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Numerical investigations of the structural behavior of a balloon expandable stent design using finite element method

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ABSTRACT

This paper discusses some issues regarding the structural behavior of a Balloon-Expandable (BE) stent made of stainless steel material (AISI316L). BE stent is a tubular, often mesh-like, structure which is expanded inside a diseased (stenosed) artery segment to restore blood flow and keep the vessel open following angioplasty. Most of BE stent designs have two fundamental constituents: expandable ring elements, and connecting elements “bridges” which connect adjacent rings together. The stent design is a major factor which determines its reliability during insertion into the blocked artery and throughout the long term in vivo service. The objective of this paper is to study the structural behavior of the stent in order to show the effect of the stent design, especially the geometry of the “bridges” in terms of flexibility, torsion and expansion. The numerical investigation is based on Finite Element Analysis (FEA) using Abaqus© finite element code. It has been demonstrated by FEA that the geometry of the connecting elements “bridges” has a significant impact on the structural behavior of the stent.

1. Introduction

Cardiovascular BE stents are tiny mesh-like devices placed into an artery, blood vessel, or other duct to hold the structure open. They are commonly used to treat conditions that result from blocked or damaged blood vessels in the body. Most of BE stents are made from stainless steel material that can be plastically deformed through the inflation of a balloon, upon deployment, BE stents can undergo as much as 20–30% plastic strain. After the balloon is deflated the stent remains in its expanded shape, except for a slight recoil caused by the elastic portion of the deformation. Numerous stents design are used in clinical practice today [1], they may be made from cylindrical braided wire meshes, coiled strip, laser-cut metal tubes or etched sheet. The majority of stents are made from laser cut tubing. In any case, all stents contain stress-concentration features at which the stress is locally high, and it is at these locations that failure may potentially occur. The stent design is a major factor which determines its reliability during insertion into the blocked artery and throughout the long term in vivo service. Some design requirements should be considered when designing BE stents such as: high radial strength, good flexibility, good fatigue properties, low elastic radial and longitudinal recoil and optimum scaffolding.

FEA is an extremely useful complement and has proven to be effective and capable of providing a better and a more detailed understanding for fatigue and design [2–9] of BE stents. The mechanical and structural behavior of some BE stents have been investigated recently by few researchers such as De Beule et al. [10], Wu et al. [11], Gervaso et al. [12], Walke et al. [13], Barrera et al. [14], and Park et al. [15]. Indeed, these contributions are very useful and provide valuable information about the structural integrity of cardiovascular implants. However, a little attention has been focused on determining the influence of the connecting element “bridges” on the structural behavior of BE stents. Therefore, this present paper discusses using FEA the importance of the bridges geometry and their location when designing BE stents. The objective is to perform numerical investigations that will provide quantitative data of stresses over the bridges of the stent that are generated by mechanical loadings: bending, torsion and expansion. These numerical data could be used to show how the stent behaves and to study the factors that have an influence on the fatigue lifetime of the cardiovascular BE stent. At first, some details regarding the stent design and FE Modeling methodology are presented. Then, some results obtained by numerical simulations are illustrated and followed by a general discussion about BE stent design. Finally, some concluding remarks are presented in Section 5.

2. Stent design

The choice of a particular type of stent design depends on the possible performance of that device in the lesion that is going to be treated. For example, laser-cut tube stent made of stainless steel are mainly used for the treatment of coronary heart disease, in the

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other hand stents made of Nickel–Titanium alloy are more appropriate for the treatment of peripheral vascular disease located in femoral, renal, carotid or abdominal arteries because of their super-elasticity and shape memory properties [16]. Most of BE stent designs have two fundamental constituents: expandable ring elements and spring-like connecting elements "bridges" which connect adjacent rings together (Fig. 1). Expandable rings are typically comprised of some number of struts arranged in a zigzag pattern with inflection points (tips or elbows) located at the end of each strut. The sequential ring type of construction has proven to be most functional and popular for BE stents. They offer the best combination of strength, flexibility, and small diameter for most vascular applications.

The stent geometry is parameterized and updated by changing the 2D CAD sketch (sketched in the Cartesian coordinates system (Fig. 1a)) and then wrapping it onto a cylindrical surface in order to obtain a 3D CAD model (transformed to a cylindrical coordinates system (Fig. 1b)) using a python© script [17]. The 3D CAD geometry of each component of the numerical model can be modified and remeshed automatically using the python script.

The mechanical properties of BE stents such as: flexibility, radial strength and fatigue resistance depend on the stent design characteristics, strut dimensions and connecting elements geometry "bridges". The strut and bridges geometry may be parameterized using four design variables: length, curvature radius, width and thickness (Fig. 1b). These design variables affect differently the stent performance such as fatigue resistance, elastic recoil, foreshortening and flexibility [15]. Decreasing the strut thickness will prevent excessive flow disturbances and reduce catheter system. Decreasing the strut length will improve 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 coverage (scaffolding) and reduce the vessel tissue prolapse between the struts.

