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Can the Current Stent Manufacturing Process be Used for Making Metallic Biodegradable Stents?

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Abstract. Stents have been routinely used for the treatment of coronary artery occlusion since the last two decades. They are made of corrosion resistant alloys such as stainless steel 316L, titanium and cobalt-chromium alloys; in addition, their manufacturing process is well developed. Currently, corrodible metals have been proposed for making stents that can degrade after serving its function (biodegradable stents). This article discusses applicability of the current laser-cutting-based stent manufacturing process for making biodegradable stents: from materials production to stent fabrication until implantation. It covers some practical and technical points extracted from literatures and author's experiences with clinicians and industrialists to be considered in developing metallic biodegradable stents.

Introduction

Coronary stent is a tiny tubular-mesh-like implant made of corrosion resistant alloys mostly 316L type stainless steel (SS316L) which is used effectively for treating coronary artery occlusion (Fig. 1). Lately, a new class of stents, namely biodegradable stents, was introduced and being developed. These stents are expected to progressively degrade after fulfilling their function [1]. Therefore, they offer advantage over permanently implanted stents in avoiding long-term clinical complications such as late-stent thrombosis.

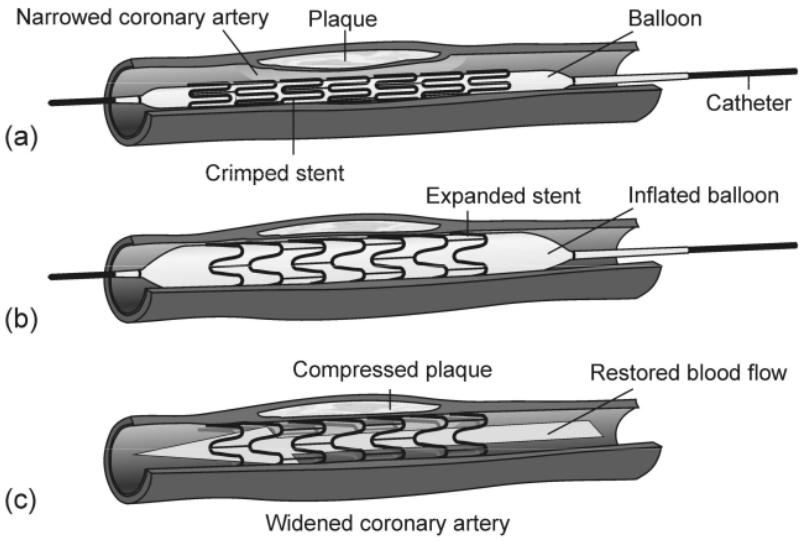

Figure 1 Illustration of stent implantation: (a) a stent crimped over balloon is delivered by a catheter into a narrowed artery; (b) the balloon is inflated thus allowing the stent to expand and to open the artery; (c) the catheter is retracted thus leaving the stent to scaffold the artery and restoring the blood flow. Adapted from [2].

Since early 1990s, coronary stents made of corrosion resistant alloys have been in clinical use [3]. Their materials selection, manufacturing process and implantation protocol have been developed and in common practical use. However, this is not the case for the newly introduced stents made of biodegradable metals; hereafter is called as metallic biodegradable stents. Currently, most recent report on the development of metallic biodegradable stents was about the preclinical study of magnesium alloy stents in adult [4]. However, no report has been published on their manufacturing process. Up to now, biodegradable metals can be classified as magnesium-based, such as Mg-Ca and Mg-RE, and iron-based alloys, such as pure Fe and Fe-Mn [2]. Most of the research on metals for biodegradable stents concerned on materials design and development, referring to properties of the current stents without considering processing steps during manufacturing of the stent itself. By referring to the major differences between corrosion resistant and biodegradable metals as shown in Table 1, every aspect in the manufacturing cycle of metallic biodegradable stents should be carefully reviewed and be adjusted with the special feature of biodegradable metals.

Table 1. Principle differences in viewing corrosion resistant and biodegradable metals for implants.

