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Finite element analyses for optimization design of biodegradable magnesium alloy stent

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ABSTRACT

Stents made of biodegradable magnesium alloys are expected to provide a temporary opening into a narrowed arterial vessel until it remodels and will progressively disappear thereafter. Inferior mechanical properties and fast corrosion of the magnesium alloys are the two crucial factors that impede the clinical application of the magnesium alloy stents (MAS). In the present study, gradual strut width, addition of the peak-to-valley unit and introduction of the annealing technology were designed and investigated by finite element analysis in order to improve the performance of the MAS. Two experiments were carried out for a preliminary validation of the simulation.

1. Introduction

Stent implantation in coronary arteries is currently the major way in the therapy of patients with cardiovascular diseases [1]. Current stent technology is based on the use of permanent implants, and they have been in clinical application for many years. However, potential risks during their service in human body, such as late stent thrombosis [2], hypersensitivity reactions [3,4], in-stent restenosis (ISR) [5] and the need for prolonged antiplatelet therapy [6], are more and more mentioned, which limit their more widespread application. The drawbacks are mainly originated from long-term biological incompatibility caused by the interaction between the vessel and the permanent stent [7]. A concept of the ideal stent has been proposed by some researchers [8]. They indicted that an ideal stent should provide a temporary mechanical opening support and prevent early recoil to the arterial vessel. Along with the remodeling of the arterial vessel, the stent can biodegrade gradually. Finally, the stent will fully degrade and be absorbed by human body until the arterial tissue finds a new equilibrium by the deployment of the stent. Benefiting from their degradability and excellent biocompatibility, the biodegradable magnesium alloy stents (MAS) are expected to achieve the concept of this ideal stent [8].

Based on this idea, studies of magnesium alloy stents have become one of the most revolutionary research topics at the forefront of biomaterials [9]. Biodegradable magnesium alloy stents have not yet entered the clinical practice, but results from early studies have shown their feasibility and generated great expectation for clinicians, patients, industrialists and researchers [10–13].

The elastic modulus and strength of magnesium alloys are far less than those of the stainless. Furthermore, the width and thickness of the stent struts will decrease along with the degradation of the magnesium alloys. Therefore, the MAS need wider and thicker stent struts to provide adequate scaffolding during the remodeling period of the arterial [14]. When the width and thickness of the stent struts are increased, the strain and residual stress of the stent after deployment will become larger. If the plastic deformation surpasses the ultimate breaking strain of magnesium alloys, the stent breaks and leads to the failure of the operation [15]. Additionally, the degradation of magnesium alloys is sensitive to the stress corrosion. Excessive residual stress is prone to lead to early fracture of the stent struts duo to the local stress corrosion [16]. The premature loss of scaffolding due to corrosion has been reported to be a primary reason for the relatively poor device efficacy in the first clinical trial of AMS in coronary applications [12].

Efforts have been made to improve the performance of the device through development of the magnesium alloys with improved mechanical properties and corrosion resistance [1,13,17]. Besides that, the design of the stent structure can be an efficient way to improve the mechanical performance and corrosion resistance of the stent [15]. Optimization techniques based on finite element analysis (FEA) have proven to be efficient and low cost in the stent designs with desirable attributes [18–24].

In this study, some new stent optimization methods were developed with advantages in terms of decreased Max. Von Mises strain, more uniform distributed deformation and lower residual stress. Finite element modeling in consideration of gradual strut width, addition of the

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peak-to-valley unit, and introduction of the annealing technology were designed to optimize the performance of the MAS. Experiments were carried out for qualitative validation of the simulation results.

2. Method

2.1. Geometry models

The CAD model of a common stent [25,26] is shown in Fig. 1a. It has six rings connected by curved links, presenting five peak-to-valley struts in the circular direction.

This common stent structure consists of few basic geometric elements such as straight lines and arcs. The design as shown in Fig. 1b is a common structure for stainless steel stent. The width and thickness of strut for a stainless steel stent are usually in the range of 0.05 mm to 0.10 mm because of the excellent mechanical properties of the stainless steel [14]. A thinner strut makes the stainless steel stent to possess enough space to accommodate more peak-to-valley struts in the circle direction. The MAS with thicker and wider struts is usually designed to possess four to six peak-to-valley struts [10–12,15], which makes each peak-to-valley unit to stand larger stain duo to the change of the opening angle of the peak-to-valley strut during the crimping and expanding processes of the stent [25]. Therefore, the optimization of the stent structure has to be performed to make it fit to the inferior mechanical properties of the magnesium alloys [15].

