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Micromechanical methodology for fatigue in cardiovascular stents

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ABSTRACT

A finite element based micromechanical methodology for cyclic plasticity and fatigue crack initiation in cardiovascular stents is presented. The methodology is based on the combined use of a (global) three-dimensional continuum stent-artery model, a local micromechanical stent model, the development of a combined kinematic–isotropic hardening crystal plasticity constitutive formulation, and the application of microstructure sensitive crack initiation parameters. The methodology is applied to 316L stainless steel stents with random polycrystalline microstructures, based on scanning electron microscopy images of the grain morphology, under realistic elastic–plastic loading histories, including crimp, deployment and *in vivo* systolic–diastolic cyclic pressurisation. Identification of the micromechanical cyclic plasticity and failure constants is achieved via application of an objective function and a unit cell representative volume element for 316L stainless steel. Cyclic stent deformations are compared with the J_2-predicted response and conventional fatigue life prediction techniques. It is shown that micromechanical fatigue analysis of stents is necessary due to the significant predicted effects of material inhomogeneity on micro-plasticity and micro-crack initiation.

1. Introduction

The use of balloon expandable stents as part of the angioplasty procedure has revolutionised the treatment of heart disease. Although stent design is a relatively mature topic, numerous instances of stent fatigue fracture have been reported. This is particularly the case recently with the advent of drug eluting stents where tissue in-growth over stent struts is impeded, allowing deformed geometries and fractures to be more clearly revealed than before. Shaikh and co-workers [1] and Sianos and co-workers [2] provide intravascular ultrasound images depicting cases of stent fracture in the right coronary artery allowing the artery to collapse. Such severe fracture indicates a clear need to gain a deeper understanding of stent fracture and fatigue behaviour and to develop failure prediction methods to aid stent design refinements.

The fatigue life of a component can be decomposed into different stages [3] illustrated by the equation:

$$N_f = N_i + N_{MSC} + N_{PSC} + N_{LC} \quad (1)$$

where N_f is the total fatigue life, N_i is the number of cycles required to initiate a crack and N_{MSC}, N_{PSC}, N_{LC} represent the regimes of microstructurally small crack growth, physically small crack growth and long crack growth respectively. Continuum techniques for modelling long and physically small crack growth have been reasonably well established [4]. Microstructurally small crack growth refers to cracks spanning no more than a few grains. Growth rate in this regime is strongly influenced by inhomogeneous microstructural barriers and cannot be modelled using established continuum plasticity approaches. Crystal plasticity (CP) theory [5], which provides a means of explicitly modelling microstructural grains in a polycrystalline material, should therefore be applied to the modelling of crack initiation and microstructurally small crack growth.

As a minimum requirement stent components are designed to have an operational life in excess of 10 years as recommended by the US Food and Drug Administration (FDA) [6]. This corresponds to a fatigue life in excess of approximately 4×10^8 systolic–diastolic pulsatile cycles (assuming a heart beat rate of 72 beats per minute). Such a fatigue life is considered to be in the high cycle fatigue (HCF) regime, corresponding to stress amplitudes below the macroscopic yield. However, as typical stent strut dimensions are comparable with microstructural geometry, such as grain size [7–10], it can be anticipated that inhomogeneity effects introduced by microstructure will cause localised (grain level) plastic deformation even at macroscopically elastic strains. Therefore crack initiation and microstructurally small crack propagation can occur during stent operational life. As a stent strut typically has only a few grains across its thickness [9,11] a crack is likely to cause fracture in the microstructurally small crack growth regime without ever entering the regime of physically small crack growth. This indicates the need for a stent fatigue model based on CP theory.

As a subject of growing interest, different approaches have already been proposed for stent fatigue analysis. Continuum mechanics approaches have been employed to predict stent fatigue

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life through comparison of mean and alternating stress, extracted for one cycle of pulsatile loading, with fatigue loci on the Goodman diagram [8,12,13]. A continuum fracture mechanics approach has also been applied to the investigation of the effect of a flaw at the worst case fatigue location of a stent [8]. One of the key conclusions of this work was that a CP stent design approach was required as such a macroscopic continuum material model was inadequate for the modelling of physically small components, such as stents. Another approach involved the application of the theory of critical distances (TCD) to the fatigue analysis of 316L stainless steel stent material [14]. The common drawback of these methodologies is the use of macroscopic continuum material models which are incapable of explicitly capturing microstructural effects. While the TCD accounts for stress-gradient effects, it does not capture the effects of microstructural inhomogeneity. CP theory has been applied to the monotonic loading of 316L stainless steel stent material [7,9,10,15], giving good correlation to experimental work and capable of capturing size effects in the macroscopic response. Finally a quasi-3D CP model has been used to assess stent fatigue life via the Goodman diagram [11], but this work (i) did not use a cyclic plasticity model, (ii) assumed a regular crystal lattice, (iii) did not predict life and (iv) only employed continuum fatigue methods.