Cycle	Corrosion resistant alloys	Biodegradable metals
Design	To be corrosion resistant or inert within human body	To be not-corrosion resistant or to be degraded within human body
Biological assessment	No corrosion product	Involve corrosion/degradation products
Implant processing	Chemically stable, oxidation resistant	Chemical stability and oxidation resistance are questionable

In this article, the manufacturing cycle of stents is defined as processes experienced by stents starting from materials production to stent fabrication plus stent implantation procedure. Three different fields of expertise are involved in the assessment of the cycle: materials scientists/engineers (mostly academicians), industrialists and clinicians, respectively. However, in many cases an active exchange of information among these specialists is very limited. Therefore, this article aims to provide some technical and practical points extracted from literatures and author's experiences with clinicians and industrialists to be considered in developing metals for biodegradable stents. The article is divided into three sections following the existing stent manufacturing process: (a) from bulk material to minitube, (b) from minitube to stent, and (c) from production line to implantation site. The most used alloy for fabricating stents, the SS316L, and the current laser-cutting-based technology will be taken as references.

From Bulk Material to Minitube

The medical grade alloys for stents, i.e. SS316L and Co-Cr alloys, are commonly made by vacuum melting process to obtain ultra high purity materials. They are then thermo-mechanically treated and delivered as a bulk under annealed condition in the form of billet or rod. The bulk is then cold drawn to form minitubes, the preform for laser cutting, and furnished under cold-worked condition to provide dimensional accuracy, ease of handling and to avoid bending during laser cutting [5]. Figure 2 shows an example on transformation of an iron alloy from its bulk to minitube. Commonly, the desired metallurgical condition of SS316L minitubes will be under ¾ hardness, having grain size of ASTM 7-8 (24-34 μm) with 8-10 grains across the wall [6]. Hence, there are two different states of materials with different properties: the ductile bulk material and the hard minitube material.

In this stage, similar process is also employed for biodegradable metals where most of them are produced through melting and thermomechanical treatment. Extrusion was then employed to produce minitubes in the case of the experimental magnesium-based alloys stents [7]. However, for

iron alloy stents, the minitube was made through a machining process (Fig. 2). In this case, the metallurgical condition of the iron alloy in a bulk and in a minitube remains the same.

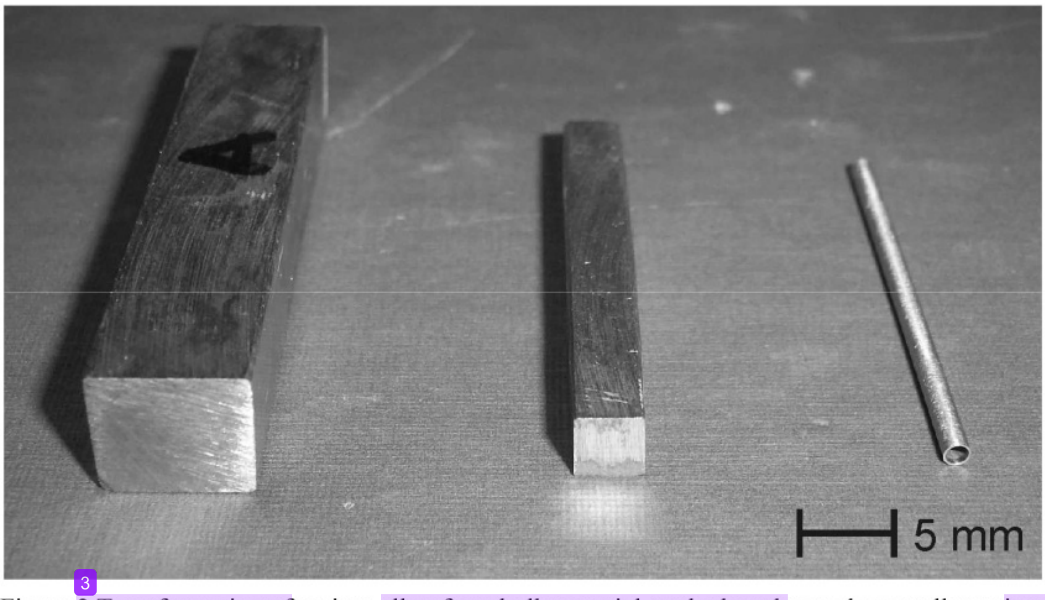

Figure 2 Transformation of an iron alloy from bulk material made though powder metallurgy into minitube. Adapted from [2].

From Minitube to Stent

A common method of making stents is by laser cutting where the minitubes are cut out following a determined pattern. Consecutively, the laser-cut minitubes are then annealed, acid pickled (descaled) and electropolished [2]. Figure 3 shows a typical laser cutting process for making stents in which a stationary laser cuts the moving (translating and rotating) long and continuous minitube.

