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Assessment of structural and hemodynamic performance of vascular stents modelled as periodic lattices

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ABSTRACT

This work considers vascular stents with tubular geometry assumed to follow a periodic arrangement of repeating unit cells. Structural and hemodynamic metrics are presented to assess alternative stent geometries, each defined by the topology of the unit cell. Structural metrics include foreshortening, elastic recoil and radial stiffness, whereas hemodynamic performance is described by a wall shear stress index quantifying the impact of in-stent restenosis. A representative volume element (RVE) modelling approach is used, and results are compared to those obtained from full simulations of entire stents. We demonstrate that the RVE approach can be used to quantify the impact of the topology of the repeating unit on the structural and hemodynamic properties of a stent, and thus support clinicians in making proper choices among alternative stent geometries.

1. Introduction

Coronary heart disease is the most common type of heart disease and the leading cause of death in the developed world [1]. It is mainly caused by the development of an atherosclerotic lesion in an artery. The lesion results in plaque build-up along the inner walls of the artery and eventually leads to an occlusion, restricting blood flow. A common treatment is angioplasty, which involves inserting percutaneously a balloon at the end of a catheter into the site of the occlusion. The balloon is then inflated to increase the size of the lumen to restore blood flow. As a result, restenosis can follow immediately after the procedure due to the elastic recoil of the vessel. This may be prevented by using a stent (a tubular scaffold) to support the blood vessel from the inside of the lumen. Stents were introduced in the early 90s, and have been successful at reducing angioplasty-related restenosis [2]. They can also be used to provide support for arterial grafting or aortic valve replacement. Despite a large variety of stent designs in the market, adverse biological responses, such as in-stent restenosis, have not been addressed adequately. While the causes of restenosis are not completely understood, several studies have shown that low shear stress at the arterial wall is one of the main causes [3–6].

Three main mechanical properties govern the structural function of a stent: radial stiffness, elastic recoil and foreshortening [7]. Higher radial stiffness is desired to prevent collapse of the stent, once it is in place. Foreshortening refers to the change in length of the stent upon expansion. During deployment, a desirable property is that the stent has zero foreshortening and low elastic recoil. Placement accuracy is not a trivial matter for the clinical practitioner [8]. A change in length may result in missing the lesion, thus increasing complications requiring further procedures.

Various mechanical stent properties have been studied, including foreshortening, recoil, radial stiffness and fatigue. These attributes have been investigated by means of finite element analysis and experimental investigation [9–18]. Stents with geometry represented by a periodic arrangement of structural units are often studied [14,19,20]. The study of a single unit cell has the advantage of reducing the computational effort that would be required to analyse the entire geometry of the stent. In this manner, the mechanical properties of a stent can be quantified with reduced analysis of its unit cell. For instance, Tan et al. quantified the impact of stent cell geometry on compliance and foreshortening, compromising of voids and struts, such as in a lattice [14]. Finite element analysis was used to systematically compare dissimilar cell geometries and attain desired deformation characteristics. Recently, Douglas et al. followed this approach to study the expansion mechanism of balloon expandable vascular stents without considering their hemodynamic performance [19]. Based on the assumption that the stent consists of repeating units, analytic and kinetic models were developed to quantify foreshortening. Finite element analysis was used to compute radial compliance and recoil for a variety of stents.

Blood flow has a substantial impact on stent restenosis. In most cases, restenosis after a coronary stent implantation is due to the

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thickening of the intima of the blood vessel, i.e., intimal hyperplasia [2]. Intimal hyperplasia is often observed at specific locations in the stented region [21]. It has been observed that regions of moderate to high shear stress are spared of intimal thickening, while focal lesions develop only in areas of low and recirculating flow [22]. This is the result of a dramatic alteration to the arterial geometry following the implantation of a stent. The change directly affects the velocity profile of the blood flowing through, thereby resulting in a change in the distribution of wall shear stress (WSS) along the entire length of the stented artery [23].

To assess the hemodynamic performance of a stent following implantation, Mejia et al. [24] introduced a set of metrics based on the statistical moments of the WSS distribution, which have been shown to be promising in correctly assessing the performance of the strut profiles of several stents. In addition, they showed that "*appropriate strut apposition can lead to a significant improvement in terms of the hemodynamic performance of a stent*". This suggests that modifying the design of the stent can improve its hemodynamic performance. A number of studies have investigated the effect of stent design on the distribution of WSS [23,25–29]. Previous work [24] is limited to stent profiles of a single strut and cannot quantify the critical role of a given strut's layout within the unit cell.

