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Numerical fatigue life assessment of cardiovascular stents: A two-scale plasticity-damage model

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Abstract. Cardiovascular disease has become a major global health care problem in the last decades. To tackle this problem, the use of cardiovascular stents has been considered a promising and effective approach. Numerical simulations to evaluate the *in vivo* behavior of stents are becoming more and more important to assess potential failures. As the material failure of a stent device has been often associated with fatigue issues, numerical approaches for fatigue life assessment of stents have gained special interest in the engineering community. Numerical fatigue life predictions can be used to modify the design and prevent failure without making and testing numerous physical devices, thus preventing from undesired fatigue failures. We present a numerical fatigue life model for the analysis of cardiovascular balloon-expandable stainless steel stents that can hopefully provide useful information either to be used for product improvement or for clinicians to make life-saving decisions. This model incorporates a two-scale continuum damage mechanics model and the so-called Soderberg fatigue failure criterion. We provide numerical results for both Palmaz-Schatz and Cypher stent designs and demonstrate that a good agreement is found between the numerical and the available experimental results.

1. Introduction

Stents are small tube-like medical devices used to restore patency of blood vessels where the lumen area is reduced due to atherosclerosis, a degenerative disease of the vessel wall. A stent acts as a mechanical scaffold for the vessel and its implant is performed by a minimally-invasive procedure inserting a catheter through a small incision in the femoral artery. Stenting is nowadays a common clinical practice especially for the treatment of cardiovascular stenosis, which has a high economical and social impact in the Western countries.

As the heart beats, and hence the arteries pulse, at typically 70 times per minute (around 40 million times per year), stents are subjected to long-term cyclic loading conditions. The US regulatory authority over these devices (FDA) recommends that stents must withstand 10-15 years of pulsatile loading *in vivo*, the equivalent to 400-600 million loading cycles. Therefore, the long-term structural integrity of a stent, in particular its mechanical fatigue behavior, must be one of the major design considerations.

The fatigue behavior of a stent results from a complex interaction of two stress states. The first of these is the state to which the device is statically loaded and deformed as a result from the positioning of the stent within the vessel. This state is typically characterized by high plastic strain levels in some parts of the stent and, therefore, by high residual stresses. A second state



is then imposed, which corresponds to the cyclic component of the loading as a consequence of the pulsatile blood-pressure variations in the vessel. The first state will be hereafter termed the mean stress state, whereas the second will be referred to as the alternating stress state.

For stents made of standard metallic materials, the fatigue damage induced by the alternating stress state can be divided into three main stages: crack initiation, stable crack growth and final failure [1]. Approaches to fatigue life prediction traditionally focus on one of the two first stages of the fatigue damage process. Total-life approaches define failure as the initiation of a crack and the number of loading cycles before crack initiation is assumed as the total fatigue life. These approaches are based either on $S - N$ or $\varepsilon - N$ experiments, both giving the number of loading cycles until a plain specimen fails. While $S - N$ curves are suited for materials in the high-cycle fatigue regime, where typically more than 10^5 cycles at low stresses are required to failure, and where deformation is primarily elastic, $\varepsilon - N$ curves are usually employed for materials in the low-cycle regime, where less than 10^5 cycles characterized by stresses that are high enough for plastic deformations to occur are required to failure.

Stents are typically designed to work in the high-cycle fatigue regime. In this regime, the equivalent von Mises stresses are above the fatigue limit (usually defined as the stress amplitude requiring 10^6 load cycles up to rupture), but considerably below the yield stress [1]. This leads very often to a number of loading cycles to failure greater than 10^5 . In this regime, damage can be considered as a microscale process of progressive deterioration of the material with no influence on the mesoscopic behavior, where, up to crack initiation, the material deforms primarily elastically at the scale of the representative volume element (mesoscale), and coupling between plasticity and damage may be neglected everywhere but at the microscale [2].

The material degradation caused by the initiation, growth and coalescence of microcracks due to cyclic loading is well suited for characterization by the theory of continuum damage mechanics, *e.g.* [3]. Centered on microcrack development, the continuum damage mechanics theory provides a good understanding of the mechanisms of fatigue failure by means of damage variables. Different continuum damage mechanics based models have been proposed in the literature for the high-cycle fatigue analysis of metallic structures: (i) models based on two-scale approaches in which micro and meso scales are linked by means of a localization law [4, 5, 2, 6]; and (ii) models relying on a single (macroscopic) scale [7, 8].

