A COMPUTATIONAL STUDY TO INVESTIGATE DEBONDING IN COATED BIORESORBABLE STENTS

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1. Introduction

Hybrid bioresorbable stents (HBSs), like magnesium alloy stents coated with a degradable polymer, are a very promising solution for coronary artery diseases.[1,2] The magnesium alloy substrate will be resorbed by the body after they have completed their function,[3] limiting long term complications related to the body inflammatory response caused by permanent implants. Furthermore, the polymer

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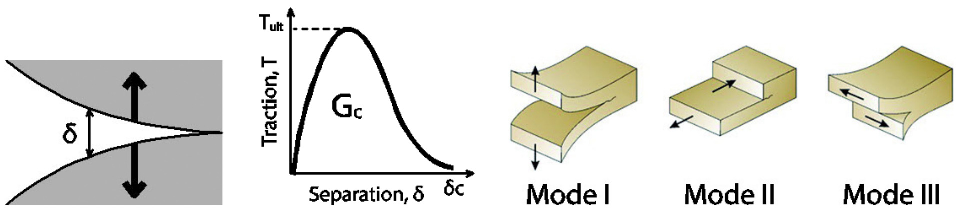
coating can improve the desired degradation kinetics, ensuring a protective action from the corrosive environment which can cause too fast degradation of stent substrates.[4] However, when a HBS undergoes high strains during balloon expansion, the coating may debond from the substrate and lose the protective function on the corrodible substrate. Computational analyses are a useful and convenient tool to investigate the interaction between the coating and the stent and to optimize the device performance. In this paper, the delamination of a HBS made of AZ31 magnesium alloy coated by polycaprolactone (PCL) or polylactide (PLA) is deeply investigated using a commercial finite element (FE) code (Abaqus, 6.10-1). The main goal of this study is to provide a greater understanding of the occurrence of delamination during stent expansion and to give preliminary design inputs for developing HBSs.

2. The Computational Method

Cohesive zone model (CZM) using cohesive elements is applied to represent the bond between the coating and the stent. The CZM theory relates the tractional force, T, needed to keep the surfaces bonded, to the displacement, δ, between the bonded interfaces (Fig. 1(a)), through a traction-separation law. This law is characterized by the ultimate strength, T_{ult}, that is the maximum value of the tractional stress and the critical displacement, δ_c, that is the maximum distance between the two surfaces when failure occurs. The energy release rate, G_c, also known as critical fracture energy or fracture toughness, is the area under the law curve and it is a material parameter that characterizes the amount of energy a bond dissipates per unit area of crack growth (Fig. 1(b)). The separation can occur in the normal direction to the bonded interfaces (mode I) and in the two tangential directions to the bonded interfaces (mode II and mode III), as shown in Fig. 1(c).

In our model the cohesive zone is modeled with a monolayer of cohesive elements of zero thickness connected, top and bottom, to the adjoining stent and coating elements. To overcome the difficulty of obtaining the CZM model parameters, a penalty-based method was applied depending only on the energy release rate G_c, which can be experimentally detected with a peeling test. With a triangular



(a) (b) (c)

Fig. 1. (a) The separating cohesive zone with the opening displacement, δ. (b) The general cohesive law. (c) Modes of separation.

traction-separation law, T_{ult} and δ_c can be determined through preliminary numerical analyses: the penalty parameter δ_c should be as small as possible until numerical ill-conditioning is reached.[5]

3. Materials and Methods

First, 90° peeling simulations were performed on a thin elastic polymeric strip bonded to a rigid substrate with a layer of cohesive elements. These analyses evaluated the influence of the cohesive parameters on the debonding behavior; and they allowed to select the suitable elements size for the coated stent model. The value of G_c ($= 0.0025\,\text{J/mm}^2$) was obtained from experimental peel tests on AZ31 magnesium alloy plates coated by PCL[6] and was used for all the simulations in this study. Through varying the penalty parameter δ_c, the most suitable value characterizing the bond was selected comparing the peeling force predicted by simulation with the corresponding force measured experimentally. Second, two-dimensional (2D) models resembling a *C-shaped* portion of stent rings were developed (Fig. 2(a)), in order to investigate which debonding mode takes place at the tensile side of a stent-like shape structure, and how the coating thickness and Young modulus influence the delamination. Three models were investigated: *thin-PCL*, *thick-PCL* and *thin-PLA* with a thickness of 0.01, 0.03 and 0.01 mm, and Young modulus of 88, 88 and 792 MPa, respectively. In these three simulations, opposite displacements orthogonal to the stent axis were imposed at the two straight arms to reproduce the stent expansion.

