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A strain-mediated corrosion model for bioabsorbable metallic stents

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ABSTRACT

This paper presents a strain-mediated phenomenological corrosion model, based on the discrete finite element modelling method which was developed for use with the ANSYS Implicit finite element code. The corrosion model was calibrated from experimental data and used to simulate the corrosion performance of a WE43 magnesium alloy stent. The model was found to be capable of predicting the experimentally observed plastic strain-mediated mass loss profile. The non-linear plastic strain model, extrapolated from the experimental data, was also found to adequately capture the corrosion-induced reduction in the radial stiffness of the stent over time. The model developed will help direct future design efforts towards the minimisation of plastic strain during device manufacture, deployment and in-service, in order to reduce corrosion rates and prolong the mechanical integrity of magnesium devices.

Statement of Significance

The need for corrosion models that explore the interaction of strain with corrosion damage has been recognised as one of the current challenges in degradable material modelling (Gastaldi et al., 2011). A finite element based plastic strain-mediated phenomenological corrosion model was developed in this work and was calibrated based on the results of the corrosion experiments. It was found to be capable of predicting the experimentally observed plastic strain-mediated mass loss profile and the corrosion-induced reduction in the radial stiffness of the stent over time. To the author's knowledge, the results presented here represent the first experimental calibration of a plastic strain-mediated corrosion model of a corroding magnesium stent.

1. Introduction

Whilst bioabsorbable medical devices, and in particular intravascular stents, have gained attention in recent years as an alternative to permanent metallic implants, the complex and temporal corrosion environment *in vivo* makes it difficult to predict the corrosion behaviour of such implants. The *in vivo* environment is characterised by dynamic chemical and physiological processes, mechanical and thermal loading patterns, and bioelectric potentials, all of which have a significant role to play in the corrosion of biodegradable devices [1]. Knowledge of the mechanical integrity and degradation of biodegradable stents, and how this changes over time, is critical to the performance of a stent in terms of arterial scaffolding and vessel patency as well the timeline for anti-coagulation therapies. Numerical modelling can be used to elucidate the role of various phenomena on the corrosion performance of bioabsorbable metallic stents but incorporating the key drivers of this corrosion remains a significant challenge.

To date, a number of numerical models for galvanic corrosion have been proposed and Gastaldi et al. [2] provide a good overview of the research in this area. A macroscale corrosion damage internal state variable model that captured the effects of multiple corrosion processes (general, pitting and intergranular corrosion) was developed by Walton et al. [3] and applied to the AZ31 magnesium alloy, an alloy that has been used in metal biodegradable stents [4]. Models of other corrosion processes have been developed and applied to magnesium alloys such as stress corrosion cracking (SCC) [5] fatigue cracking [6] and crevice corrosion [7]. However, many of the aforementioned modelling approaches focus on specific corrosion processes that are not easily applicable to coronary stents due to the difficulty of establishing the model

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parameters using experimental calibration procedures. In addition, there are high computational costs associated with three-dimensional (3-D) geometries where complex corrosion processes are applied together. Consequently, in recent years a number of alternative models have been developed specifically for modelling the corrosion of absorbable metallic stents.

Most notably, a phenomenological corrosion model was proposed by Gastaldi et al. [2] using a continuum damage modelling (CDM) approach and implemented within a finite element (FE) framework in order to account for the effects of uniform micro-galvanic corrosion and SCC processes on the behaviour of a 3-D magnesium alloy stent geometry. The model was calibrated from experimental corrosion studies performed on mechanically polished cylindrical specimens of extruded magnesium alloys (AZ, ZK and ZM series). The same corrosion model was later calibrated from experimental studies performed on specimens that were cut from magnesium alloy sheets and extruded bars and used to perform optimisation studies for magnesium stents in which outputs such as stress, strain, stent recoil and mass loss were examined [8,9]. In a combined experimental and numerical study, Wu et al. [10] produced an AZ31 magnesium alloy stent and compared experimentally observed elastic recoil and mass loss with those predicted by the corrosion model. Grogan et al. [11] added an element-specific pitting corrosion parameter to the damage law developed previously by Gastaldi et al. [2] in order to incorporate the effects of heterogeneous or pitting corrosion in the modelling framework. The model was calibrated based on corrosion experiments involving mechanically polished AZ31 foil specimens and was used to predict the corrosion-induced recoil and mass loss of an AZ31 stent that was deployed in an idealised coronary artery model. A physical corrosion model, based on the finite element method with adaptive meshing, was also proposed by Grogan et al. [12] to model the diffusion-controlled corrosion of a pure magnesium stent strut section. The study was predicated on a transport-controlled process, based on the assumption that metallic ion transport, particularly diffusion, was slower than the electrochemical reaction rate for the stent surrounded by layers of corrosion product and tissue in the body. The model predicted that the mass loss rate was proportional to the saturation concentration of magnesium ions in solution. The diffusivity of the surrounding environment was also shown to influence the corrosion rate.