Due to its inherent multi-scale manifestation, high-cycle fatigue damage can only be properly captured by resorting to models which are capable of dealing with plasticity and damage on a scale smaller than the macroscopic scale. Furthermore, as the experiments for a stent device are challenging, due to its small size, the fatigue life assessment of a cardiovascular stent is not a trivial task. Computational tools, such as the finite element method, have proved extensively their usefulness to analyze cardiovascular stents, see *e.g.* [9, 10, 11, 12]. None of these works have however addressed the fatigue life assessment of stents. Exceptions to this can be found in [13, 14, 15, 16].

We present a numerical model for the fatigue life assessment of cardiovascular balloon-expandable stainless steel stents [17]. This model incorporates the two-scale plasticity-damage model proposed by [4, 5], modified by means of the so-called Soderberg fatigue relation [18].

2. Overview of the proposed model

One of the first attempts to extend the framework of continuum damage mechanics to the fatigue field including its multi-scale aspect is the model proposed in [19], which was later on further extended and improved in [20, 4, 5, 2]. This model considers two phases. One represents a microscopic spherical inclusion with an elasto-plastic coupled with isotropic damage behavior, and the other represents a mesoscopic elastic, possibly elasto-plastic, matrix represented through the representative volume element in which the inclusion is embedded. The two phases are assumed to have the same elastic behavior. The matrix behavior is characterized by its yield

stress, its ultimate stress and its asymptotic fatigue limit, the latter viewed as the asymptote of a $S - N$ curve. As for the inclusion, an elasto-plastic material behavior with strain hardening is assumed. This allows to produce results which are coherent with most of the experimental results obtained in the high-cycle fatigue regime of metals. A weakness of the inclusion is considered by assuming that its corresponding yield stress is identical to the asymptotic fatigue limit of the matrix material.

The two-scale plasticity-damage model was conceived to capture degradation by means of a locally coupled strain-driven analysis [20]. This basically consists in performing first a global elastic structural analysis, using for instance the finite element method to compute stress and strain variables defined at the mesoscale, followed by a time integration of the elasto-plastic-damage constitutive equations, required to compute the microscopic stress, strain, hardening and damage variables. The time integration is only performed at critical points, as a post-processing scheme using the history of mesoscopic stresses and strains as inputs. This corresponds to a separated multi-scale model, as micro and meso calculations are performed independently. Time integration is performed step by step until a stabilized cycle is reached, after which a jump in cycles procedure is considered to avoid a large number of steps. This post-processing procedure is repeated until the critical damage value is reached at the critical point, indicating microcrack initiation. The critical point is assumed as the point featuring the maximum damage equivalent mesoscopic stress.

Experiments have shown that, at fixed amplitude the fatigue life decreases as the mean stress increases [1]. As pointed out in [21], the crack closure parameter of the two-scale plasticity-damage model is not sufficient to realistically represent the material behavior at high mean stresses. Hence, and as cardiovascular stents work under high levels of mean stresses, the two-scale model must be modified in order to be applicable to the fatigue life prediction of stents. The strategy adopted in this work consisted in, rather than using a fixed asymptotic fatigue limit within the yield potential, as was considered in [4, 5], taking an asymptotic fatigue limit which varies with respect to the mean stress defined at the mesoscale. This was accomplished in the present work by resorting to the Soderberg relation [18]. A Goodman relation could alternatively have been employed. For further details on the model, the reader is referred to [17].

3. Application of the model to the fatigue life prediction of cardiovascular balloon-expandable stents

Two stent design models were analyzed. We first analyzed a *Palmaz-Schatz* stent, as this was the one for which we could find some fatigue experimental results, indeed required to validate the numerical results provided by the proposed model. We then analyzed a *Cypher* stent, one of the most adopted stent designs nowadays.

