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Procedia Structural Integrity 13 (2018) 187–191

Structural Integrity Procedia

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ECF22 - Loading and Environmental Effects on Structural Integrity

Computational Evaluation of Artery Damage in Stent Deployment

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Abstract

This paper aims to evaluate damage in an arterial wall and plaque caused by percutaneous coronary intervention using a finite-element (FE) method. Hyperelastic damage models, verified against experimental results, were used to describe stress-stretch responses of arterial layers and plaque in the lumen; these models are capable to simulate softening behaviour of the tissue due to damage. Abaqus CAE was employed to create the FE models for an artery wall with two constituent layers (media and adventitia), a symmetric uniform plaque, a bioresorbable polymeric stent and a tri-folded expansion balloon. The effect of percutaneous coronary intervention on vessel damage was investigated by simulating the processes of vessel pre-dilation, stent deployment and post-stenting dilation. Energy dissipation density was used to assess the extent of damage in the tissue. Overall, the plaque experienced the most severe damage due to its direct contact with the stent, followed by the media and adventitia layers. Softening of the plaque and the artery due to the pre-dilation-induced damage can facilitate the subsequent stent-deployment process. The plaque and artery experienced heterogeneous damage behaviour after the stent deployment, caused by non-uniform deformation. The post-stenting dilation was effective to achieve a full expansion of the stent but caused additional damage to the artery. The computational evaluation of artery damage can be also potentially used to assess the risk of in-stent restenosis after percutaneous coronary intervention.

Peer-review under responsibility of the ECF22 organizers.

Keywords: Artery damage; Hyperelastic damage model; Finite element; Pre/post-dilation; Stent deployment

1. Introduction

Percutaneous Coronary Intervention (PCI) is a prevalent treatment for atherosclerosis to restore the normal blood flow in the coronary artery. During this stenting procedure, a balloon is positioned in the diseased part of the vessel and used to inflate a stent to open the blocked blood vessel. In some cases, such as patients with severe stenosis, pre-dilation needs

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Peer-review under responsibility of the ECF22 organizers.
10.1016/j.prostr.2018.12.031

to be performed before stenting in order to clear the path for easier positioning of balloon and stent, and also facilitate the expansion of the vessel. The mechanical stretching of the vessel induced by the stenting procedures may lead to injury of the vessel and even rupture of the plaque and dissection of the arterial wall. The associated tissue damage intends to activate an inflammatory reaction of the vessel, leading to the development of in-stent restenosis.

Considerable efforts have been made to study the PCI-induced damage of the arterial wall and the plaque, especially using computational simulations. Balzani et al. (2006) simulated a process of overstretching of an atherosclerotic artery with the finite-element method (FEM), considering discontinuous damage and residual stresses in the arterial wall. It was demonstrated that a stress-free configuration required not only a radial cut but also a circumferential cut between the media and the adventitia of the artery. Sáez et al. (2012) developed an anisotropic damage model for a fibrous soft tissue, and the model was capable of assessing damage of collagen fibres caused by angioplasty. Fereidoonnezhad et al. (2016) proposed an anisotropic damage model for the arterial tissue, which was capable of simulating both the Mullins effect and permanent deformation, with model parameters calibrated against the experimental data in Weisbecker et al. (2012).

On the other hand, clinical outcomes of PCI with pre- or post-dilation were frequently reported in the literature. Martínez-Elbal et al. (2002) concluded that the overall safety and efficacies were similar for direct stenting and stenting with pre-dilation according to their randomized study. Oblitas et al. (2013) demonstrated that stenting with pre-dilation was able to achieve better angiographic or clinical outcomes when compared to direct stenting.

Still, computational studies on the contributions of pre/post-dilations to the final PCI outcomes are in their infancy, especially with regard to the damage caused to the arterial wall. Therefore, the aim of this paper is to investigate the effects of pre- and post-dilation on stenting outcomes and assess the damage in the arterial wall due to the PCI procedure. Appropriate damage models were introduced into simulations to describe the softening effect of the plaque and the vessel wall. FE analysis was carried out to simulate the PCI procedure with or without pre/post-dilation.

