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Use of sheet material for rapid prototyping of cardiovascular stents

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Abstract

Manufacturing of cardiovascular stents most commonly involve the use of tubular precursors and laser microcutting of the stent mesh, followed by chemical and electrochemical surface treatments. For mass manufacturing purposes, this production route is well-established, while for small batch or prototype production it proves to be cumbersome. Especially concerning newly developed alloys based, the production of microtubes is time consuming and highly costly. On the other hand, production of these new alloys in sheet metal form is a simpler approach, since the process uses non-dedicated tools and is easier as opposed to extrusion and tube drawing. Accordingly, in this work, the use of sheet material as precursor for rapid prototyping of cardiovascular stents is proposed. In particular, a ns-pulsed fiber laser is used for cutting permanent AISI 316L. Laser microcutting conditions are investigated in terms of generated spatter and kerf geometry. Chemical etching is employed to clean the dross generated around the cut kerf. A novel stent geometry allowing for transforming the sheet material to a tubular form is employed to produce prototype stents.

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Keywords: Cardiovascular stent, laser microcutting, stainless steel, chemical etching.

1. Introduction

Coronary angioplasty with deployment of stent is the most popular non-surgical treatment of cardiovascular diseases, which caused narrowing or occlusion (stenosis) of the affected vessel. Usually, cardiovascular stent is a mesh-like tubular structure used to restore normal blood flow following coronary artery obstruction due to the

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presence of atherosclerosis [1].Stents can be divided in balloon-expandable and self-expanding. According to the type of stent different materials are employed [2]. Stainless steel 316L is the most widely used. For this reason, it is considered as the reference material in terms of mechanical properties. In addition to metals, also polymers are used for stents. Drug eluting stents are also available, which permit a controlled long-term release of drugs inside the body [3]. AISI 316L stainless steel (SS) provides good resistance to corrosion, and excellent mechanical properties but biocompatibility remains limited by the thrombosis issue. However, out of eight coronary stents approved by the US Food and Drug Administration (FDA), seven are made from 316L SS [1]. Stents are cylindrical structures: their structure has been studied over the years in order to guarantee a perfect expansion, a simpler introduction and better mechanical properties. A stent, usually, has 1.5-2.5 mm diameter and 0.05-0.2 mm strut thickness, but the dimension and feature design are very different by a producer to others because everyone search an optimal balance of strength and flexibility. Existing methods of profiling thin tubular metallic materials are based, mainly, on the use of lasers microcutting technologies. Meng et al. analyzed a metallic cardiovascular stent cutting system based on fiber laser with continuous wave and output laser power of 50W [4]. Many authors therefore investigated in recent years various production solutions of cardiovascular stent by laser micro-cutting in order to improve the cutting quality and to realize a medical device more precise and clean [5],[6]. Demir et al. made a comparative study to reveal the importance of gas process on AISI316L microlaser cutting stents [7]. In any case after cutting the stent requires post processing, that mostly means it needs to be cleaned from the dross along the cutting [8]. This operation is usually carried out by chemical etching: the stent is submerged for some seconds or minutes in a slightly aggressive solvent that is able to remove the undesired residues.

An important issue regarding the stent manufacturing is the production of the tubular precursor. The small dimensions and stringent geometrical tolerances required, render this process difficult. Sheet material, on the other hand, is relatively easier to produce and requires non-dedicated tools. At a prototyping stage, minitube production is generates further issues. The use of sheet material as precursor for stent production is an appealing option, however, specific design rules are required. A planar approach in stent production was studied by Takahata and Gianchandani. These stents were realised through a micro-EDM machine and had the problem that sharp edges were present, due to the limitation of the machine wire. These could generate problems during the insertion in human vessels and also decrease mechanical properties after the expansion [8]. The use of such geometry can be much more adequate combined with the conventional manufacturing scheme based on laser microcutting.

In this work a prototype flat permanent stent was realized, starting from an innovative mesh design. Using an industrial ns fiber laser stent microcutting was performed. A chemical etching was used to clean kerf profile. For a preliminary analysis of the concept feasibility, prototype stent was deployed from sheet material to tubular form using a catheter.

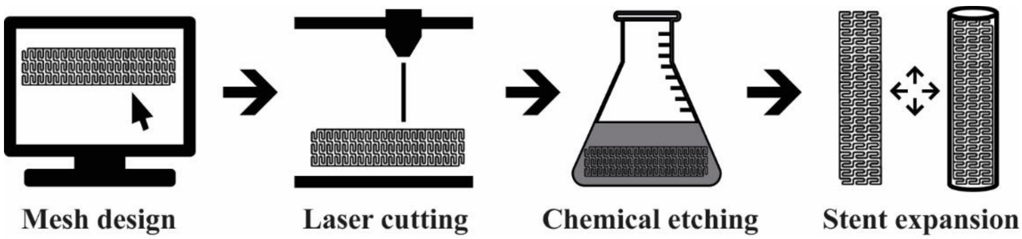

Fig. 1. Diagram of stent production.

2. Experimental

The stent production with a sheet metal follows a similar cycle with the traditional stent manufacturing employing tubular precursor. It consists of mesh design, laser microcutting of the mesh, chemical etching for the complete separation between the material and scrap. Concerning the of sheet material, the changes are related to the mesh design and the fact that it requires a specific mode of deployment (Fig. 1). A specific stent mesh is required to be adapted for flat to tube expansion. The design should allow for the generation of a tubular structure through the