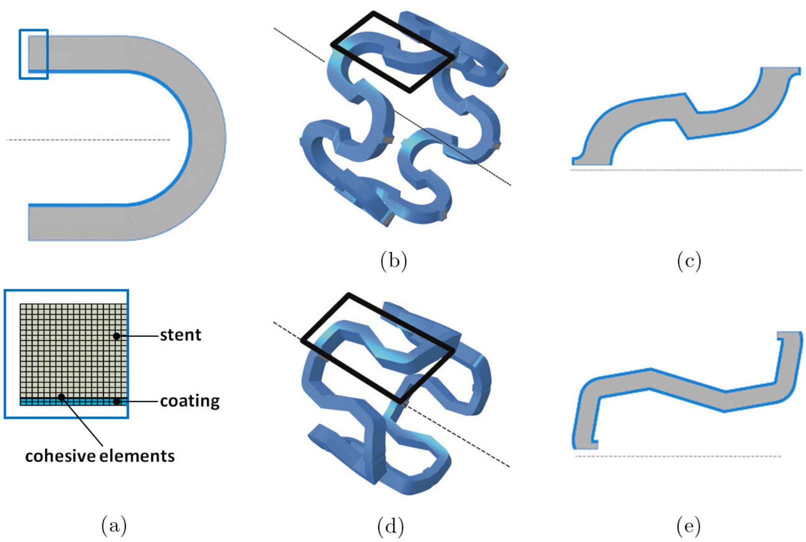


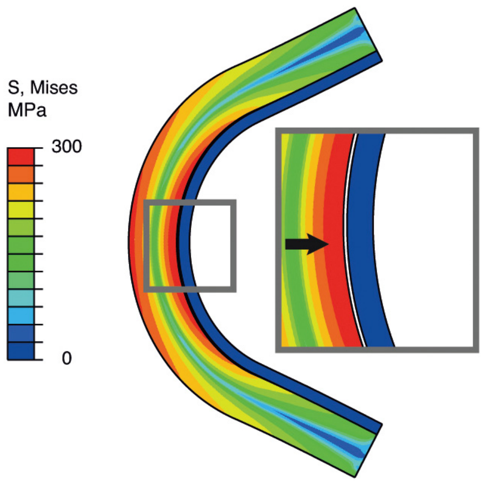
Fig. 2. (a) 2D coated *C-shape* model, and the zoom-in view shows how the mesh was created. The cohesive elements are invisible because they have zero thickness. (b) three-dimensional (3D) and (c) 2D model of the coated *stent A*. (d) 3D and (e) 2D model of the coated *stent B* unit. Dash lines indicate the axes.

Third, two HBS designs resembling two typical stent geometries, named stent A and stent B, having the same diameter in the unexpanded configuration but a different number of units per ring (Figs. 2(b) and 2(d)), were studied. In particular 2D flat models of the two units were built: the expansion of the two stents up to the same final diameter was simulated imposing a displacement orthogonal to the stent axis to the two models (Figs. 2(c) and 2(e)). A parametric study on the fracture toughness of the two stent units was also conducted, in order to find the minimum value over which the delamination does not happen.

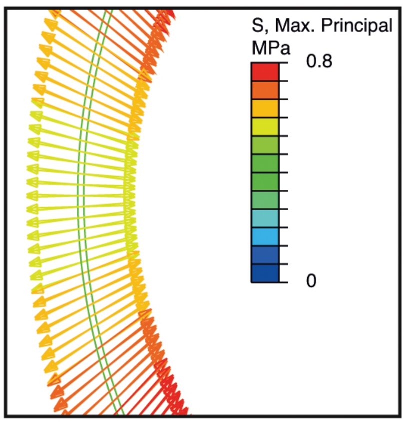
4. Results and Discussion

The simulations of the 90° peel test (not shown), which varied the mesh ratio between the cohesive elements and the coating/stent elements, showed that the ratio of 1:1 provided a good description of the interaction between coating and substrate. Moreover, with the same δ_c the peeling behavior was insensitive to the element size. Meanwhile, a suitable value of 0.0084 mm was determined for the δ_c, which is small enough and does not trigger ill-behaved simulation.[5]

The expansion of the *C-shape* model was in agreement with the real coating debonding phenomenon[7]: the debonding started at the tensile side of the curved part of the model (Figs. 3(a) and 3(b)), where plastic hinge takes place (mainly mode I); furthermore, coating at the straight arms of the model separates from substrate with mixed mode (both modes I and II), as shown in Figs. 3(c) and 3(d). The

