A PHENOMENOLOGICAL MODEL OF CORROSION IN BIODEGRADABLE METALLIC STENTS

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ABSTRACT
Coronary stents are tiny scaffolds that are used in the treatment of heart disease. A new generation of metallic stents that dissolve in the body when no longer required have shown promise in a number of clinical applications. However, one of the primary challenges in developing such a stent is maintaining adequate control over the rate at which it dissolves. A model that is capable of representing corrosion induced material degradation in a finite element framework is being developed. Such a model will prove useful in predicting the lifetime of biodegradable metallic stents \textit{in vivo}.

INTRODUCTION
The primary function of the coronary stent is to provide mechanical support to an arterial vessel, thereby preventing early recoil \cite{1}. The continued presence of a stent in the long term has been found to lead to a number of clinical problems, including in-stent restenosis \cite{2}. This has lead to an interest in the development of stents that gradually dissolve in the body, allowing stressed arterial tissue to re-model in a natural manner.

Magnesium alloys have shown promise in biodegradable stent applications \cite{3}. Advantages of magnesium include its superior mechanical strength when compared to common biodegradable polymers and the relatively high concentrations at which it can be tolerated in the blood (85-121 mg L\textsuperscript{-1}) \cite{4}. However, one of the major challenges in the development of biodegradable magnesium stents is in achieving control over its rate of corrosion in the body \cite{3}.

The goal of this work is to develop models that are capable of representing corrosion induced material degradation in biodegradable metallic stents. The models are developed in a finite element framework and are implemented in the Abaqus® commercial finite element code. The development of such models will allow the lifetime of biodegradable stent designs \textit{in vivo} to be predicted.

METHOD
The rate of magnesium mass loss from the surface of magnesium alloy (AM60B-F) coupons, when immersed in a physiologically realistic laminar flow of simulated biological fluid, has been found by Lévesque \textit{et al.} \cite{5} to be given by:

$$\frac{dm_{Ms}}{dt} = 1.94(t^{0.5}) + 1.17 \tag{1}$$

where $m_{Ms}$ is the mass of magnesium lost (in mg) from an exposed surface area of 1 cm\textsuperscript{2} at a time of $t$ hours. This mass loss rate is implemented directly as an outgoing mass flux in a mass diffusion analysis in the Abaqus® finite element code, through the use of a user defined flux (DFLUX). The resulting mass concentration profile $M_{Ms}$ is used to describe a scalar degradation field $d_{u}$. This field is chosen to reflect the effects of mass loss due to uniform surface corrosion on the mechanical properties of the material, and is given by:

$$d_{u} = 1 - \frac{M_{Ms}}{100} \tag{2}$$

where $M_{Ms}$ is the percent concentration of magnesium at a given point.

Since the rate of mass loss of magnesium is also a function of plastic strain, due to an increased presence of dislocations on the surface of plastically deformed metals, a second degradation field $d_{ep}$ is introduced, with:

$$d_{ep} = F^{pl} \frac{t}{\tau} \tag{3}$$

where $F^{pl}$ is the equivalent plastic strain (based on a Von Mises plasticity material description) at the surface, and $\tau$ is a time constant, set at 50 hours. In this case a simple linear relationship is chosen to describe the effect of plastic strain on the rate of corrosion, as the exact relationship is not currently known. The nature of this relationship is currently being explored experimentally.
Material softening is controlled by the evolution of a total degradation field \( d \), which is given by a linear superposition of \( d_u \) and \( d_{ep} \). Material is deemed fully degraded, and thus unable to support a load, where the field has a value of one.

The corrosion model is applied to a 3-D stent geometry that is representative of a commercially available permanent stent. The stent is expanded under the application of a uniform internal pressure and is then allowed to recoil. Corrosion is simulated on the surfaces of the stent that would not normally come into contact with the artery. Interactions with the surrounding artery are not explicitly modelled.

**RESULTS**

The degradation profile in the stent due to uniform and strain based corrosion is shown Fig. 1. Degradation is most prevalent at the exposed inner edges of the struts and at the plastic hinges.

The progressive degradation of the stent over time is shown in Fig. 2. Elements in which the degradation field has reached a value of one are removed from the plot, allowing the extent of degradation in the stent to be seen more clearly. It is observed that as degradation of the stent proceeds, individual struts become detached from the main body of the stent such those circled in Fig. 2. Such an occurrence would increase the risk of patient injury should it occur with an actual stent design, thus highlighting the necessity of stent designs that are tailored for use with biodegradable metals.

**DISCUSSION**

In the application of eqn. (1) a uniform corrosion profile is assumed over the surface of the stent. Although such a assumption has been shown to be appropriate in a macroscopic sense [5], due to the microscopic size of stent struts the influence of features such as grain boundaries and phase differences on the corrosion profile should also be accounted for. Despite this, the phenomenological model presented here will be useful in the development of a physically based, and more realistic, model of corrosion at the microscale. As part of the further development of this model, the effect of plastic strain on corrosion rates is being investigated in magnesium alloy samples (AZ31), as well as the influence of surface shear stresses, induced by blood flow, on corrosion.

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**REFERENCES**