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A corrosion model for bioabsorbable metallic stents

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ABSTRACT

In this study a numerical model is developed to predict the effects of corrosion on the mechanical integrity of bioabsorbable metallic stents. To calibrate the model, the effects of corrosion on the integrity of biodegradable metallic foils are assessed experimentally. In addition, the effects of mechanical loading on the corrosion behaviour of the foil samples are determined. A phenomenological corrosion model is developed and applied within a finite element framework, allowing for the analysis of complex three-dimensional structures. The model is used to predict the performance of a bioabsorbable stent in an idealized arterial geometry as it is subject to corrosion over time. The effects of homogeneous and heterogeneous corrosion processes on long-term stent scaffolding ability are contrasted based on model predictions.

1. Introduction

A new generation of implants based on metals that are gradually broken down in the body are attracting much interest [1–3]. One promising application of biodegradable metals is in the development of bioabsorbable coronary stents. The primary purpose of coronary stents, which are small mesh-like scaffolds, is to provide mechanical support to the arteries of the heart following the angioplasty procedure, thus preventing elastic arterial recoil [4]. However, considering the healing time for an artery is approximately 6–12 months following the angioplasty procedure [5,6], the requirement for long-term arterial scaffolding can be questioned, especially in light of increased long-term injury risk due to the presence of the stent [7,8]. The current generation of absorbable metallic stents (AMS) have shown promise in non-randomized human clinical trials; however, high rates of neo-intimal hyperplasia were observed following the stenting procedure, most likely as a result of premature loss in stent scaffolding support [3]. As such, it is evident that further work is required in characterizing and optimizing AMS performance in the body before this technology can be proven as a viable replacement for conventional stenting.

The design of AMS brings a number of new challenges over that of conventional stents. To date, the process of absorption of the stent in the surrounding tissue is not fully understood. In vitro studies on the corrosion behaviour of biodegradable alloys in simulated physiological fluids have shown that the rate of corrosion and the underlying corrosion process depend on a variety of factors, including, but not limited to, alloy composition [9], surface treatments and coatings [10], solution composition [11] and solution transport conditions [12]. Further studies have also suggested that mechanical loading, both static [13] and dynamic [14], may contribute to the corrosion behaviour of AMS.

In order to characterize the behaviour of a bioabsorbable device in the body, and in particular coronary stents, it is important to consider not only the form and rate of corrosion observed, but also the effect that this corrosion process has on overall device mechanical integrity. It is noted that relatively few studies have been performed to this end for biodegradable metals in vitro, with the study of Zhang et al. [15] on the reduction in bending strength of biodegradable alloy specimens following corrosion being the most applicable to date. Further to this, while a number of studies, such as that of Bobby Kannan et al. [13], have investigated the effects of mechanical loading on specimen corrosion behaviour, such studies have focused on the corrosion behaviour in specimens with dimensions at least an order of magnitude larger than those of coronary stent struts.

The first objective of this work is the determination of the effects of corrosion on the mechanical integrity of biodegradable foil specimens in simulated physiological solution. Since the thickness of the foil samples is of the same order of magnitude as that of the struts used in AMS, it is believed that such an approach may give a more appropriate indication of the effects of corrosion on AMS scaffolding support than that given in previous studies on larger samples. The second objective of this work is the determination of the effects of mechanical loading on the corrosion behaviour of the biodegradable alloy foil specimens. Again, it is believed that such an approach can give a more appropriate indication of the

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effects of mechanical loading on the corrosion behaviour of AMS than tests on larger size samples.

In addition to experimental alloy characterization, computational modelling of the corrosion process can give important insights into the fundamental corrosion mechanisms that lead to the gradual breaking down of an AMS in the body. Also, such models can prove useful in the design of AMS, through device assessment simulations and the optimization of device geometries for improved duration of structural integrity as corrosion progresses. Since the development of AMS is a relatively new field, there are few computational approaches specifically developed for modelling the effects of corrosion and the resulting reduction in mechanical integrity of the devices. While a wealth of modelling approaches exists for predicting the effects of corrosion on specimen structural integrity, many are based on probabilistic approaches, with a focus on predicting time to failure in large-scale industrial components in corrosive environments [16,17]. Other approaches consider modelling corrosion through complex, physically based models, for example that of Saito and Kuniya [18]. However, such models are often focused on particular corrosion phenomena, with it often proving challenging to obtain the required model parameters experimentally, making their implementation in the assessment of AMS performance difficult.

Hence, the third objective is the development of a phenomenological corrosion model that is detailed enough to give a better understanding of the corrosion behaviour of an AMS in the body, yet simple enough to allow the model to be calibrated through readily performed experiments and implemented for use with a commercial finite element (FE) code. The approach taken is built on recent work by Gastaldi et al. [19], who developed what is the only direct application of a corrosion model in a stent assessment application to date. In Ref. [19] the effects of corrosion on device mechanical integrity are represented through the evolution of a continuum damage parameter, allowing an assessment of the overall stent damage as corrosion proceeds. While adopting this continuum damage parameter approach, this work focuses on the development and calibration of a corrosion damage model that has the added ability to capture the effects of heterogeneous corrosion behaviour on AMS scaffolding support over time.

