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Micromechanical modeling for the probabilistic failure prediction of stents in high-cycle fatigue

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ABSTRACT

The present paper introduces a methodology for the high-cycle fatigue design of balloon-expandable stents. The proposed approach is based on a micromechanical model coupled with a probabilistic methodology for the failure prediction of stents. This allows to account for material heterogeneity and fatigue scatter, to introduce a fatigue criterion able to consider stress gradients, and to perform a probabilistic analysis to obtain general predictions from a limited number of realizations of microstructures investigated. Numerical simulations have allowed to highlight the noteworthy characteristics of the mechanical response in the stent as well as the heterogeneity of the mechanical fields due to stress concentrations in the unit cell geometry and to strain incompatibilities between the grains induced by the anisotropy of their mechanical behavior. The predicted survival probability of the stent is in accordance with the experimental data from the literature. Moreover, the influence of the amplitude of the arterial pressure on the fatigue strength of the stent has been evaluated.

1. Introduction

Stenting intervention has been largely exploited in the treatment of cardiovascular diseases which represent the leading cause of death and illness accounting for 30% of the deaths worldwide annually [1]. Stents are small tube-like devices used to sustain narrowed or weakened arteries. The success of stenting is partly due to minimally-invasive procedures like the balloon-expandable coronary stents employed to prevent coronary restenosis after angioplasty.

Recently, stent failure has emerged as a major concern within the clinical and engineering community [2]. From the clinical point of view, failure of stents may lead to restenosis, thrombosis, pseudoaneurysm formation, and embolization, resulting in both short- and long-term morbidity and mortality [3]. From a mechanical point of view, failure of stents can be due to static loading during deployment or to cyclic loading caused by pulsatile blood pressure, bending, torsion, tension, and compression, due to the movement and muscle contractions of the patient [4]. The factors affecting the fatigue performance of stents are, on the one hand, the material properties, the design and the manufacturing of the stent and, on the other hand, the specificities of the patient as his anatomy and his lifestyle.

Stents are manufactured either through welding of microscopic wires or through laser cutting from thin-walled tubes. The characteristic dimensions of the repeated unit cell play distinct functions within the deformation of the stent and can enhance its specific performance. The final stent structure of both manufacturing procedures is a truss lattice composed of struts connected by hinges, with cross-sections in the range of 50–150 μm and small radii, affecting stent performance due to high stress concentrations [5,1,6].

Given the small scale of such devices and the complex loading conditions combining both hard and soft materials (the metallic stent and the blood vessel respectively), experimental measurements are difficult to perform, time-consuming and expensive, especially considering that current regulatory bodies require or recommend at least a ten-year life for stents, that corresponds to $4 \cdot 10^8$ systolic–diastolic pulsatile cycles [7,8]. Therefore, computer-based modeling is now used as a cost-effective tool for providing useful insight concerning the prediction of stent performance; see Ref. [9] for a review on fatigue of metallic stents. Numerical procedures, combined with experimental investigations, allow to make life-saving decisions and to possibly improve both the clinical procedure and stent design. Several studies exploring, investigating and inquiring the numerical fatigue-life assessment of balloon-expandable stents have been reported in the literature [10–21].

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However, the larger number of analyses are not matched with experimental data as a complete validation method would require [22].

Moreover, the proposed fatigue prediction methodologies generally neglect the inhomogeneous nature of the microstructure [11,13–16,21] and although they may provide a practical and relevant answer to the fatigue design of stents, they cannot predict the scatter of the fatigue strength which might be induced by this heterogeneity [18]. Indeed, in high-cycle fatigue, the crack initiation is intimately related to localization of the plastic slip which strongly depends on the crystallographic orientations of the grains. Moreover, given the small size of stents with respect to the mean grain size and thus, the lack of representativeness of the crystalline orientations in the vicinity of the critical regions of stents, the fatigue strength can significantly vary from one crystalline orientation configuration to another.

The micromechanical framework introduced, in the context of fatigue analysis of stents, by Sweeney et al. [17–20] offers new perspectives as it enables to model the anisotropic elastic–plastic crystals and to define their orientations. However, the fatigue criteria proposed by the authors may not be able to accurately predict the fatigue behavior of stents. Indeed, the presence of small curvature radii in stent struts are responsible for high stress concentrations. The resulting stress gradients in the structure have a beneficial effect on the fatigue strength which requires the adoption of specific approaches (e.g. the theory of critical distance [14], volumetric approaches [23]) to be predicted.

The present work aims to provide answers to some outstanding issues and especially concerning the effect of the lack of representativeness of the crystalline orientations on the scatter of the fatigue strength. To this purpose, we introduce a micromechanical model coupled with a probabilistic methodology for the failure prediction of stents. This allows to (i) account for material heterogeneity and thus the scatter in fatigue due to the variability of crystalline orientations, (ii) introduce a fatigue criterion able to consider stress gradients, and (iii) perform a probabilistic analysis to obtain general predictions from a limited number of realizations of microstructures investigated.

