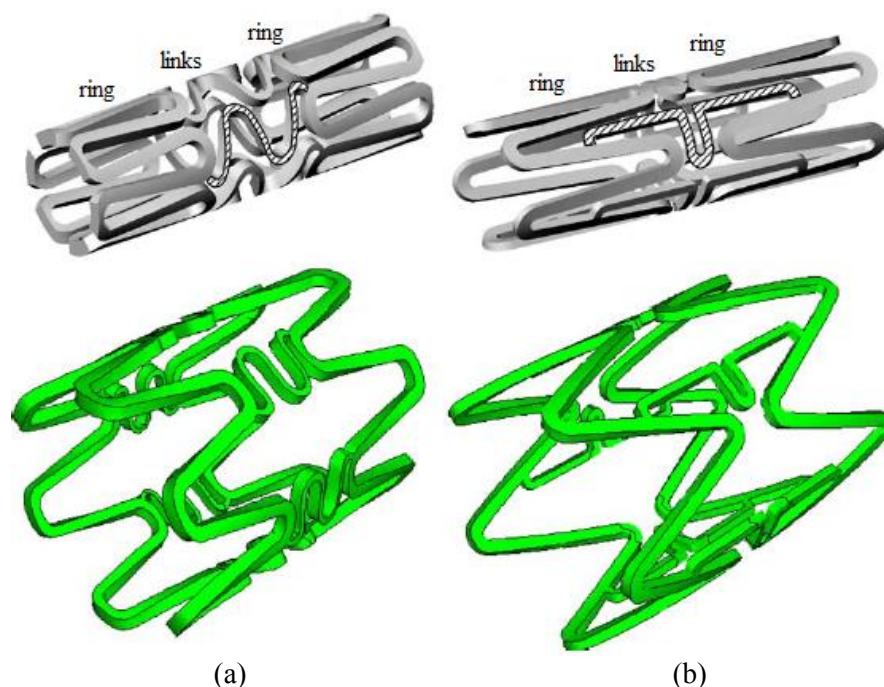


Figure 3. Geometries of (a) CV and (b) SC models in unexpanded (top) and expanded (bottom) configurations [27].

Petrini et al. [27] has studied the performance of stent by analysing three-dimensional models of two generation of stent: Cordis BX-Velocity (CV) and Sirius Carbostent (SC) (Figure 3) using FEA and demonstrated interference between link struts at the compressive side and the stent thickness. Bending tests in unexpanded and expanded configurations were carried out. During unexpanded bending analysis, CV links show a high ability to independently deform from the rings compare to SC model. For SC model, rings and links do not deform independently. This can be described based on the links geometries shown in Figure 3. The links of CV stent have two crests and are connected with the top of the ring (Figure 4(a)), while the links of the SC model have only one crest and are connected with the center of the ring (Figure 4(b)). The expanded bending responses reveal a tendency similar to the unexpanded stent response, but with a lower flexibility. Different thicknesses of the stent models would also influence the stent response during bending. Indeed, this study showed the influence of link geometry and stent thickness on stent performance in terms of flexibility.

Mori and Saito [28] have evaluated stent flexibility using FEM with four different link structures shown in Figure 5. From the results, N-stent was the most flexible however W-stent was the most rigid stent. This can be explained by the link configuration that deforms flexibly associates from symmetric or asymmetric link configuration and link strut length. The FEM analysis demonstrated that the W-

stent rigidity with a non-point symmetric link configuration resulted from interference between the struts. The narrow distance between the link struts subsequent interference between struts at the compressive side leading to reduction of flexibility and promotion of buckling deformation.

Closed-cell and open-cell stent design is vital to be considered during optimization of stent performance. The primary advantage of closed-cell design (Figure 6(a)) is supply uniform vessel scaffolding of the stenosed region probably reduce overall stent flexibility leading to fracture [29–31]. In contrast, an open-cell design (Figure 6(b)) allows fewer internal inflection points and connection to bridging elements, thus allowing for less vessel scaffolding but offer greater flexibility reducing the probability of SF.

The selection of a particular type of stent design relies on the possible performance of stent in the target lesion that is going to be cured. For example, laser-cut tube stent made of stainless steel are mostly used on coronary heart disease treatment, while stents made of Nickel-Titanium alloy are more suitable for the treatment of peripheral vascular disease positioned in femoral, abdominal, carotid or renal arteries because of their shape memory and super-elasticity properties [33].