Annealing brings the stent material into annealed condition, thereby increases ductility and eliminates possible microstructural inhomogeneity induced during laser cutting [5]. For SS316L stents, it is desirable to have the grain size of ASTM 8-9 (20-24 µm) and 8-10 grains across the strut thickness as the final metallurgical condition of stent material [6]. Annealing of laser cut SS316L minitubes is commonly carried out under vacuum. In the case of biodegradable metals containing reactive alloying elements like Fe-Mn alloys, vacuum is unsuitable since it accelerates the loss of manganese [2]. In addition, the influence of microstructural changes to mechanical property, i.e. grain size reduction to strength increment, should not only be taking into consideration since it can also alter the corrosion property, i.e. grain size reduction may accelerate corrosion rate.

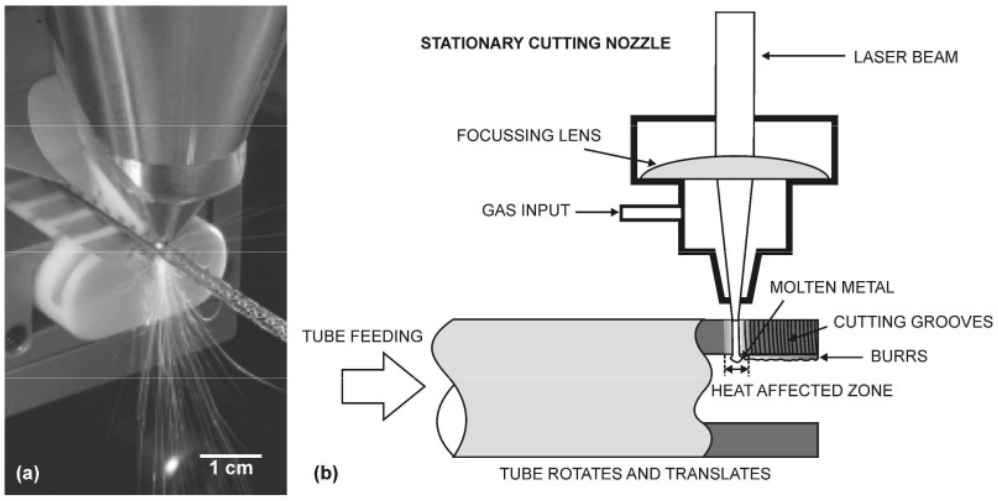

Figure 3 Laser cutting process of stents: (a) photograph; (b) schematic illustration. Adapted from [2].

Furthermore, acid pickling and electropolishing steps, which use a corrosive solution, might be harmful for biodegradable stents since it readily initiates corrosion of stents. Figure 4 shows a rough surface of an iron alloy stent after acid pickling whereas the resulted surface irregularities might serve as crack initiators during stent expansion leading to fracture. Therefore, a less aggressive chemical or other technique that does not involve corrosive solution should be further examined. However, the conservativeness of industrialists who have invested in production facilities dedicated to the fabrication of corrosion resistant stents may resist any major alteration to their established process protocol.

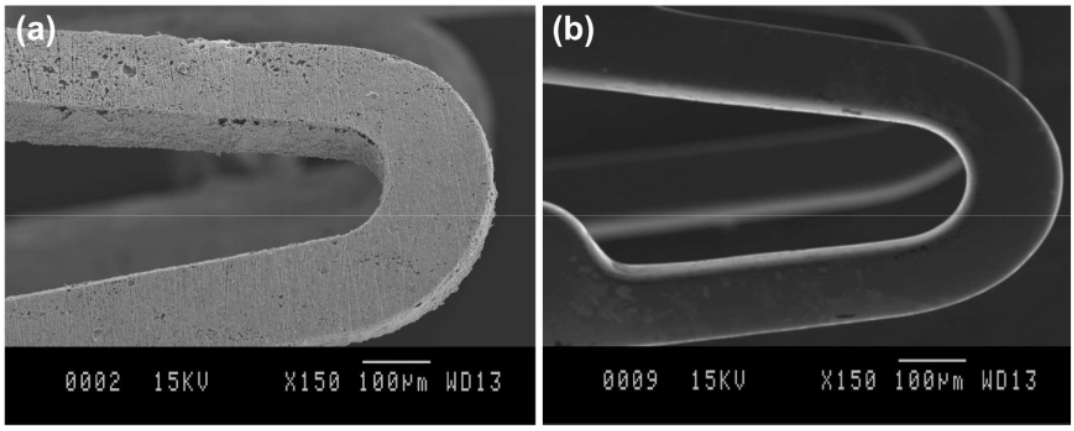

Figure 4 SEM images of: (a) descaled degradable iron alloy stent; (b) electropolished SS316L stent. Adapted from [2].

