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Original Research

Forming of magnesium alloy microtubes in the fabrication of biodegradable stents

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Abstract

Magnesium alloys have, in recent years, been recognized as highly promising biodegradable materials, especially for vascular stent applications. Forming of magnesium alloys into high-precision thin-wall tubes has however presented a technological barrier in the fabrication of vascular stents, because of the poor workability of magnesium at room temperature. In the present study, the forming processes, i.e., hot indirect extrusion and multi-pass cold drawing were used to fabricate seamless microtubes of a magnesium alloy. The magnesium alloy ZM21 was selected as a representative biomaterial for biodegradable stent applications. Microtubes with an outside diameter of 2.9 mm and a wall thickness of 0.2 mm were successfully produced at the fourth pass of cold drawing without inter-pass annealing. Dimensional evaluation showed that multi-pass cold drawing was effective in correcting dimensional non-uniformity arising from hot indirect extrusion. Examinations of the microstructures of microtubes revealed the generation of a large number of twins as a result of accumulated work hardening at the third and fourth passes of cold drawing, corresponding to the significantly raised forming forces. The work demonstrated the viability of the forming process route selected for the fabrication of biodegradable magnesium alloy microtubes.

Keywords: Vascular stent; Microtube; Magnesium alloy; Extrusion; Drawing

1. Introduction

In recent years, balloon-mounted vascular stenting has become the primary choice for the treatment of atherosclerosis, coronary artery diseases in particular. At present, more than three million stent implantations to reopen stenosed vessels are performed every year [1,2]. The vast majority of the stents currently in clinic use are made of stainless steels or cobalt–chromium alloys [3] and permanently stay in blood vessels. Although these metallic materials in general possess excellent mechanical properties and acceptable biocompabilities, such stents may produce serious postoperative side-effects such as thrombosis and in-stent restenosis [4,5], thereby limiting the long-term success of stenting [6]. One of the approaches to reducing and even circumventing these side-effects is to implant temporary stents made of biodegradable materials. Polymer-based biodegradable stents developed so far still suffer from the major drawback of limited mechanical performance. Much attention has recently been paid to metallic biomaterials for biodegradable stents. Pure magnesium, as biodegradable and biocompatible metallic material, presents itself as a promising material for biodegradable stents [7]. However, alloying, although making the biocompatibility issue complex, is necessary to enhance the biocorrosion resistance and mechanical properties of magnesium. By adding appropriate alloying elements to magnesium, magnesium alloy stents are expected to be able to perform their biomechanical functions by supporting the arterial wall during the remodeling process over a period of 6–12 months and then progressively degrade. Rare earth (RE) elements have been found to be able to serve the purposes of alloying better than most of other bio-tolerable elements. RE-containing magnesium alloys such as WE43 alloy and AE21 have therefore been subjected to extensive in vitro investigations [8]. Furthermore, a number of in vivo evaluations of RE-containing magnesium alloy stents have been performed. Encouraging results have been obtained and new

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strategies to optimize the performance of metallic biodegradable stents have been mapped out, focusing on alloying, coating and microstructure control.

In developing metallic biodegradable stents, developing the fabrication technology is of equal importance, as the fabrication technology determines the feasibility of converting a piece of starting stock to a functional medical device in a cost-effective manner. The research in this aspect has however received insufficient attention. In the case of fabricating permanent metallic stents, tubing is produced in the seamless form, followed by tube drawing and laser slitting. In the case of magnesium alloys, however, it is very difficult to produce cold-drawn seamless tubes with exact dimensions on the microscale due to their poor plasticity at room temperature. Only a few studies have so far been conducted on developing the fabrication technology for magnesium alloy microtubes and improving the mechanical properties as well as the dimension accuracy of the semi-finished products for stents [9,10]. Ge et al. obtained ultrafine-grained (UFG) tubes of magnesium alloy ZM21 through severe plastic deformation using the equal channel angular pressing (ECAP) method [11]. Faraji et al. succeeded in producing AZ91 UFG tubes by means of multi-pass tubular channel angular pressing (TCAP) [12]. With the ultrafine-grained structure created during these severe plastic deformation processes, the mechanical properties of magnesium alloy tubes could be enhanced considerably [13] and even biocorrosion resistance could be improved to a certain extent, both of which are beneficial for stent applications. Furushima et al. successfully produced AZ31 magnesium alloy microtubes from ECAP-processed and extruded billets by using the multi-pass dieless drawing method [14]. Local heating was applied during dieless drawing to make the heated area with an initial outside diameter of 2 mm and a wall thickness of 0.5 mm thinner. However, the process did not allow the change of the ratio of the inside diameter to the outside diameter of microtubes and as such its applicability is rather limited. Moreover, the refined grain structures from the ECAP process would increase the difficulties in subsequent forming processes to the near net shape of stents by greatly enhancing the forming force. It would therefore be of practical significance, if magnesium alloy microtubes could be drawn from the billets without going through a severe plastic deformation process.