2. Methods

2.1. Alloy characterization

The corrosion behaviour of a biodegradable magnesium alloy (AZ31) was determined in a solution of modified Hank's balanced salts (H1387, Sigma–Aldrich, USA). The AZ31 alloy was sourced in the form of 0.23 mm thick foil (Goodfellow, UK) from which test specimens of length 50.0 mm and width 4.65 mm were cut, as shown schematically in Fig. 1(a). A 20.0 mm long test region was created at the centre of each specimen by reducing the foil thickness to 0.21 mm in this region, as shown in Fig. 1(b). This was accomplished by mechanical polishing with 600-grit emery paper, resulting in a final average surface roughness of 0.2 μm as measured using a profilometer (Surftest – 211, Mitutoyo, USA). Prior to testing, samples were cleaned in anhydrous ethanol and left to dry for a period of 24 h, allowing for a consistent oxidization of all polished sample surfaces. Regions of the sample outside the test section were covered in a layer of petroleum jelly to restrict corrosion attack to the region of interest. For corrosion testing, specimens were immersed in the solution of modified Hank's balanced salts, with the solution temperature being maintained at 37 °C by means of a thermostatically controlled water bath. The solution volume (ml) to surface area (cm^2) ratio was maintained between 25:1 and 50:1 in all tests, with this range being deemed appropriate based on the work of Yang and Zhang [20], who showed that increasing the volume to area ratio beyond 6.7 had little influence on the corrosion behaviour of a similar biodegradable magnesium alloy in Hank's solution.

In order to comprehensively characterize the corrosion behaviour of the biodegradable alloy, three independent experiments were performed, as listed in Table 1. The first experiment, A, was

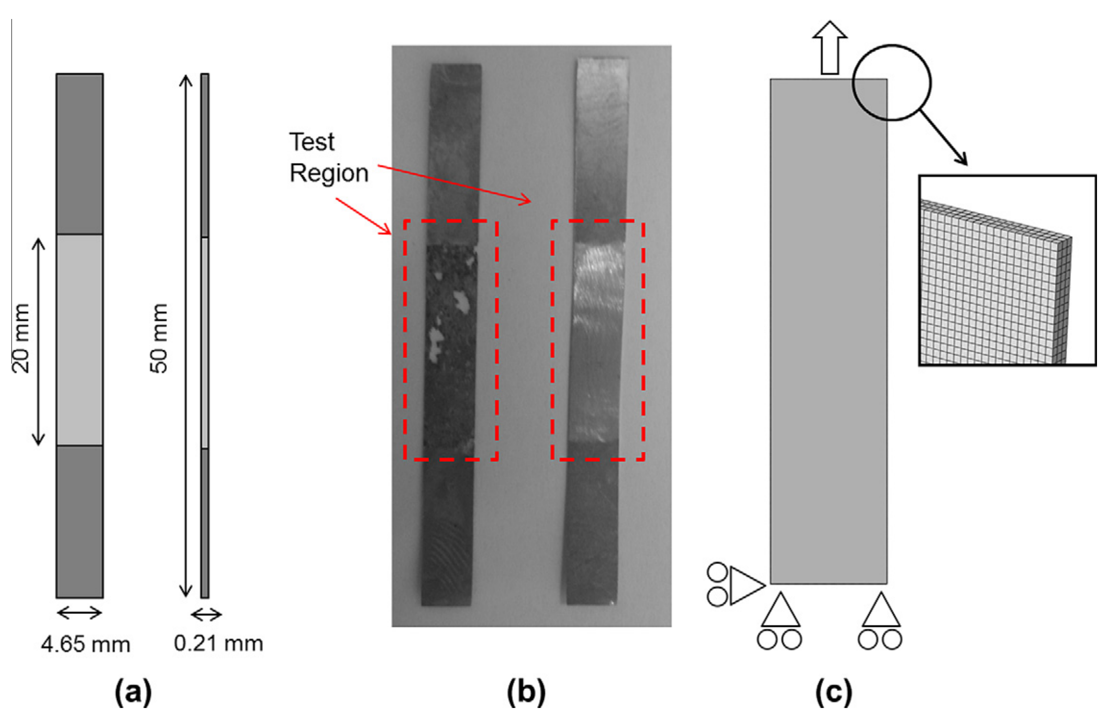

Fig. 1. (a) The AZ31 alloy foil specimen geometry used in experiments A, B and C. (b) The polished test region in a corroded (left) and non-corroded (right) foil specimen. (c) Boundary and loading conditions for the FE corrosion simulations.