From Production Line to Implantation Site

Out of production line, stents are normally delivered under crimped (compressed) onto a balloon catheter for practical purpose. During stent implantation procedure, this crimped stent is inserted into the artery through a small incision in arm or groin, delivered through a tortuous passage to reach the targeting site and then expanded under a contact with blood. The whole procedure may

take 1.5 to 2.5 hours [8], but the time frame for a stent, starting from insertion until deployment may take about 15 to 30 minutes. For a biodegradable stent, this could readily initiate degradation process.

The stent should be under uncorroded condition when expanded to avoid fracture. Mechanically, the stent should also be ductile enough to withstand the compressive and tension stress generated from crimping and expansion procedure. As illustrated in Fig. 5, a typical external diameter of SS316L stent for large artery is produced at 1.8 mm, crimped to 1.0 mm and expanded to 3.0 mm.

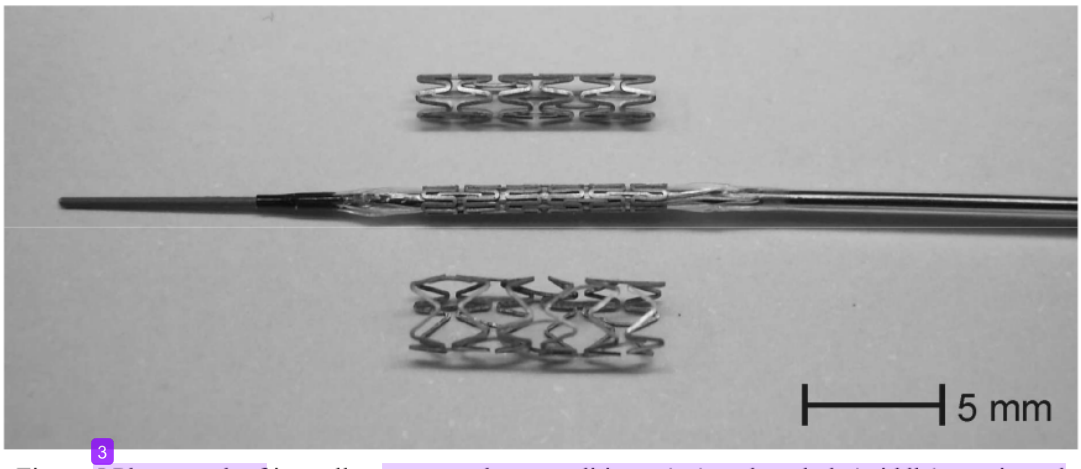

Figure 5 Photograph of iron alloy stents at three conditions: (up) as descaled; (middle) as crimped over balloon; (bottom) as expanded. Adapted from [2].

During the implantation period, these conditions are favourable for environmentally induced corrosion: corrosive environment (blood and its ions content), degradable metal (the stent), static mechanical stress generated onto the stent during crimping and expansion, and dynamic loading from heart beating. These conditions may lead to localized corrosion under stress, namely stress corrosion cracking (SCC) and corrosion fatigue [9]. SCC was observed on Fe35Mn alloy tested under flowing Modified Hank's solution at 37°C, under applied stress and strain of 483 MPa and 9%, respectively, after 2 weeks of degradation test [10]. Therefore, electrochemical or immersion tests cannot be used alone for the in vitro validation of degradation behaviour of proposed alloys for biodegradable stents in real environment. A more comprehensive in vitro degradation test method accommodating flow condition, stress condition (crimping and expansion), short-term (insertion to expansion) and long-term (expansion to complete degradation) periods should be developed.

Conclusions

Starting from materials production, to stent fabrication until stent implantation, some important technical and practical points should be taking into consideration in developing metals for biodegradable stents. Starting from materials, the properties of bulk materials usually differ from those of the final stent materials. During stent fabrication, the established process parameters for manufacturing corrosion resistant stents might not all suitable to process metallic biodegradable stents. Finally, details on stent implantation procedure and events during implantation period should become other inputs in designing the alloys, their mechanical properties and degradation testing protocol.

Acknowledgment

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