3.1. Finite element analysis

In the unexpanded configuration, the *Palmaz-Schatz* stent was assumed to be a tube with rectangular slots along its length. Its initial length, inner and outer diameters were taken as 16mm , 1mm and 1.2mm , respectively (strut thickness is $200\mu\text{m}$). The stent has 5 slots in the longitudinal direction and 12 slots in the circumferential direction, each slot measuring 2.88mm and 0.24mm , respectively. The mesh was built from the CAD geometry constructed using Rhinoceros v. 4.0 Educational (McNeel & associates, Seattle, WA, USA). As for the *Cypher* stent, the length, inner diameter and outer diameter were set to 8.4mm , 0.85mm and 1.15mm , respectively, *i.e.*, the thickness of the struts were taken as $300\mu\text{m}$. This geometry resembles the *Cypher* stent geometry (Boston Scientific Co., Natick, MA, USA) with a nominal diameter and length of 3mm and 8mm , respectively.

In both stent designs, the cardiovascular artery was modeled as an idealized vessel represented by a thin-walled pipe with an initial inner diameter of 2.5mm , wall thickness 0.5mm and length 12mm .

The *Palmaz-Schatz* stent was assumed to be made of a SS316LN stainless steel, similar to the SS316L steel used in many commercial balloon-expandable stents, such as the original J & J *PalmazSchatz*. As for the *Cypher* stent, it was assumed to be made of a AISI 316L stainless steel. We assumed an elasto-plastic perfect constitutive behavior for both stent designs, characterized by Young's modulus $E = 196\text{GPa}$ and Poisson's ratio $\nu = 0.3$. As for the yield stress, we adopted $\sigma_y = 205\text{MPa}$ for the *Palmaz-Schatz* stent [22] and $\sigma_y = 375\text{MPa}$ for the *Cypher* stent [23].

The material of the artery wall was modeled using a 5-parameter second-order Mooney-Rivlin hyperelastic model suitable for incompressible isotropic materials [10].

The loadings on the stents were considered in different steps to simulate the loading conditions they experience in service, namely, balloon-inflation, recoil and physiological loading within the artery. For both stent designs, the stent expansion was modeled as a displacement driven process, by enforcing the radial displacements of a rigid cylinder (previously introduced into the stent) to expand the stent to an inner diameter of 3mm . The expansion of the stents was performed into a hyperelastic thin-walled pipe. The stent expansion step was accomplished by modeling contact between the expansion cylinder and the stent, as well as between the stent and the internal surface of the tube. After the expansion step, the stent/vessel systems were allowed to recoil by removing the deployment boundary conditions. This step was taken to simulate the balloon deflation and retraction of the catheter. Maximal and minimal uniform pressure loads of $120\text{mmHg} = 0.015\text{MPa}$ and $80\text{mmHg} = 0.010\text{MPa}$ were then sequentially applied to the inner surface of the pipes to conservatively represent physiological systolic and diastolic blood-pressure loads within the arteries. Appropriate kinematic boundary conditions were set.

The analyses of the stents under the mean stress state were performed using ABAQUS/Standard finite element code (Simulia, Dassault Systems, Providence, RI, USA).

In the *Palmaz-Schatz* test case, the stent and the thin-walled pipe were modeled using 10716 and 6080 C3D8R (8-node three-dimensional brick 'reduced-integration') elements, respectively. The rigid cylinder was modeled using 408 SFM3D4 (4-node quadrilateral surface) elements. As for the *Cypher* case, the stent and the thin-walled pipe were modeled using 31848 and 15808 C3D8R elements, respectively, whereas the rigid cylinder was modeled using 1909 SFM3D4 elements.

The finite element analyses performed over the *Cypher* stent showed that, although some parts of the stent were characterized by relatively high plastic strains, which is indeed a consequence of the expansion and subsequent recoil of the balloon catheter, leading in turn to high residual stresses in the material, the material response was found to be linear-elastic during the fatigue cycles. As for the *Palmaz-Schatz* stent case, the material response was found to be elasto-plastic, even during the fatigue cycles.

3.2. Fatigue life assessment

3.2.1. Material Parameters Identification There were 10 parameters to be identified: 4 on the mesoscale (asymptotic fatigue limit σ_f , ultimate stress σ_u , rupture stress σ_R and plastic modulus C), 5 damage parameters (damage strength S , damage exponent s , damage threshold ε_D^p , critical damage D_c and correction parameter m), and the microdefects closure parameter h .

