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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.

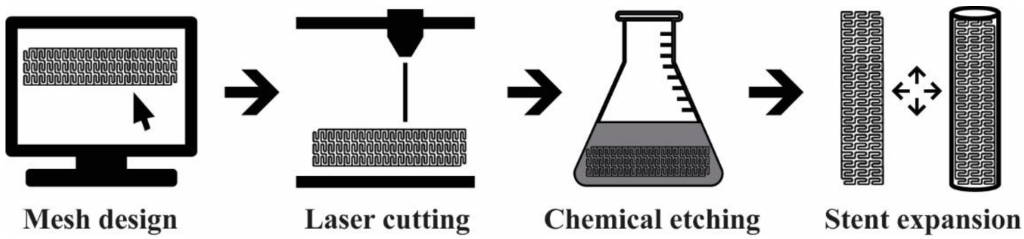

Fig. 1. Diagram of stent production.

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 plastic deformation 2D mesh. For this purpose, the catheter needs to be placed in a certain way through the 2D mesh, as seen in the schematic description in Fig. 2. By the end of the catheter expansion the sheet metal takes tubular form. The following describes the details of the phases demonstrated in Fig. 1.

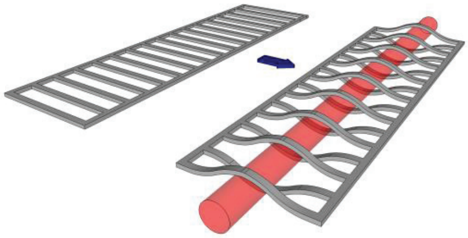

Fig. 2 Scheme of stent expansion.

2.1. Stent design

The use of sheet material for rapid prototyping of stents relies on the mesh design. The stent mesh should be adaptable to flat to tubular expansion as described in Fig. 2. Takahata and Gianchandani [8] proposed a stent design able to deform the sheet metal into a tubular form. The design was optimized for micro EDM, and has been later on applied with and reactive ion etching technique [9]. The mesh design has been adapted to laser microcutting employing basic design for manufacturing rules without aiming to modify the mesh for optimized mechanical properties. Corner radii were increased from 0 μm to 150 μm and horizontal struts were thickened from 50 μm to 100 μm. This particular type of design results in a very small piece, long 11 mm, with the presence of many scrap parts. Destruction cuts were introduced to reduce scrap part size and provide an easier detachment from the stent mesh. The modified mesh design is shown in Fig. 3.

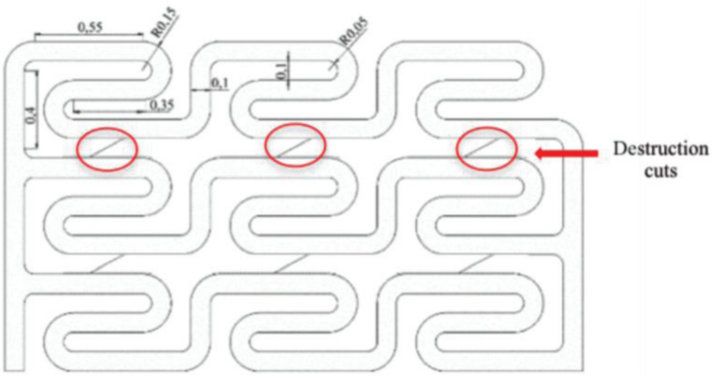

Fig. 3 Detail of the stent design adapted from Takahata et al [8].

2.2. Material

A cold rolled and annealed sheet of AISI316L stainless steel was used for this experimentation. The sheet material used was 0.2 mm in thickness and chemical composition is reported in Table 1.

Table 1 Nominal chemical composition of AISI 316L stainless steel [10].

AISI 316L									
Element	C	Mn	Si	P	S	Mo	Cr	Ni	Fe
wt. %	0.03	2.0	0.75	0.045	0.03	3.0	18.0	14.0	Balance

2.3. Laser microcutting setup

The employed laser source was an IPG YLP-1/100/50/50 Q-switched pulsed active fiber laser. The wavelength is in the range of infrared, i.e. 1064 nm. This source uses an opto-acoustic Q-switch mechanism that generates pulse frequency between 20-80 kHz and pulse durations around 250ns. The main characteristics of the laser source are summarized in Table 2. Downstream the laser source is coupled to a micromachining head, μ Laser Processing Head (LaserMech) with a 60 mm focal lens and 0.5 diameter nozzle for process gas addition. Using this optical configuration a 23 μm waist beam diameter was obtained. For positioning a linear axis with air bearings and spindle both with micrometric precision were used, Aerotech ALS-130, ACS-150 (Fig. 4).

Table 2. IPG YLP-1/100/50/50 laser source characteristics.

