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Mechanical Performance of Self-expandable Nitinol Stent with Lesion-specific Design

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Abstract

This paper aims to assess the performance of a self-expandable nitinol stent, with lesion-specific design, using a finite-element (FE) method. A superelastic model was adopted to describe the superelasticity of nitinol. Hyperelastic models with damage, calibrated against experimental results, were used to describe the stress-stretch responses of arterial layers and plaque. Abaqus CAE was used to create FE models for a femoral artery with non-uniform diffusive stenosis and a nitinol stent with a lesion-specific design. In numerical simulations, an elastic tube was used to crimp and release the self-expandable stent in the diseased artery. The effect of this lesion-specific design on lumen gain was investigated by employing FE results for a commercial stent with a uniform design as a reference. The obtained results showed that the lesion-specific stent achieved larger lumen area in the artery with diffusive lesions.

Keywords: Lesion-specific design; Nitinol stent; Self-expandable; Finite element; Diffuse stenosis

1. Introduction

Stenosis is a progressive vascular disease, in which the arterial wall thickens compared to its healthy condition,

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caused by migration and proliferation of native cells and accumulation of blood borne species which include lipid, fibro-fatty composites and calcium salts (Walsh et al. 2014). It can be treated by a non-surgical procedure, stenting, by placing a stent to expand and hold the diseased artery.

Nitinol is a highly biocompatible material and commonly used in self-expandable stents. It has two closely related and unique properties, shape memory effect and superelasticity, derived from reversible solid-state phase transformations. Shape memory effect is the ability of nitinol to undergo deformation at one temperature below its martensite start temperature, then recover its original, undeformed shape when the temperature increases beyond its austenite finish temperature. Superelasticity occurs above its austenite finish temperature; in this case, the limit of its elastic deformation is 10–30 times that of ordinary metal.

A few studies have been carried out to simulate the effect of nitinol stent design on the outcomes of stenting in patient-specific arteries. Auricchio et al. (2011) investigated the performance of six self-expandable stents in different sizes and configurations using patient-specific finite element (FE) simulations. Their results indicated that the stent size and the configuration did not have significant effects on lumen gain, stress induced in the arterial wall or vessel straightening. De Bock et al. (2012) compared the outcomes of open and closed cell nitinol stents in treating intracranial aneurysms based on FE simulations, and concluded that open cell stent had better flexibility and lower straightening than closed cell one but with fish scaling. However, both studies considered the artery as one-layer isotropic material, with the ignorance of plaque.

In addition, all the commercial stents currently on the market have uniform designs. However in reality, stenosis is highly patient specific (Von Birgelen et al. 2001) and uniform stent design may not produce the desired outcomes. Hence, the design of next generation stents should consider the patient-specific nature of stenosis (Ako et al. 2007). Mechanical performance of nitinol stent with lesion-specific design has not been studied in literature yet.

The aim of this study is to simulate the deployment of nitinol stent in an artery with diffusive stenosis. A lesion-specific design was proposed for the stent based on the diffusive nature of stenosis. The advantage of lesion-specific design was evaluated by comparing its performance against that of a commercial stent with uniform design.

2. Finite element simulations

2.1. Descriptions of the artery, plaque, stent, and balloon models

For the artery, a two-layered model was created, with an inner diameter of 4 mm and a length of 50 mm. The overall thickness of arterial wall is 1.15 mm, including 0.41 mm adventitia layer and 0.74 mm media layer (Wong et al. 1993). The intima was ignored in the simulations of this study due to its single-layer cell structure. Two plaques, with a stenosis rate of 60% (Plaque 1) and 30% (Plaque 2), were modelled as symmetric layers inside the artery. Both plaques had a length of 7.5 mm and the gap between them was 3 mm. Hexahedral brick elements with reduced integration behaviour (C3D8R) were used to mesh the artery and the plaque. The uniform nitinol stent model was built based on the geometry of Zilver Flex® Vascular Self-Expanding Stent by Abaqus, with a length of 21.5 mm, an outer diameter of 5 mm and a strut width of 0.125 mm. The lesion-specific nitinol stent model had variable strut widths in the longitudinal direction, depending on the rate of stenosis. Specifically, the strut width was increased from 0.125 mm (uniform design) to 0.175 mm and 0.150 mm for the sections inside Plaque 1 and 2, respectively; while struts of the rest sections were kept unchanged (i.e., 0.125 mm). C3D8R were used to mesh both stents. Fig. 1. shows the artery-plaque model to be inflated with lesion-specific and uniform stents.