2. Finite-element simulation

2.1. Description of finite-element models

Simulations were carried out with the Abaqus explicit solver (Abaqus, 2017). The step time was chosen to be 0.1 s for each pre-dilation, stenting and post-dilation step, while a time increment was of the order of 10^{-7} s throughout the analysis. For the artery, a two-layer model was developed, with an inner diameter of 3 mm and a length of 40 mm. The overall thickness of arterial wall was 0.66 mm, including an adventitia layer of 0.34 mm and a media layer 0.32 mm (Holzapfel et al., 2005). The extremely-thin intima layer was not considered in the simulations due to its negligible contributions to artery deformation. This is different from the literature, where intima was always modelled as a layer with a largely overestimated thickness (i.e., ~0.28 mm), which is biologically incorrect. The plaque was modelled as a symmetric layer inside the artery, with a length of 10 mm and a stenosis of 50% (i.e., an inner diameter of 1.5 mm). Hexahedral elements with reduced integration (C3D8R) were used to mesh the artery and the plaque. The stent had a length of 12.66 mm and an outer diameter of 3 mm; while the respective parameters of a tri-folded balloon had a length of 16 mm and a diameter of 3.2 mm in a fully inflated shape. C3D8R and M3D4R (three-dimensional 4-node membrane elements with reduced integration) elements were used to mesh the stent and the balloon, respectively. The stent-balloon assembly was preliminarily crimped by 12 rigid plates before introduced into the artery-plaque assembly. The FE mesh for the artery-plaque-stent-balloon assembly is presented in Fig. 1.

2.2. Interaction, loading and boundary conditions

Linear-elastic tube was used to expand the artery during the pre-dilation procedure. Different velocities were used to control the expansion of the tube to different desired diameters. Both ends of the artery were fully constrained throughout the simulations to consider the constraints imposed by the human-body environment. Interaction between the artery and the tube was modelled as frictionless general hard contact. Stent expansion in a diseased artery consists of inflation and deflation steps. The inflation step was performed by applying pressure on the inner surface of balloon. The level of pressure was increased linearly from 0 to 0.6 MPa. Interactions between artery, stent and balloon were modelled as general hard contacts with a coefficient of friction of 0.25 (Ju et al., 2008). Subsequently, the deflation step was modelled by releasing the pressure on the inner surface of balloon, which allowed the expanded stent to recoil freely. Interactions

between stent, the balloon and the plaque were maintained in this step. Post-dilation was simulated by re-inflating the balloon using different maximum pressure

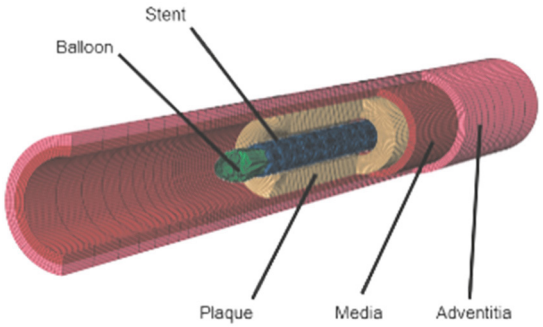

Fig. 1. Finite-element model for the artery-plaque-stent-balloon assembly

2.3. Material models

The first-order Ogden model, with Mullins effect and permanent deformation, was adopted to describe the mechanical behaviour of the plaque, where the parameters were determined by fitting the experimental data of echolucent plaque provided in Maher et al. (2011). A variant of the Holzapfel-Gasser-Ogden HGO-C damage model was adopted to describe the mechanical behaviour of the arterial layers, with its parameters determined by fitting the experimental data in Weisbecker et al. (2012) and Fereidoonnezhad et al. (2016).

A modern cardiovascular stent – Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) (Abbott Vascular, USA) – was considered in the simulations. It is made of PLLA with density of 1400 kg/m^3, the Young's modulus of 2200 MPa and the Poisson's ratio of 0.3 (Schiavone et al., 2016); plastic behaviour of PLLA was described in Pauck and Reddy (2015). The balloon was assumed to be poly(1,8-octanediol-co-citrate) (POC), with a density of 1100 kg/m^3, the Young's modulus of 49.79 MPa and the Poisson's ratio of 0.31 (Ponkala et al., 2012).

3. Results

The results of stenting obtained in the FE simulations with and without pre-dilation are presented in Fig. 2. The inflation and deflation for pre-dilation lasted from 0 to 0.2 s, and those for stenting - from 0.2 to 0.4 s. Stenting with pre-dilation was able to achieve a larger lumen diameter compared to the stenting-only procedure. The higher the extent of stretch of the plaque-artery in the pre-dilation step, the larger the lumen diameter in the subsequent stenting step. The damage of the plaque, presented in terms of respective dissipated energy, increased significantly when the lumen diameter increased (Fig. 2b), which is also the case for the arterial layers. Excessive arterial damage potentially increases the risk of in-stent restenosis after PCI.