In this study, an optimized stent structure is characterized by the gradual size (from 0.11 mm to 0.14 mm) of the strut width for stent. To make the stent structure be smooth, a fine adjustment was applied to the common stent structure. The stent structure after optimization is shown in Fig. 1c and the 3D models of the stents with the common structure and the optimized structure are shown in Fig. 1d and e, respectively. They are contributed with a thickness of 0.14 mm. Additionally, two stent models with five and six optimized peak-to-valley struts are also created to investigate the influence of different numbers of peak-to-valley struts on the performance of the stent.

2.2. Material properties

An extruded AZ31 was chosen as the stent material in a present study. The thermally deformed magnesium alloys normally present better mechanical properties compared with the cast magnesium alloys. The extrusion process increased the deformability of the AZ31 significantly, which is a critical factor regarding the stent material properties. The extruded AZ31 has a modulus of 43.5 GPa and a Poisson's ratio of 0.35 [27]. It was modeled as a homogeneous, isotropic, elasto-plastic material through a Von Mises–Hill plasticity model with an isotropic hardening rule. The true strain–stress curve of AZ31 is taken from the literature [18].

2.3. Crimping and expansion model

The two FEA models are composed of a stent ring and two cylinders, as shown in Fig. 2. The length of the cylinder is slightly longer than that of the stent. The outer cylinder is used to crimp the stent to the balloon. Then the outer cylinder is moved away and let the stent to recoil. The stent is expanded to a certain size by means of the expanding of the inner balloon. The stent recoils again after removing the balloon. The stent and cylinders are coaxial.

There are five steps for the simulation. Initially, a radial displacement is applied to the crimping cylinder to reduce the inner stent diameters down to 1.0 mm (step 1). Then the crimping cylinder is released and the stent recoils (step 2). After that, the expanded cylinder has a radial displacement to increase the inner stent diameter to 3.0 mm (step 3). Then the stent recoils again with release of the expanded cylinder (step 4). The maximum Von Mises strain during expansion, the instant recoil and the residual stress after step 4 are analyzed. Finally, the radial compression of each stent is simulated by introducing a thin elastic

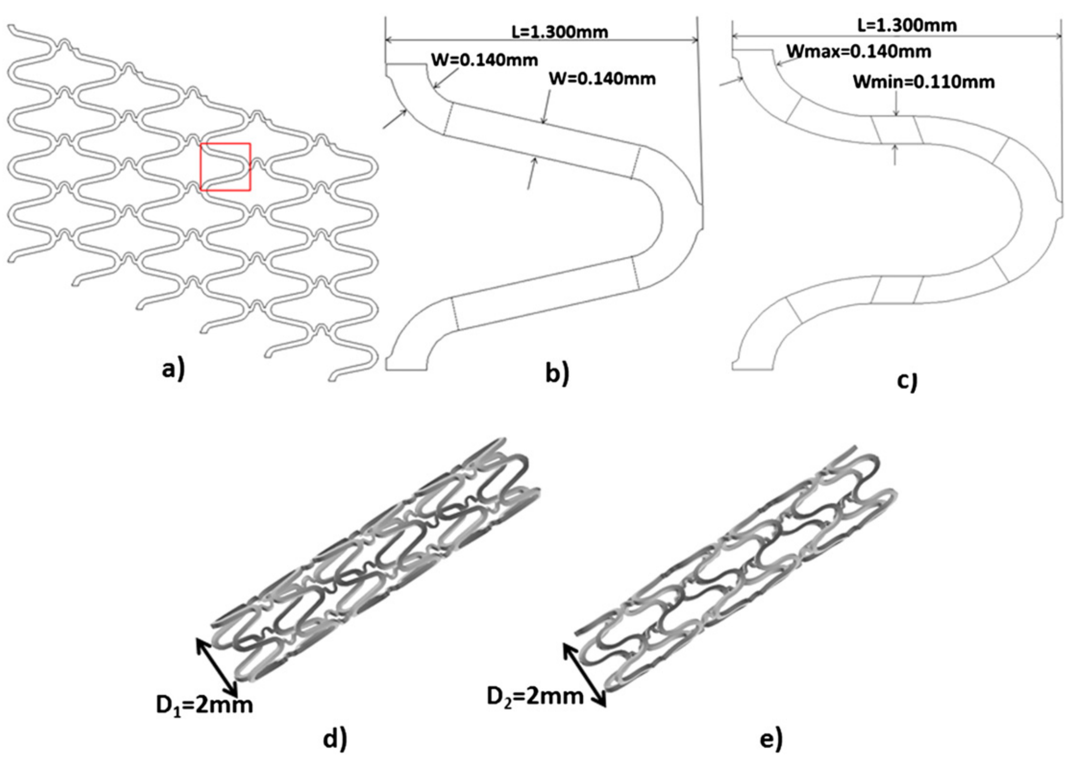

Fig. 1. (a) 2D model of a common stent, (b) one strut unit (in the red box) for the optimization; (c) one strut unit after the optimization; 3D model of the common stent (d) and the optimized stent (e).