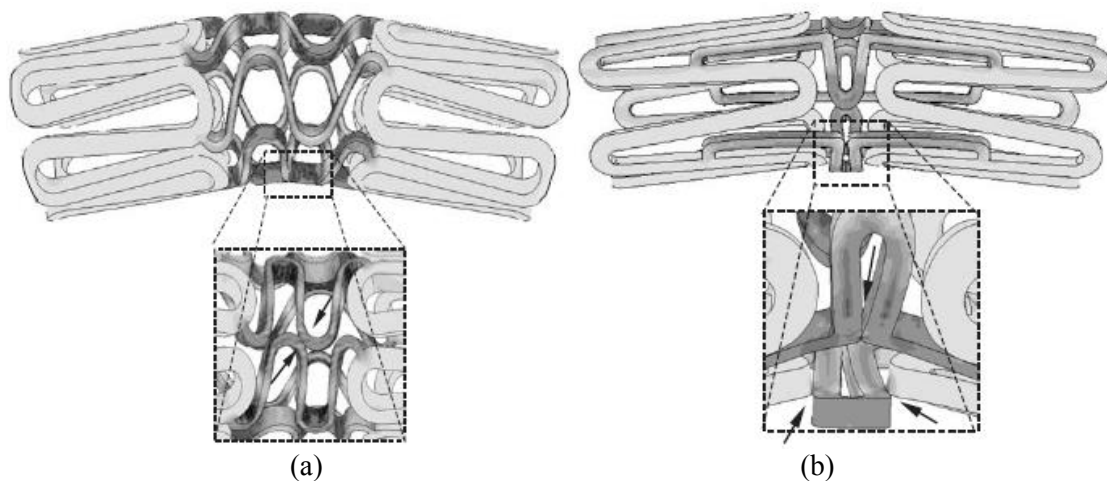


Figure 4. Von Mises stresses for the (a) CV and (b) SC models in the unexpanded configuration [27].

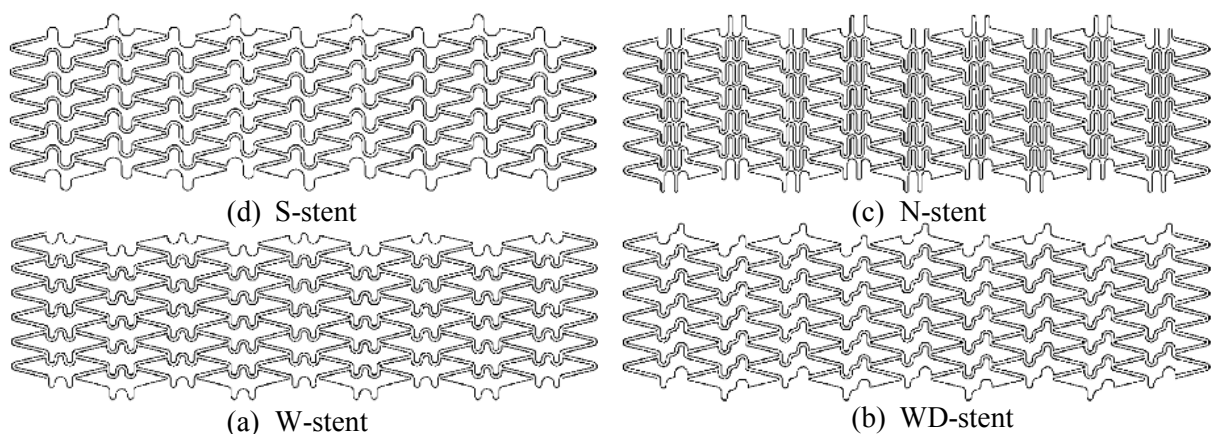


Figure 5. Link strut configurations of stent specimens [28].

2.1.2. Torsion

Since FP artery located in the largest segment of the artery branches, composed of SFA in the proximal region and PA in the distal region, stent need to twists around the femur as it through behind the knee during deliverability described by its tortuous geometry [8], thus torsion ability of a stent is

an important factor need to be considered in this review. Similarly to bending, torsion is measured by constraining one extremity of the stent and moment of torsion is applied at the constrained extremity of the stent unit cell during simulation test analysis. Azaouzi et al. [24] studied the influence of bridge geometry on the torsion ability of the stent. It is resulted the unsymmetrical N-shaped bridge (Figure 2) is obtained as the most impressive in terms of torsion ability. These results are very useful to understand the influence of bridge geometrical configuration on torsion ability of stent during insertion along tortuous FP artery.