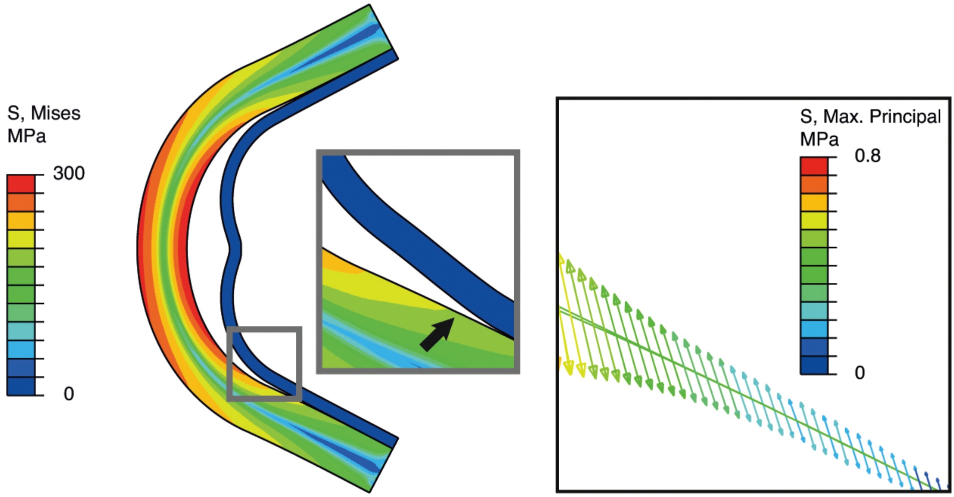


(a)



(b)

Fig. 3. (a) Debonding starts at the center of the model curved part and it is mode I, as also shown by (b) the maximum principal stress directions of the corresponding cohesive elements. (c) Increasing the stent expansion, debonding proceeds along the model straight arms and it is a mixed mode, as also shown by (d) the maximum principal stress directions of the corresponding cohesive elements.

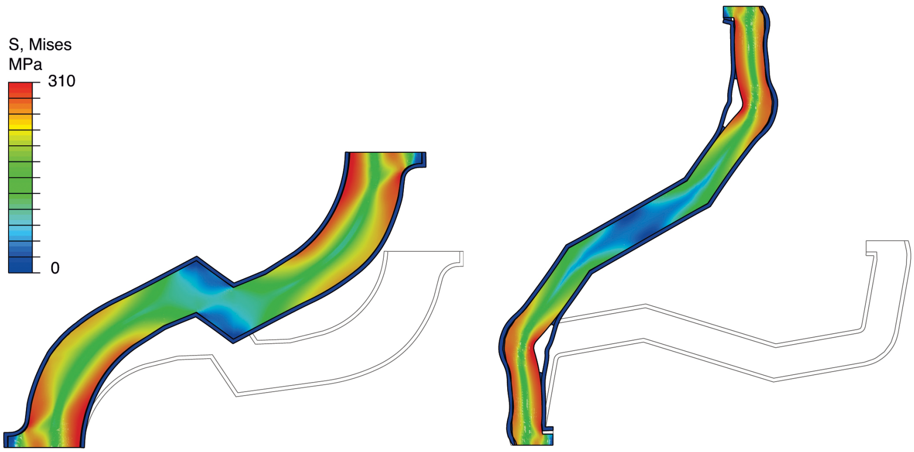


(c) (d)

Fig. 3. (*Continued*)

simulations of the three different coatings showed that in the *thin-PCL* model the coating delamination is absent, while the coating debonded from the stent in the *thick-PCL* and the *thin-PLA* models. These results suggest that thinner and more flexible coatings are more resistant to debonding during stent deployment.

As shown in Fig. 4, in the expansion simulations of the 2D stent unit, debonding is absent in *stent A*, whereas *stent B* showed delamination at different regions, in



(a) (b)

Fig. 4. Undeformed (frame lines) and deformed shapes (colorful) of (a) the *stent A* and (b) *stent B* unit bidimensional models.

particular at the tensile side of the plastic hinge and at the link angle. It has to be pointed out that to obtain the same final expanded diameter of the rings, the unit of model B has to be expanded more than the unit of model A (0.63 mm versus 0.26 mm). These results clearly indicate that the stent design influences the delamination and a stent shape with reduced strain concentration behaves better than one with highly localized strains. Moreover, the parametric study of fracture toughness showed that *stent A* and *stent B* should have a minimum G_c of 1.17 mJ/mm^2 and 7.5 mJ/mm^2, respectively, to avoid delamination. These results confirmed that the *stent A* design is more applicable to prevent coating delamination.

5. Conclusions

A series of preliminary computational analyses were performed to study the debonding of polymer coating from magnesium alloy stent substrate. The 90° peeling model provided the fundamental parameters used in the study, including the discretization ratio between the cohesive elements and the surrounding elements, and the critical displacement value on the coating delamination. Then the influences of coating thickness and elastic modulus on debonding were studied using a *C-shape* model. Finally, the delamination of 2D models of single stent units was studied and the results suggested some preliminary considerations for optimizing the design of HBS. In the future the 3D simulations will be considered to verify if the interaction between balloon and stent during stent expansion can significatively affect the coating integrity. It is expected that 3D analyses provide further understanding of the complexity of the mechanism of delamination.

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