This work focuses on the role the unit cell topology plays on the mechanics and hemodynamic performance of stents. Our objective is to assess their structural and hemodynamic performance via a unit cell approach (or representative volume element – RVE). The existing literature does not include any methodology to quantify the hemodynamic compatibility of stents using a single metric. The main objective of this paper is to introduce a metric for assessing the hemodynamic performance of a stent during the design process.

2. Stent modelling using representative volume elements

The stent designs considered in this work are periodic arrangements of closed unit cells, similar to a tessellation of cells along independent directions that is typical of lattice materials. As with any lattice, the properties of a stent of this kind can be specifically tailored by controlling the topology of its repeating unit.

Performing full-scale finite element analysis of a periodic domain is generally computationally expensive, especially if it is used repeatedly in design optimization studies. It is more appropriate to resort to homogenization schemes that model a single unit cell as representative of the overall domain response. This is feasible if the unit cell size is sufficiently small relative to the size of the periodic structure. Applying such a method involves imposing assumptions that are equivalent to considering that the size of the RVE is negligible with respect to the size of the macroscopic domain of the lattice [20,30–38].

Fig. 1 illustrates the methodological approach followed in this work, where the structural finite element model and the computational fluid dynamics model are built using only the RVE. An additional advantage of this strategy is that parametric models of a stent can be easily created from the parameterization of a single unit.

2.1. Choice of stent unit topology

As in the recent work of Douglas et al. [19], we examine five stent designs, whose unit cells are depicted in Table 1. Other stent parameters are listed in Table 2. We assume that the stents are made of an elastoplastic material with elastic modulus $E = 193$ GPa, yield strength $\sigma_y = 260$ MPa, tangential modulus $E_t = 0$ GPa and Poisson ratio $\nu = 0.3$ [39]. To simplify the numerical models, the interaction between the wall and atherosclerotic plaque is ignored.

2.2. Stent model and boundary conditions for structural analysis

A stent is implanted using a balloon catheter. The balloon is expanded to plastically deform the stent in place. For this work, the load on the stent is assumed to be entirely radial. The forces exerted in the axial direction by the balloon, artery wall and blood flow are neglected. The expansion mechanism can therefore be modelled by applying a radial strain to the stent. When using an RVE approach, periodic boundary conditions are generally applied to ensure compatibility of deformation and correct computation of stress and strain. The repeating unit is subjected to 3D periodic boundary conditions, expressed using a cylindrical coordinate system by:

$$u_\theta(r, 0, z) = -u_\theta\left(r, \frac{\pi}{N_c}, z\right) \tag{1}$$

$$u_z(r, \theta, 0) \ = -u_z\left(r, \theta, \frac{L}{N_a}\right), \tag{2}$$

where u_θ is the displacement in θ, u_z is the displacement in z and N_a is the number of cells in the axial direction

$$u_r\left(\frac{D_i}{2}, \theta, z\right) = \begin{cases} \frac{(D_f - D_i)\pi}{N_c} \\ '\mathit{free}' \\ -\frac{1}{4}\frac{(D_f - D_i)\pi}{N_c} \end{cases} \tag{3}$$

where u_r is the displacement in r, and D_f, D_i, N_c are listed in Table 2. N_c is the number of cells in the circumferential direction. The first stage consists of a load corresponding to a stent expansion from D_i to D_f. In the second stage, the load is removed to allow for elastic recoil, hence the 'free' boundary condition. Finally, the third stage consists of decreasing the diameter to 25% of the initial diameter change. The finite element solutions obtained from the first, second and third stages, are used to determine respectively foreshortening, recoil and radial stiffness.

2.2.1. Structural performance metrics

The structural metrics considered in this work are foreshortening, elastic recoil and radial stiffness. Small foreshortening improves the placement accuracy of the stent. A low elastic recoil helps to achieve a more accurate final stent diameter. Finally, a high radial stiffness prevents the blood vessel to close under load.

The foreshortening is defined as the ratio of the change in the length of the stent during the first stage to the initial length before balloon expansion.

$$\partial l = \frac{L_{load} - L_{unload}}{L_{load}}. \tag{4}$$

Elastic recoil is defined as the ratio of the change in radius of the stent during the second stage to the radius before the load is removed.

$$R_e = \frac{R_{load} - R_{unload}}{R_{load}}. \tag{5}$$

The radial stiffness is defined as the ratio of the change in pressure on the outside of the stent to the change in radial strain