The aforementioned corrosion models of magnesium stent performance [2,11] involve stress-mediated corrosion processes. Several experimental studies have provided correlations between the magnitude of specimen stress and corrosion behaviour in magnesium alloys [5,13,14]. Clearly therefore stress-induced strain also has a role to play in corrosion of biodegradable materials. In fact, the deformation-induced changes in electrochemical behaviour have been shown to play a crucial role in the micro-galvanic corrosion processes that are observed in magnesium alloys [15–17]. Whilst the instantaneous stresses in a stent are indicative of the loaded state, they cannot provide insights into the permanent deformation that may exist in the material which could influence the degree of corrosion induced in a biodegradable material. During a stent deployment procedure, highly inhomogeneous strains are induced in a stent. Whilst elastic recoil occurs during unloading of the deployment balloon, large plastic strains, as high as 20–30% [18], are known to remain in the stent struts. Corrosion models that explore the interaction between plastic strain and corrosion damage would provide key insights into the role of strain in the corrosion processes of deployed intravascular stents. To-date the stress-mediated corrosion models have neglected the plastic strains induced during the deployment stage of the stent expansion procedure [2,11] and therefore one of the main aims of this work is the development of a plastic strain-mediated corrosion model for magnesium alloys which can be implemented using the FE method framework and is suitable for the study of biodegradable stents.

In addition, many of the aforementioned corrosion models were calibrated from experiments that used magnesium specimens that had materials processing, surface treatments, and loading regimes that were dissimilar to those of coronary stents; all of which are known to bear a significant influence on the mechanical and corrosion behaviour of magnesium materials [11,13,19–21].

Therefore, in this study the corrosion model parameters were established from experimental calibration procedures that involved mechanical and corrosion testing of magnesium specimens and stents with materials processing, surface treatments and loading regimes that were relevant to coronary stents [22].

2. Methods

The corrosion model developed represents a modification of the CDM model proposed by Gastaldi et al. [2] which allows the effects of corrosion-induced micro-scale geometric discontinuities on overall specimen mechanical integrity to be accounted for, without explicitly modelling their progression. However, in this study, a discrete rather than continuum modelling approach was adopted. A flowchart outlining the operation of the corrosion model, which was written in the ANSYS parametric design language (APDL), is shown in Fig. 1. An initial analysis was carried out of the stent deployment process and stent recoil. The strain results for each element, which included the magnitude of the first principal plastic strain, ε_{p1}, were written to arrays in preparation for corrosion simulation. Element connectivity was determined and the elements on the corrosion surface were identified. The material behaviour of each element was initially modelled by a single elastic-plastic material model that was representative of the mechanical properties of the material prior to the onset of corrosion. The loss of mechanical integrity due to the corrosion process, denoted by the damage parameter, D, was calculated on an element-by-element basis through a modified version of the damage evolution law (Eq. (1)) described by Gastaldi et al. [2]. The temporal value of the damage parameter, D, was calculated over a discrete volume of material governed by the element size, L_e and, over a discrete time-step, Δ_t. When L_e and Δ_t were sufficiently small; the damage parameter at a fixed time, D_e, was given by the relation:

$$D_e = D_{e-1} + \frac{\delta_u}{L_e} k_u \varphi_e \Delta_t \kappa_e \tag{1}$$

where D_{e-1} was the element damage at the previous time step, δ_U is the critical thickness of the corrosion film and L_e represents the average element length in the FE model, both in units of mm. k_u is a parameter related to the kinetics of the uniform corrosion process, in units of h^{-1}, as described previously in Ref. [2]. An element-specific dimensionless plastic strain parameter,φ_e, was introduced in this work in order to account for the effects of plastic strain-induced corrosion in the modelling framework. The value of φ_e for each element was dependent on both the magnitude of elemental ε_{p1} and the simulated corrosion time, t, and was estimated from a table of values that were established in experimental corrosion tests briefly described below and given in detail in [22].

Depending on the number of element faces (NEF) that were exposed to the corrosion environment, the element damage calculated at each time step was modulated by an element-specific exposure parameter, κ_e. κ_e was a simple scaling parameter that was derived from a linear approximation of the slope of the curve that described the rate of diffusion through a brick element when NEF varied from one to six, as shown in Fig. 2(a). κ_e was included in