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Numerical models of net-structure stents inserted into arteries

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ABSTRACT

Introduction: Restenosis is strongly attributed to stresses caused by stent–artery interactions generated in the artery after balloon angioplasty. Numerical methods are often used to examine the stent–artery mechanical interactions. To overcome the extensive computational requirements demanded by these simulations, simplifications are needed.
Objective: We introduce simplified models to calculate the mechanical interactions between net-structured stents and arteries, and discuss their validity and implications.
Methods: 2D simplified numerical models are suggested, which allow cost effective assessment of arterial stresses and the potential damage factor (DF). In these models, several contact problems were solved for arteries with hyper elastic mechanical properties. Stresses were calculated for a large range of cases and for different numerical model types. The effects of model simplifications, oversizing mismatch and stenosis rate and length and symmetry on the resulting stresses were analyzed.
Results & conclusions: Results obtained from planar 2D models were found in good agreement with results obtained from complex 3D models for cases with axisymmetric constant or varying stenosis. This high correlation between the results of 3D cases with varying stenosis and the more simple 2D cases can be used as a simplified and convenient tool for calculating the arterial wall stresses in complex cases. Maximal stresses obtained by the 2D model with an asymmetric stenosis are lower than the maximal stresses obtained in the axisymmetric case with the same stenosis percentage. Therefore, axisymmetric models may provide the worst-case estimation values for a stent of interest.

1. Introduction

During stent implantation, the mismatch between the stent and the artery diameters cause elevated stress in the arterial wall, leading to local injury of the artery. These stent induced arterial injuries and stresses are believed to be a determining factor in the onset and progression of in-stent restenosis [1]. After stent deployment, artery injury by the stent's struts leads to thrombus formation and a cascade of inflammatory events [2]. Inflammation caused by the above mentioned arterial injury plays a central role in the formation of a new layer of scar tissue (neointima) further narrowing the arterial lumen and increasing the risk for restenosis [3–5]. The developing stresses in the artery wall are major contributors to neointima formation, even in the absence of deep injury [6,7].

Studies have shown that stent design including its geometric dimensions and mechanical properties are important factors in the clinical outcomes [8]. In the context of stent optimization, the design objective is to minimize the stress level in the arterial wall following stent deployment [9,10]. Computational models of stent deployment, such as finite element (FE) models, may serve as powerful and cost effective tools for optimizing stent designs. FE methods enable investigation of specific design parameters, or allow comparison between different designs, using a vast range of criteria for stent performance. FE models can be utilized to reduce arterial injury or to assess the potential risk of injury in the early design phase and hence minimize in-stent restenosis [8,11–17]. Strut thickness, for example, was found as an independent predictor of restenosis. Stents with thinner struts have a lower restenosis rate, while stents with thicker struts induce higher stresses within the artery wall [18–20].

When modeling an interaction between a stent and an artery, many challenges arise, among them, the construction of arterial model geometry, the complex contact interaction and the material properties [21]. To overcome these challenges, several simplified methods have been suggested [2]. Zahedmanesh et al. showed that direct application of pressure to the stent inner surface may be used as a good approximation for blood pressure [22]. Auriccio et al. focused on the interaction between a balloon expanded stent

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and the artery, suggesting a modified design of the stent to reduce the nonuniformity of the contact stress distribution [23]. In previous studies, our group focused on the mechanical interaction between the stent and artery using analytical and numerical models [24–27]. These studies assessed the effect of stent and arterial geometric and mechanical properties on the distribution of stresses developed at the stent–artery interface.

Many studies have used FE models to investigate the effect of plaque composition [10,21,23,28–31], or to simulate the arterial biological response [11,31]. To overcome the extensive computational requirements that these simulations demand, such studies used 2D models to estimate the stresses acting on the arterial wall. Zahedmanesh et al. [2] used an axisymmetric hyperelastic FE model of an artery to employ the biological response to an implant using mechanobiological models. In their model, the stents struts were represented using a simple square cross section pressed against the artery wall, neglecting the stiffness of the stent structure and the effect of stent oversizing. In addition, their model considered the beam as perpendicular to the axial axis, while in reality it is mainly parallel. Boyle et al. [32] used a more realistic 2D geometry of axisymmetric artery and stent cross-section of a symmetrically stenosed artery with six stent struts. A 1/6 segment was considered due to symmetry. The stents beams were represented by circular cross sections. In their model, a displacement was applied to the circular strut, neglecting the stiffness of the stent structure and the effect of stent oversizing. Teodorescu et al. [33] used 2D models to predict the arterial wall subsurface stress field due to individual stent beams cross sections. In their models, they compared squared and circular cross sections for modeling stent struts, revealing the effect of sharp edges on stress concentrations. For the contact mechanics, they used a method which decomposes the contact pressure distribution into a series of harmonic waves that predicts the subsurface stress and strain fields for each harmonic [34].