Methodologies for the modelling of fatigue crack propagation are continually developing. Established continuum fracture mechanics approaches have been adapted to facilitate predictions for small crack growth. For example a modified version of the Paris crack growth equation has been developed for physically small crack growth based on a crack length ($l + l_0$) for a stress intensity factor range, where l_0 (intrinsic crack length) is a transition crack length, below which the threshold stress intensity factor range decreases [16]. Methodologies for the modelling of crack initiation are less firmly established than those for crack growth. Fatigue indicator parameters (FIPs), based on macroscopic stress and strain values, have been developed for predicting the number of cycles to crack initiation along with the locations of crack initiation [3]. A critical plane approach has often been employed in conjunction with FIPs such as the Fatemi–Socie parameter [17] and the Smith–Watson–Topper parameter [18,19], whereby the FIP is maximised via identification of the worst affected plane. However modelling of crack initiation based on values of FIPs at discrete points often gives overly conservative predictions of fatigue life. Volume averaging techniques have been developed [20,21] to predict crack initiation based on the stress state of a volume of material. While these techniques can give reasonable results they are based on continuum mechanics and are incapable of capturing microstructural inhomogeneity effects. Hence, the selection of the averaging dimension is typically empirical, based on calibration against test data rather than based on fundamental microstructural dimensions, such as grain size. Attempts to meet the need of microstructural representation in crack initiation predictions have been made, such as the Dang Van approach for predicting damage in multiaxial fatigue based on local microscopic stresses, evaluated as a function of macroscopic stress [22]. Tanaka and Mura postulated that crack initiation in a slip band is related to the accumulation of dislocation diploes [23]. However, inhomogeneity effects observed in explicit modelling of random crystalline microstructures cannot be captured by these methodologies. Finally, a number of microstructure-sensitive FIPs, such as accumulated crystallographic slip [24,25], used in conjunction with CP theory in micromechanical models have proved successful in the prediction of fatigue crack initiation observed experimentally. A similar approach is adopted in this work as the basis for stent fatigue analysis.

This paper presents a finite element (FE)-based stent fatigue methodology based on CP theory for prediction of crack initiation using microstructural FIPs. A Voronoi Tessellation methodology is developed for the automated generation of realistic polycrystalline microstructures for real 316L stainless steel (SS) stent material. A combined kinematic–isotropic hardening CP constitutive material model for microscopic cyclic plasticity analysis is developed and calibrated via simulation of macroscopic 316L SS cyclic behaviour. A 3D stent-artery model is developed to identify boundary conditions for a unit cell (micromechanical) stent submodel. Two candidate microstructure-sensitive FIPs are implemented in the CP user material model and applied to the prediction of crack initiation for different stent microstructures.

2. Methodology

This section outlines the development and calibration of a micromechanical methodology and the application of this methodology to assess the fatigue behaviour of a generic stent. A flowchart illustrating the methodology is provided in Fig. 1. Referring to Fig. 1, it is necessary to implement the novel crystal (cyclic) plasticity constitutive model developed here within an FE model of a realistic polycrystalline geometry for calibration (via a least squares objective function). This is achieved vis-à-vis comparison of the strain-controlled response of this periodic microstructure model against a target (cyclic) J_2 continuum (macroscopic) response for 316L SS. Once calibrated (identification of the CP material constants), the CP material model and the J_2 continuum (macroscopic) model are both implemented within a 2D unit cell submodel of the stent, with fatigue boundary conditions for the stent unit cell submodel extracted from a global 3D continuum stent-artery model. Finally, the fatigue life predictions of the microstructure-sensitive approach and the traditional continuum approach are compared for the stent submodel.

2.1. Cyclic crystal plasticity material model

Stent fatigue behaviour is affected by (i) the initial deformation due to the crimp and deployment processes and (ii) systolic–diastolic cyclic loading. Therefore a material model must be adopted which simulates both monotonic and cyclic loading behaviour of a real material. Cyclic behaviour of a material can be defined by (i) evolution of the stress–strain curve prior to a stabilized response and (ii) the stabilized cyclic stress–strain curve (CSSC). Isotropic hardening (allowing yield surface expansion) defines the evolution of stress magnitudes reached in a cyclic stress–strain response and controls the rate at which saturation, and thus a stabilized response, is achieved. A CP constitutive model with isotropic hardening only has been used in previous work for modelling the monotonic loading of 316L SS stent material [7,9]. Calibration of the isotropic CP model against cyclic behaviour of a J_2 continuum 316L SS material model has also been carried out [19]. However the isotropic CP model, once calibrated for cyclic behaviour, is unable to capture the initial monotonic behaviour of the J_2 continuum model. Furthermore, discrepancies exist between the stabilized hysteresis loop shapes of the two models. It has been shown that crack initiation and propagation can be correlated against cyclic strain energy dissipation [26,27], calculated by the area bounded by a hysteresis loop. Therefore, the discrepancies between hysteresis loop shapes need to be rectified. Kinematic hardening (allowing yield surface displacement) introduces a back stress into the cyclic stress–strain response. The backstress reduces yield stress upon reversal of loading, and thus influences the shape of the stabilized hysteresis curve. Hence, to facilitate computational studies of cyclic and monotonic behaviour of 316L SS it is necessary that both isotropic and kinematic hardening are implemented in the material model employed.