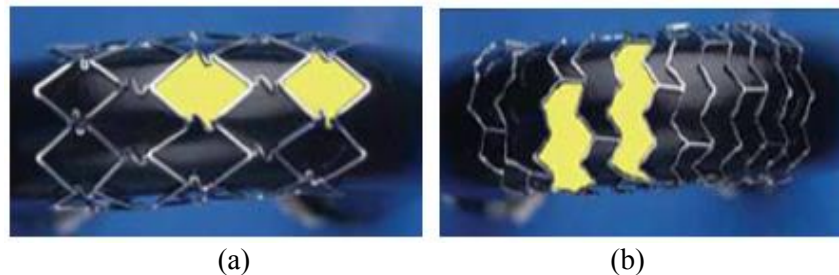


Figure 6. Stent design: (a) closed-cell design and (b) open-cell design [32].

2.2. Radial strength

Radial strength is characterized very important to prevent SF due to high calcific plaque in stenosed FP arterial segment. The strength of a stent is interpreted as the amount of recoil the vessel experiences after the stent is expanded inside the artery. The radial strength describes the capability of stent to withstand collapse under short-term or long-term external forces [24] and is the compressive resistance force of a stent to maintain the diameter and the vessel lumen after implantation [31]. The radial strength is imperative to the treatment of ostial lesions and highly calcified lesions where diameter maintenance over time is critical [34]. The choices of strut and bridge geometry, dimensions and materials are the main factors that influence stent strength leading to a better long-term efficacy of the device. Azaouzi et al. [24] studied the influence of bridge geometry on the radial strength of stent. It is observed that symmetrical N-shaped bridge (Figure 2) has high expansion due to low radial force and stresses, therefore capable to extend the life of stent.

Li et al. [29] demonstrated the influence of stent geometry on the performance of the magnesium alloy stent (MAS). The strut width of the optimized stent was designed gradually decreased from the curved end to the middle segment of the strut (Figure 7). The size distribution of the struts width is proven a superior to reduce the maximum principle strain after expansion and the maximum principle stress of the stent after recoil. The decreased size of the strut width at the middle segment caused the plastic deformation resistance weakened. Therefore, the stent is expended not only by the plastic deformation at the curved ends of the circumferential rings but also by the plastic deformation of the middle segment of the struts. Meaning that the strain is not concentrated on curved ends of the circumferential rings only, but evenly distributed on the whole struts of the stent. Moreover, optimized stent showed similar radial strength with common structure although the optimized structure has reduced gradually the strut width.

Additionally, the fundamental width of the struts has different effects. Thinner struts may incorporate more deeply into the arterial wall and cause fewer angulations and stretching of the arterial wall [35]. Although thicker struts result in greater radio-opacity and radial force for improved arterial support, the larger struts result in abnormal apposition, greater arterial injury, and neointimal proliferation. However, previous studies have observed that a reducing strut thickness (from 100 μm to about 65 μm) capable to increase radial strength of the stent, therefore improving the deliverability and life of the stent [36]. Thus, bridge geometry and stent struts thickness should be considered during modification of FP stent.

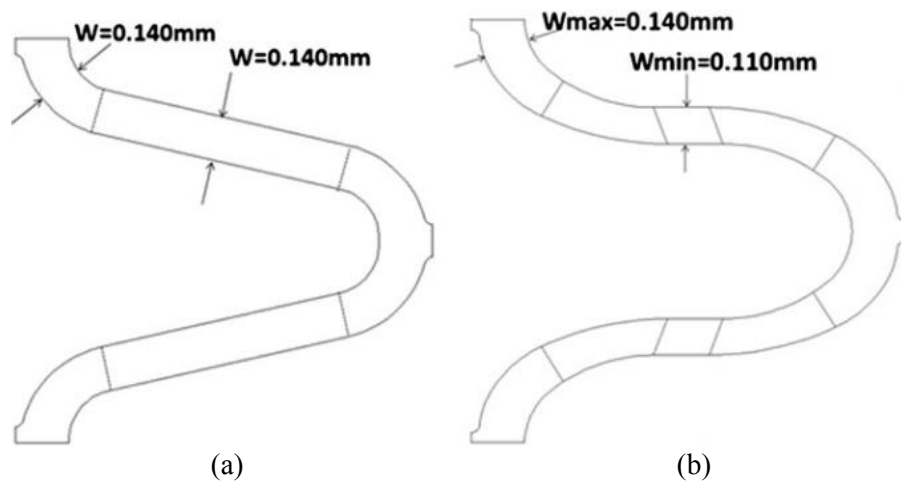


Figure 7. Stent struts width size of the common (a) and optimized (b) stent [29].

