Application of Corrosion-Resistive Polyetherimide Coating to Vascular Magnesium Stent

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Statement of Purpose: Mg and its alloys have been regarded as promising biodegradable stent materials due to its good mechanical properties as compared to other biodegradable polymers. However, rapid corrosion and corresponding mechanical degradation of Mg with hydrogen generation in physiological environments still limit the clinical applications [1]. To resolve this problem, protective coating layers on Mg have been proposed, and in particular, polyetherimide (PEI) has shown great potential as a coating layer on Mg stent applications because of its flexibility and good adhesion strength on Mg in addition to good biocompatibility [2, 3]. Therefore, in this study, PEI was evaluated as a coating material of stent applications that undergo large deformation during implantation.

Methods: PEI solution was prepared by dissolving PEI in NMP by 15 w/v%. The PEI solution was spin-coated on pure Mg substrate and dried at 70 °C. The PEI coating layer was observed by SEM. Corrosion behavior was evaluated by monitoring the increase of pH after immersing PEI-coated Mg in simulated body fluid (SBF) solution at 37 °C before and after deformation at $\varepsilon = 0.08$ ($n = 3$). To carry out tensile tests, all specimens were fabricated to have dog bone shape and were loaded to the screw-type deformation kit (Fig. 2a). PEI was also coated on the Mg stents via by spray coating technique. PEI coated stent was expanded in PBS solution at 37 °C to mimic stent implantation and then was observed by SEM to check the coating stability of PEI before and after expansion.

Results: Before applying PEI to stent applications, the coating stability of PEI layers on Mg was evaluated by using pure Mg substrates. **Fig 1** shows that PEI was well-coated on Mg with a thickness of ~ 2.5 µm. The coating thickness was controllable by the concentration of PEI solutions under the same spin coating rate, which was directly applied to the spray coating technique for optimal coating thickness. PEI-coated Mg specimens were stretched up to 8% strain to simulate stent expansion condition. The corrosion behavior of coated samples after deformation was evaluated in SBF solution as compared to undeformed Mg, and PEI-coated Mg for coating stability. Bare Mg was corroded rapidly, displaying rapid pH increase up to 9 within 2 days, but both undeformed and deformed PEI-coated Mg were relatively stable with slow pH increase, implying the coating layer protects its underneath Mg substrate even after deformation with good coating stability (Fig. 2b). The PEI coating layer was introduced to the real stent application that has complex geometry as shown in Fig. 3. By optimizing the thickness of PEI layer (~ 3 µm), PEI was found to be uniformly coated on the curved Mg stent pattern without defects (Fig. 3a, b). After the expansion of the PEI-coated stent in aqueous environments, there was no trace of delamination or defects of PEI coating, leading no corrosion of Mg stent with good structural integrity (Fig 3 (c, d)).

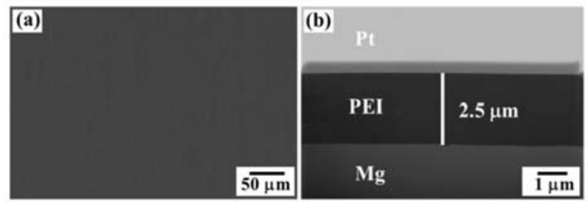

Figure 1. (a) Surface morphology and (b) the thickness of PEI layer on Mg

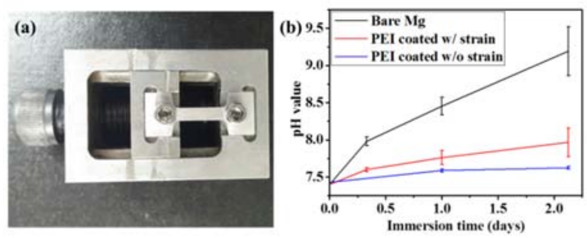

Figure 2. (a) Srew-type tension test kit with dog-bone shape Mg specimen and (b) pH variation of bare Mg, and PEI coated Mg before and after deformation ($\varepsilon = 0.08$) in SBF over time

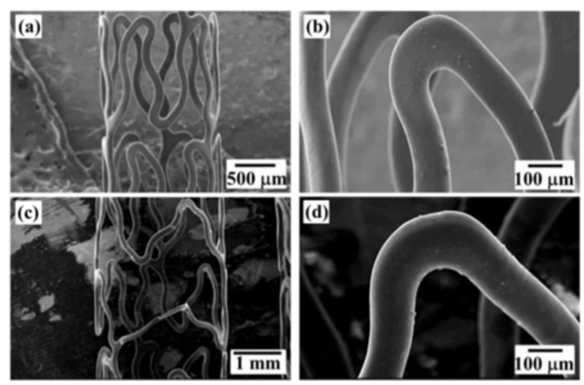

Figure 3. PEI-coated Mg stent before expansion (a, b) and after expansion (c, d) in PBS

Conclusions: PEI was successfully coated on both Mg plates and Mg stents via spin or spray coating techniques, respectively, with optimal thicknesses that provide good coating stability under large deformation of the substrates. PEI-coated Mg stents exhibit improved corrosion resistance even after deformation without any prominent defects. This PEI-coating Mg stent has great potential for real clinical applications, with a longer and reliable performance.

Reference

[1] Wang J et al. Acta Biomater 2013;9:8678-89.
[2] da Conceicao TF et al. Corros Sci 2011;53:338-46.
[3] Ruder C et al. Clin Hemorheol Micro 2012;50:101-12.