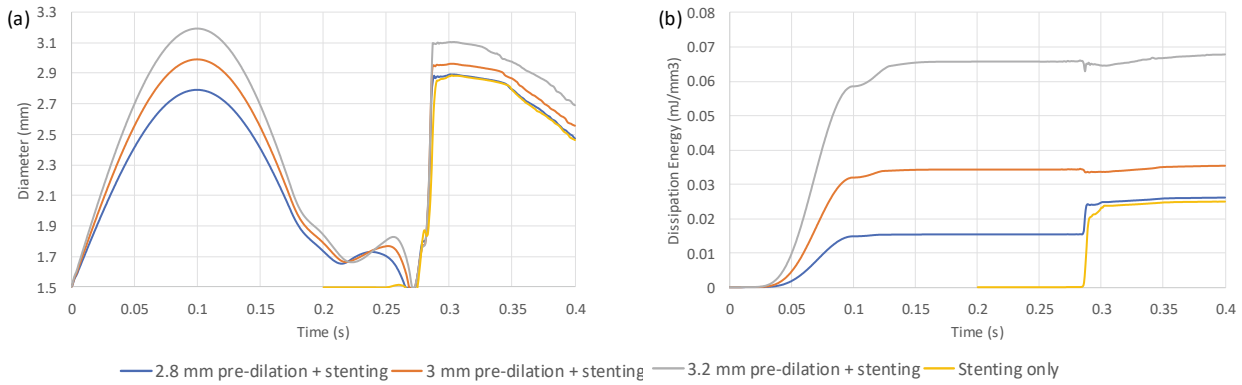

Fig. 2. Simulations results for stenting with and without pre-dilations: (a) lumen diameter vs. time; (b) dissipation energy of plaque vs. time.

The results of simulations for stenting with post-dilation under different maximum pressure, i.e., 0.6, 0.8 and 1.0 MPa are given in Fig. 3. The inflation and deflation in stenting were from 0 to 0.2 s, and those for post-dilation were from 0.2 to 0.4 s. The process of post-dilation with pressure higher than that in stenting led to an increased lumen diameter, while no clear effect was observed for it with the same pressure as that in stenting. Again, the damage of the plaque, as well as the arterial layers, increased with the growing lumen diameter achieved in post-dilation (Fig. 3b), indicating an increased risk of in-stent restenosis.

4. Conclusions

From the results of the FE simulations, it can be concluded that pre-dilation helps to achieve a larger lumen diameter in PCI thanks to softening of the plaque-artery caused by over-stretch. Post-dilation with higher pressure can also facilitate a gain of a larger lumen diameter. The damage of the plaque and artery always increases with the increase in the lumen diameter. Future work is planned to study the relationship between stenting-caused damage in the arterial wall and the development of in-stent restenosis.

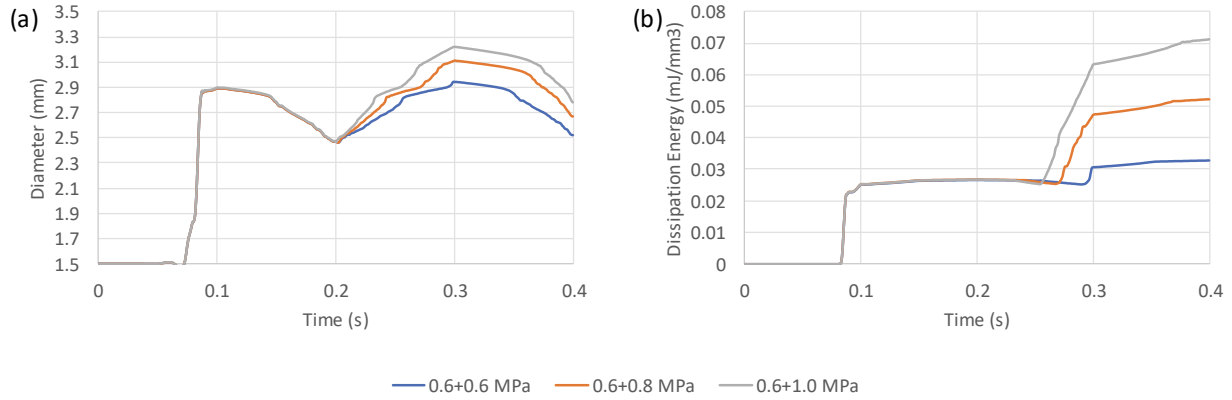

Fig. 3. Simulation results for stenting with and without post-dilation with different pressure levels: (a) lumen diameter vs. time; (b) dissipation energy of plaque vs. time.

5. Acknowledgements

We acknowledge the support from the British Heart Foundation (Grant number: FS/15/21/31424; Title: Towards controlling the mechanical performance of polymeric bioresorbable vascular scaffold during biodegradation) and the UK Royal Society (Grant number: IE160066; Title: Evaluating the Performance of Additively Manufactured Endovascular Scaffolds).

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