2.2. Interactions, loadings, and boundary conditions

Both ends of the artery were fully fixed throughout the simulations to consider the constraints imposed by the human-body environment. The displacements of two nodes in the middle of the stent were also fixed in circumferential and longitudinal directions to avoid rigid body motion. The process of stent deployment in the diseased artery consisted of crimping and releasing steps. A linear elastic tube was used to crimp and release the stent. The crimping step was performed by applying a radial velocity of 18 mm/s to all nodes on the tube. Interaction between the stent and the tube was modelled as frictionless general hard contact. The releasing step was modelled by moving the tube at a velocity of 240 mm/s in longitudinal direction. Interaction between the stent and the tube was maintained in this step. While interaction between the stent and the artery was modelled as a surface-to-surface

hard contact with a frictional coefficient of 0.09 (Ramirez, 2010). Both simulations were carried out by using the Abaqus explicit solver (Abaqus, 2017). The time parameter was chosen to be 0.1 s for each crimping and releasing step, and the time increment was of the order of 10^{-7} s throughout the simulations.

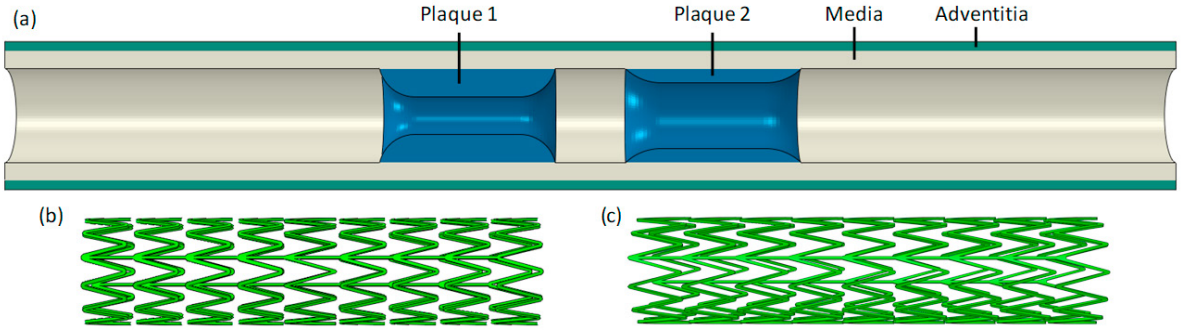

Fig. 1. (a) Artery-plaque assembly; (b) lesion-specific nitinol stent assembly; (c) uniform stent assembly.

2.3. Material Models

The first-order Ogden model with Mullins effect was adopted to describe the mechanical behaviours of the plaque, for which the parameters were determined by fitting the experimental data of echolucent plaque in Maher et al. (2011). The modified HGO-C model with damage was adopted to describe the mechanical behaviours of the arterial layers, for which the parameters were provided by Fereidoonnezhad et al. (2016). The superelastic model was used to describe the constitutive behaviour of the nitinol at body temperature. The corresponding parameter values were provided by Azaouzi et al. (2013).

3. Results and discussion

The final lumen diameters for Plaque 1 and 2 simulated using lesion-specific and uniform nitinol stents are plotted in Fig. 2. The initial lumen diameters for Plaque 1 and 2 were 1.6 and 2.8 mm, respectively. The lesion-specific stent achieved final lumen diameters of 3.15 mm for Plaque 1 and 4.61 mm for Plaque 2, while the uniform one achieved 2.86 mm for Plaque 1 and 4.27 mm for Plaque 2.

Stent with lesion-specific design showed improved outcome, in terms of lumen diameter gain, compared to uniform stent design. However, the maximum stresses and damage in the stent and the artery caused by the deployment of the lesion-specific stent were both higher than those caused by the uniform design.

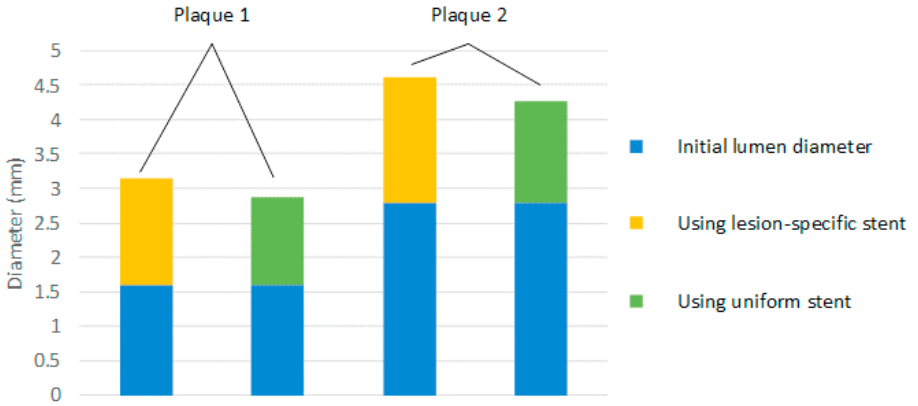

Fig. 2. Comparison of final lumen diameters for Plaque 1 and 2 simulated by using lesion-specific and uniform nitinol stents.

4. Conclusions

The results of the FE simulations indicated the capability of the lesion-specific nitinol stent to gain a larger lumen diameter when compared to a uniform stent. However, the design of lesion-specific nitinol stent still needs optimization which should be explored in future work.

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