The mechanical behavior of the stainless steel material (AISI 316L) of the stent is modeled using an elasto-plastic and isotropic constitutive material model. The material parameters [18] were obtained from experimental tests carried out on microscopic specimens (Table 1). As the pattern repeats itself symmetrically in the axial or longitudinal direction, only a fraction of the stent is modeled (Fig. 2) considering four different peak-to-peak connection between two symmetrical rings. Different connection strategies can serve to improve flexibility and influence the foreshortening characteristics of a stent. Generally, peak-to-peak bridge connection will tend to pull adjacent expanding rings apart from each other as strut angles increase during expansion. This often results in foreshortening, or a reduction in length as the stent is expanded. It should be noted that the choice of a bridge connection strategy could greatly impact the strength of a stent. A stent's strength is derived in large measure from the width of its constituent struts. The width of the struts is a function of the circumference of the tube and the utilization of the material around that circumference.

Table 1
Material parameters of the stent [18].

Young's modulus E (GPa)	210
Poisson coefficient υ	0.3
Ultimate tensile strength σ_{UTS} (MPa)	580
Yield strength σ_y (MPa)	315
Strain to failure ε_f (%)	37
Endurance limit σ_N (MPa)	115

3. Finite element modeling

The stent design is characterized by ring elements linked by connectors (bridges). As stated by Petrini et al. [19], the tubular-like ring elements mainly function is to sustain the vessel after the stent expansion, whereas the connecting links allow the ring elements to advance in a flexible way during the delivery process. It was shown by Petrini et al. [19] that the flexibility of the considered design can be studied by observing only a portion of the complete stent model composed of two rings and the links between them (Fig. 1b). On what follow the fraction of the stent represented in Fig. 1b that is retained in this work for the structural modeling of the stent will be referred to as *stent unit cell.*

The FEA is conducted using Abaqus/standard finite element code [20]. The FEA procedure is illustrated in Fig. 3. In order to study the structural behavior of the stent, three loading conditions are considered: (a) bending, (b) torsion and (c) expansion. The bending (Fig. 4a) and torsion (Fig. 4b) represent the stent flexibility. The radial strength of the stent is examined by expanding the stent unit cell in the radial direction using a cylinder (Fig. 4c). The stent flexibility is evaluated in the unexpanded state. The flexibility is measured by constraining one extremity of the stent unit cell and imposing a moment on the other extremity: (Mz = My = 1.75 N m for bending (Fig. 4a) and Mx = 1.75 N m for torsion (Fig. 4b). These

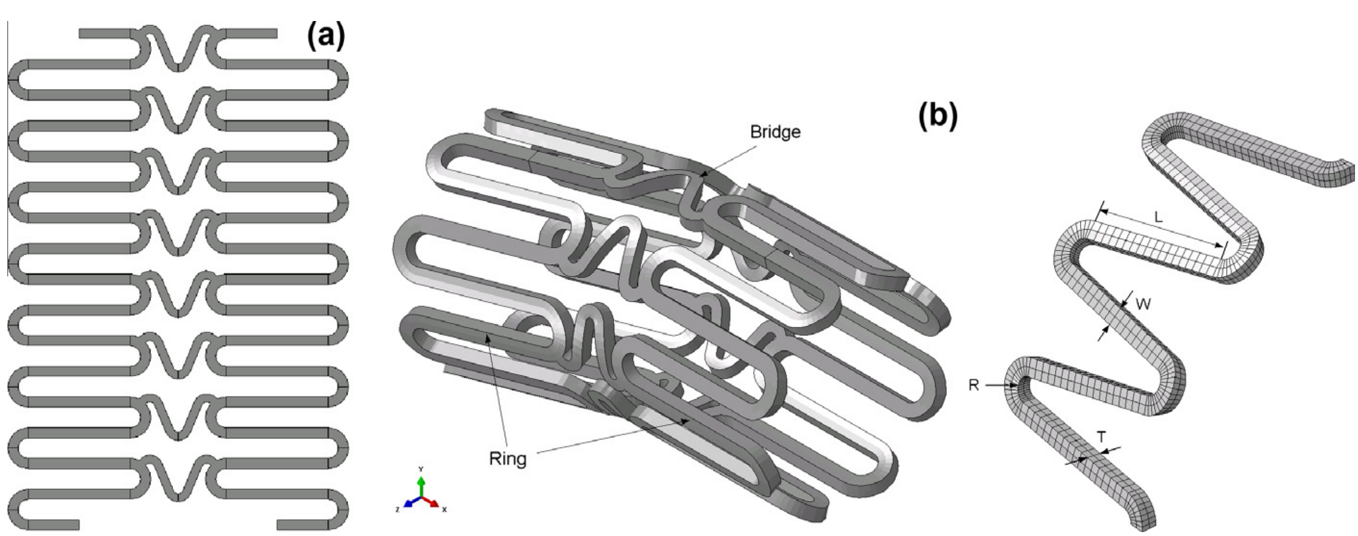

Fig. 1. Typical BE stent design (ring and connecting elements "bridges".