Due to the complexity of the problem (large number of degrees of freedom, non-linearities due to the constitutive model and the contact between the stent and the artery) and in order to achieve reasonable computation times, the numerical analysis conducted in the present work is divided in two steps, analogous to the methodology proposed by Sweeney et al. [17–20]. Firstly, a finite element analysis (FEA) modeling the stent deployment and fatigue in an artery is conducted, using a complete three-dimensional stent and a homogeneous elasto-plastic model. Secondly, the results acquired from this simulation provide an estimation of the boundary conditions which have to be applied in a simplified polycrystalline model of a fraction of the stent. This analysis has the purpose of determining the elastic shakedown mechanical state of the stent at the grain scale. Then, a probabilistic analysis, relying on a fatigue criterion sensitive to the microstructure and based on the weakest link hypothesis, is conducted in order to estimate the survival probability of the stent. The predictions obtained are compared to the results of the fatigue tests conducted on 316L austenitic steel stents by Kapnisis et al. [24] in order to assess the predictive ability of the fatigue criterion.

The present paper is organized as follows. Section 2 presents the modeling of both the homogeneous and the polycrystalline stent. Section 3 describes the mechanical responses of the polycrystalline stent. Then, Section 4 proposes a fatigue criterion that is relevant with respect to the specificities of the mechanical responses. In Section 5 a probabilistic analysis, relying on the fatigue criterion, is conducted in order to estimate the survival probability of the stent. Finally, comments and conclusions are presented in Section 6.

2. Modeling

The present work aims to model the experiment proposed by Kapnisis et al. [24], an accelerated pulsatile durability test on Cypher® stents made of 316L stainless steel and inserted in a straight mock artery made of natural rubber latex.

The particular choice of the stenting configuration does not restrain the generality of the present method and has been chosen only for the purpose of illustration. A crystal plasticity finite element model of a complete three-dimensional stent would lead to use a complex microstructure containing approximately 100,000 grains and would conduct to prohibitive computational time and resources.

As a consequence, we adopt simplifying modeling assumptions, similar to the ones adopted by Sweeney et al. [17]. The analysis will start with a three-dimensional analysis of a homogeneous stent which will provide the boundary conditions to apply in a two-dimensional "unit cell" of the stent with a crystal plasticity material behavior (see Fig. 1).

2.1. Three-dimensional homogeneous model

The three-dimensional homogeneous model consists of the stent, the surrounding vessel and a balloon (see Fig. 2a) and is described next. The mechanical analysis is performed with the FE method, using the software Abaqus/Standard (Simulia, Dassault Systèmes, Providence, RI, USA).

Stent. The Cypher® stent has an inner diameter $D_{s,i} = 0.85$ mm, an outer diameter $D_{s,o} = 1.15$ mm and a length $L_s = 8.4$ mm in the initial undeformed configuration. The strut pattern is constituted by 36 complete unit cells in addition to 12 truncated unit cells located at the extremities. The mesh is defined by 31,848 nodes and 17,280 three-dimensional linear brick elements.

The linear elastic component of the material behavior is described by the Young's modulus E and the Poisson's ratio ν. The time-independent plasticity model is defined by a von Mises yield surface:

$$f = \sqrt{\frac{3}{2}\left(\underline{\underline{\sigma}}^d - \underline{\underline{X}}^d\right) : \left(\underline{\underline{\sigma}}^d - \underline{\underline{X}}^d\right)} - \sigma^y - R \quad (1)$$

where σ^y, $\underline{\underline{\sigma}}$, $\underline{\underline{X}}$ and R denote the initial yield stress, the stress tensor, the backstress tensor and the isotropic hardening variable, respectively. The superscript $\cdot^d$ designates the deviatoric part of the tensor.

The non-linear evolution of the isotropic hardening variable R is given by Voce's law:

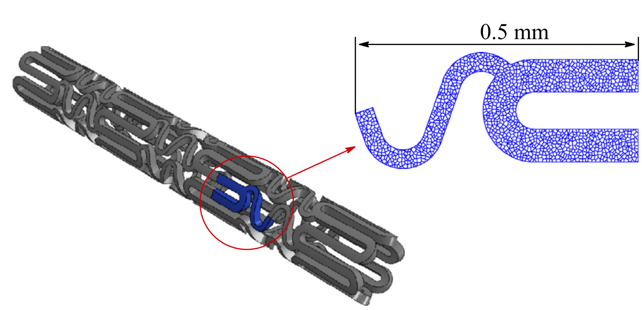

Fig. 1. Geometries of the three-dimensional Cypher® stent (the unit cell is highlighted in blue) and the two-dimensional unrolled polycrystalline unit cell. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)