The present study was an attempt to develop a forming process route for the fabrication of magnesium alloy microtubes through simple forming processes, i.e., indirect extrusion and multi-pass cold drawing without involving a severe plastic deformation process. Pre-extruded ZM21 alloy billets were used as the starting material. Dimensional accuracies and microstructures of extruded and cold-drawn tubes were examined to establish the viability of the forming process route.

2. Forming methods and experimental setup for stent microtubes

A material for tubular stents must possess (i) appropriate mechanical strength and ductility and (ii) microscale dimensions [15]. Considering these two basic requirements, hot extrusion appears to be a suitable method to convert a large-dimension as-cast ingot into a small-dimension as-extruded bar. During the process, in addition to large plastic deformation, coarse grains formed during casting are significantly refined through dynamic recrystallization (DRX), leading to enhanced workability for subsequent processing. Obviously, the direct extrusion process does not allow the production of seamless tubes and the indirect extrusion process must be utilized to convert a tubular billet to a thin-wall hollow tube. Moreover, during the indirect extrusion process, the force requirement is reduced because of the decreased friction between the billet and the mandrel. Prior to indirect extrusion, machining is applied to cut the extruded bars into cylindrical hollow billets. These hollow billets are indirectly extruded to produce seamless thin-wall tubes at an elevated temperature, followed by multi-pass cold drawing where dimensional inaccuracies arising during indirect extrusion are rectified in addition to generating the near net shape of stents and enhancing their mechanical performance.

The whole forming process route for the fabrication of stent microtubes [16] is schematically shown in Fig. 1.

2.1. *Development of the high-precision extrusion press for the hot indirect extrusion of microtubes*

A lab-scale horizontal extrusion press was developed to extrude a hollow billet into a thin-wall seamless tube (Fig. 2). The container and the mandrel were mounted on a movable platen driven by a hydraulic piston. The die was fastened to the front fixed platen. Heating elements surrounding the container were used to heat the container and the billet. Extrusion temperature was measured by a thermocouple inserted into the container to realize closed-loop temperature control around the pre-set value. During hot extrusion, the piston together with the container and the mandrel moved forward, thereby pressing the hollow billet into the die, and a thin-wall tube was extruded through the gap between the die orifice and the mandrel. Fig. 3 schematically illustrates the indirect extrusion process for the fabrication of magnesium alloy microtubes.

2.2. *Development of the special tooling for the cold drawing of microtubes*

After indirect extrusion, the wall thickness of extruded tubes would need to be reduced further and moreover the variations

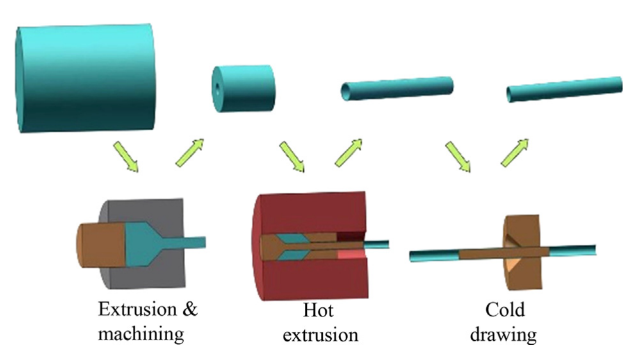

Fig. 1. Schematic illustration of the forming processes for the fabrication of seamless microtubes.