The mesoscale parameters were identified on a monotonic tensile curve [2], whereas the identification of the parameters S , s , p_D , D_c , m and h was carried out using some fatigue tests, more specifically, an experimental $S - N$ curve and some low-cycle fatigue tests.

In order to take into account the size effect, the parameters σ_u , σ_R and ε_D^p were explicitly identified from the tensile stress-strain curve obtained in [24] for a stent of $100\mu\text{m}$ of thickness.

σ_f was identified from the experimental fully reversed $S - N$ tests conducted in [25] on a non-treated stainless steel 316L. D_c , h and C were obtained following [2]. s , S and m were calibrated using the experimental $S - N$ results given in [25]

The adopted parameters are given in Table 1.

Table 1. Mesoscale material parameters

$\sigma_f(MPa)$	$\sigma_u(MPa)$	$\sigma_R(MPa)$	$C(MPa)$	$S(MPa)$	s	ε_D^p	D_c	m	h
200	820	650	1520	0.8	0.5	0.28	1.0	1.2	0.2

3.2.2. Prediction of microcrack initiation The critical points of the stents were taken as the Gauss points in which the damage equivalent mesoscopic stress was maximum. As for the *Cypher* stent model, the material behavior was found to be linear elastic during the cyclic loading, *i.e.*, the critical point did not change from cycle to cycle, and thus it was sufficient to perform the post-processing scheme at this single point. As for the *Palmaz-Schatz* stent model, the material response was found to be elasto-plastic during the cyclic loading. For this reason, the post-processing scheme was applied in the latter case over all Gauss points of the stent model. The critical point was selected as the one for which the damage variable first reached the critical damage parameter.

Application of the post-processing scheme based on the locally coupled analysis to modeling the stents under the alternating stress states led to a number of cycles up to microcrack initiation of 64 millions for the *Palmaz-Schatz* stent model, and 53 millions for the *Cypher* stent model. This is equivalent to approximately 22 and 18 months of the heart pumping in an average human adult, respectively.

Although the obtained results correspond to very short fatigue lives, our prediction for the *Palmaz-Schatz* stent design seems to be in accordance with the experiments carried out in [26], in which real stainless steel *Palmaz-SchatzTM* stents (15mm long stents from Johnson and Johnson Corporation) were tested to fatigue in a saline solution at 37°C to simulate real *in vivo* physiological conditions. Therein, the criterion for fatigue failure was considered as the rupture of the first strut of the stent. The results given in [26] show that, although 2 out of 2 tested stainless steel stents have survived to 1 million cyclic loadings, 0 out of 2 stents have survived to 10 million cycles, only 1 out of 2 stents have survived to 40 million cycles. The experimental results also indicate that 0 out of 4 stents have survived to 100 million cycles.

Clearly, the stent designs under analysis would not satisfy the requirements imposed by the US Food and Drug Administration, which recommends that a cardiovascular stent must be able to withstand at least 400 million cardiac cycles (equivalent of approximately ten years) without exhibiting fatigue-associated failure. It is worth mentioning however that the proposed fatigue life assessment model was conceived to predict crack initiation, and not fatigue rupture. To predict the total life of the stents up to final failure, the analyses should have taken into account the crack propagation effects up to final failure. Despite this, we remind that, in the high-cycle fatigue regime, the crack initiation stages may cover a large percentage of the fatigue life and, thus, we would not expect the total fatigue lives of the stent models under analysis to be considerably higher than the ones we obtained.

4. Conclusions

A numerical model was presented for the numerical fatigue life assessment of cardiovascular balloon-expandable stainless steel stents. The model relies on a two-scale continuum damage

mechanics theory and assumes the Soderberg relation as the fatigue failure criterion, which allows the model to take into account the high mean stress effects inherent to cardiovascular stents. The model was applied to the analysis of two common stent geometries, more specifically, *Palmaz-Schatz* and *Cypher* designs. For both stent geometries, the obtained results indicated a limited fatigue life. In particular, the results obtained for the *Palmaz-Schatz* stent model were shown to be in close agreement with the available experimental results. We hope that the present model can be used to modify the design and prevent from undesired fatigue failures without testing numerous physical devices.

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