3. Finite Element Analysis

FEA is a useful method and has proven to be powerful and superior providing more detailed understanding of design and fatigue [34,35]. FEA is required because prototyping process is costly, instead of traditional trial and error technique to verify and design new models of stent. FEA provides an access to extensive information under highly controlled conditions, thus, making it possible to screen different and competing stent design alternatives before to expensive stent prototype fabrication [27]. The structural behavior of the stent is normally investigated under three loading conditions: bending, torsion and radial strength. The stent flexibility: bending and torsion is normally evaluated in the expanded and unexpanded state. The bending is measured by constraining one extremity of the stent unit cell and imposing a bending moment on the other extremity. Similarly to bending, the torsion is measured by constraining one extremity of the stent and moment of torsion is applied at the constrained extremity of the stent unit cell during simulation test analysis. Petrini et al. [27] demonstrated the response of one unit of a stent is similar to the full length stent for flexibility analysis. Hence, simulation analysis to optimize stent flexibility can be performed for a unit structure only.

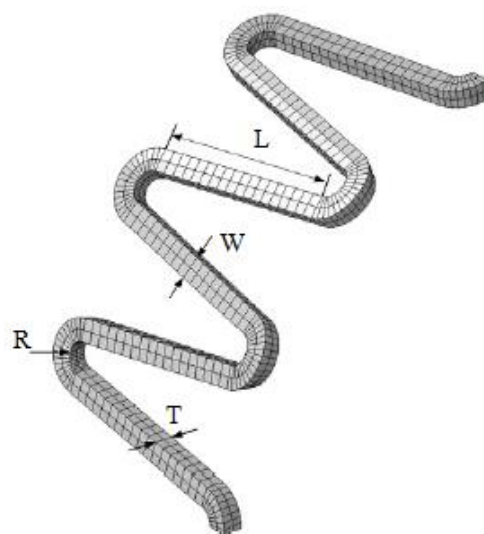


Figure 8. Design variables for strut and bridge geometry [24].

The radial strength of the stent is examined by expanding the stent unit cell in the radial direction using a cylinder. The expansion of stent is often examined by a virtual test that is developed where the stent unit cell is subjected to this loading scenario: radial displacement driven expansion of a cylindrical balloon revealing the expanded stent shape and the foreshortening reduction of the diameter of the cylindrical balloon revealing the elastic radial recoil of the stent [24]. In order to perform numerical simulations of the bending and torsion, some nodes of the stent unit cell are fixed on its constrained extremity (the translational and rotational degree of freedom of each node are constrained).

4. Discussion

Flexibility is an important property of stents during deliverability along tortuous blood vessel. FP artery associated with various mechanical loadings (bending, torsion and radial compression). Based on stress-concentration feature of stent, as the local stress is high at certain locations, fracture may potentially occur. Fracture may occur during initial deployment of the stent, which involves large amounts of plastic deformation as the stent expanded inside the stenosed artery. Optimization on strut and bridge geometry may improve the stent performances during insertion and subsequently reduce the residual stresses generated during stent placement. From the previous studies reviewed in this paper, bridge geometry configuration (symmetry and asymmetry) and stent thickness indicated a very important factor for stent flexibility (bending and torsion) and expansion. The interference between struts results in the rigidity of the stent with symmetry link configuration. In contrast, the stent with asymmetry link configuration has high flexibility because the interference between struts was geometrically averted. Besides that, stent strut width possesses a gradient size distribution influenced the amount of strain and residual stress of the stent. These findings are very useful and contribute valuable information about the structural integrity of stent purposely to minimize percentage of SF.

According to Lim et al. [39], the strut and bridge geometry may be parameterized using four design variables: length (L), curvature radius (R), width (W) and thickness (T) shown in Figure 8. These design variables differently affect the performance of the stent such as on foreshortening, elastic recoil, fatigue resistance and more importantly flexibility [39]. Reducing the strut thickness will reduce catheter system and prevent excessive flow disturbances. Reducing the strut length will upgrade the capacity of an expanded stent to assume the natural curve of a vessel without unnatural straightening. Increasing the strut width will improve the vessel scaffolding and decrease the vessel tissue prolapse between the struts. Other than that, closed-cell and open-cell design, stent material also should be considered prior stent fabrication. Thus, the specified parameters may be considered in future modification studies.

5. Conclusion

Strut and bridge geometrical configurations of stent may influence on stent performance. FEM analysis of stent is crucial to provide data of stresses generated by mechanical loadings: bending, torsion and expansion for stent modification prior to prototype fabrications. Further investigation may be conducted by combining FEA with various stent design optimization strategies aiming to improve the structural behaviour of the commercial stent in FP arterial segment to prevent SF.

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