However, we did not find any study discussing the validity of these 2D simplifications and their correlation with more realistic 3D models. In the present study, we propose simplified models for net-structured stents which are inserted into asymmetric stenosed arteries, containing two hyper elastic layers and discuss their validity and their implications. 2D simplified numerical models are also suggested. This allows for a cost effective assessment of arterial stresses and the stent's potential damage for a wide range of cases.

We used simplified models for net-structured self-expanding stents to evaluate the developing stress in the arterial wall. A potential damage factor was formulated, describing these stresses. DF was calculated for a large range of cases and for different numerical model types. The effects of model simplifications, oversizing mismatch and stenosis rate, length and symmetry on DF values were also analyzed.

2. Methods

The models in this study focus on net-structured stents. Net-structured stents are commonly used in many different stent types such as Driver™, BioMatrix™, Promus™ (for coronary arteries) and SciMed™ (for peripheral arteries), among others. These stent types are characterized by a periodic structure of beams in alternating directions (zigzag).

2.1. Potential damage factor (DF) and averaged circumferential stresses (ACS)

To assess the potential risk of stress induced restenosis due to a specific artery-stent configuration, a criteria index defined by Brand et al. [26] defined as damage factor, was used in this study. This factor is defined as the average radial stress in the contact region, normalized by blood pressure, i.e.

$$\mathrm{DF} = \frac{(1/N)\sum_{i=1:N}\sigma_{rr}(i)}{P_{\mathrm{blood}}} \tag{1}$$

where N is the number of nodes on the contact region between the beam and the artery, $\sigma_{rr}(i)$ is the radial stress on the artery at node i and $P_{\mathrm{blood}}=100$ mmHg (13.6 kPa), the average blood pressure. In addition, we defined another criterion which represents circumferential stresses, since they also have substantial influence on the remodeling of the artery. The averaged circumferential stresses calculated for all the nodes laying on the contact region are defined as:

$$\mathrm{ACS} = \frac{1}{N}\sum_{i=1:N}\sigma_{\theta\theta}(i) \tag{2}$$

where $\sigma_{\theta\theta}(i)$ is the circumferential stress in the artery at node i.

2.2. Numerical models

The numerical simulations included a thorough investigation of stresses developed in the artery wall due to self-expanded stent implantation with different oversizing values. Four different models were examined: (i) axisymmetric two-dimensional model (ii) axisymmetric three-dimensional model with constant stenosis (iii) axisymmetric three-dimensional model with varying stenosis and (iv) asymmetric two-dimensional model.

All models used the NiTinol net-structured stents, with a Poison's ratio of $\upsilon=0.3$ and Young's modulus of $E=46$ GPa. To account for standard oversizing of self-expanded stents, mismatch values between the outer diameter of the stent and the inner diameter of the artery were specified in the range of 0.5–1 mm.

Both the artery wall and plaque were considered to have nonlinear and hyper-elastic material properties. The outer layer was defined using average properties of healthy adventitia and media, based on experiments of Holzapfel et al. [21]. Similarly, the plaque was determined by the average properties of diseased fibrous intima and media. The stiffness of the plaque is approximately twenty times greater than that of the healthy layer. The stress–strain diagram of the hyperelastic properties used for the two layers in the models is shown in Fig. 1.

The curves were approximated to the Ogden form of strain energy potential, which is based on the principal stretches of left-Cauchy strain tensor for isotropic material, with the form:

$$W = \sum_{i=1}^{N}\frac{\mu_i}{\alpha_i}(\overline{\lambda}_1^{\alpha_i}+\overline{\lambda}_2^{\alpha_i}+\overline{\lambda}_3^{\alpha_i}-3) \tag{3}$$

where $\lambda_{i,j}=1,2,3$ the principal stretches, $N=1$ and μ_i, α_i are the material's constants. For the healthy layer the figures are 368.89, 17.32, and for the plaque layer they are 8608.6, 24.301, respectively.

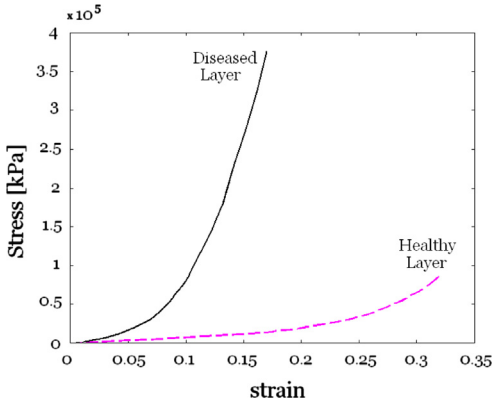

Fig. 1. Stress–strain diagram of the artery's layers: healthy (dashed line) and plaque (solid line).