IPGYLP-1/100/50/50 Q-switched laser pulse active fibre laser	
Laser wavelength	1064 nm
Minimum pulse duration	100 ns
Pulse repetition rate	20-80 kHz
Maximum average power	50 W
Pulse energy	0.1-1.2 mJ
Beam quality factor (M^2)	1.7
Waist beam diameter	23 μm

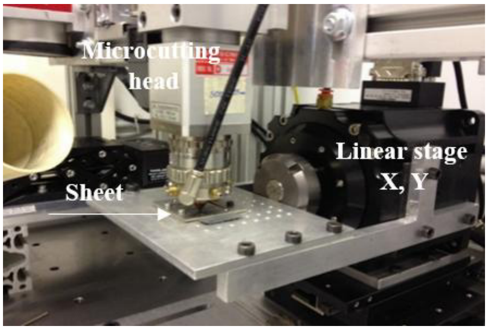

Fig. 4. Laser microcutting setup.

2.4. Production of prototype stents for concept validation

Prototype stents were produced using fixed set of parameters in order to identify the feasibility of the planar stent concept. Laser cutting parameters were adapted from previous work [7]. In particular, laser microcutting was carried out using 11 W average power and 2 mm/s cutting speed. To cut AISI316L, oxygen was used as process gas, providing oxidation enthalpy to the process. The use of inert gas was shown to not produce complete cuts. The surface oxidation, which is the inevitable defect of employing oxygen, could be removed through the consecutive chemical etching. The parameter conditions are listed in Table 3. The prepared prototype stents were then deployed to confirm the feasibility of the approach.

Table 3. Processing conditions for AISI 316L micro-laser cutting.

Processing conditions for AISI 316L micro-laser cutting	
Average power	11 W
Frequency	25 kHz
Cutting speed	2 mm/s
Focal position	0 mm
Process gas type	O_2
Process gas pressure	7 bar

3. Results

The stents were cut properly without trajectory errors on the profile, but with a large amount of dross on the surface. After laser microcutting the scrap parts remained attached to the cut mesh. This is a characteristic behaviour of laser microcutting with ns-pulsed lasers [11], [12]. Further chemical etching is applied for cleaning the kerf and completing separation. After chemical etching AISI316L stent profile was clean and enough free of dross. The solution attacks heat affected and oxidized zones removing dross and cleaning the kerf, showing a good surface quality, as shown in Fig. 5.

AISI 316L in semi-deployed configuration is shown in Fig. 6. The preliminary tests confirm the feasibility of the production route on an established permanent stent material. As can be observed in Fig. 6, the semi-deployed form is not fully circular. Moreover, the two longitudinal beams to which the spiral mesh is attached constitutes sharp edges, which may be harmful during the stent insertion. However, from prototyping view point, the mesh provides information regarding the mechanical stability of the alloy during the deployment phase. The mesh can also be used as a benchmarking form for biological performance evaluation of the new alloys. Instead of employing simple sample geometries, the use of a deployed stent mesh constitutes conditions closer to the final application at in-vitro and in-vivo experiments.

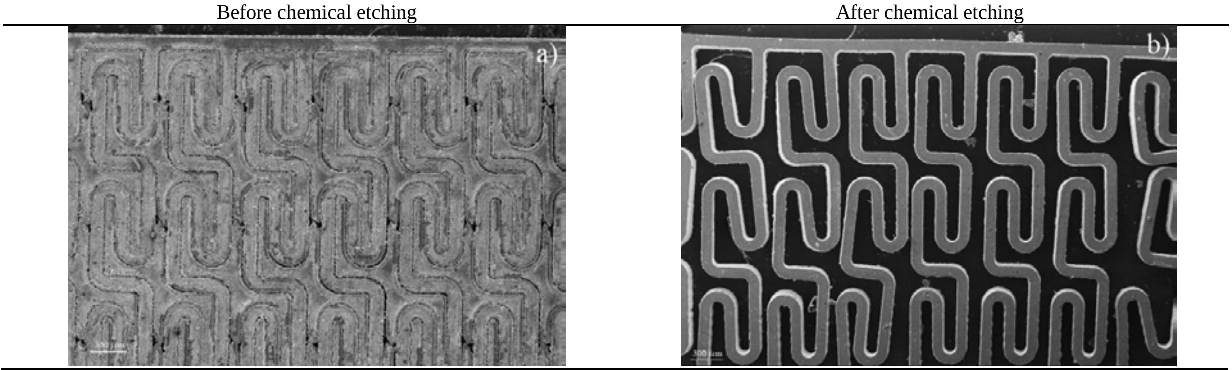

Fig. 5. SEM images of AISI316L planar stents before chemical etching a) and after chemical etching b).

4. Conclusions

This work demonstrates the use of pulsed fiber laser system to cut a new planar mesh on AISI 316L thin sheets, which can be deployed to take tubular form. The work highlights the added value to the sheet metal the through the use of a dedicated mesh design, which renders flat material tubular through expansion. The use of laser microcutting provides high flexibility in the realizable mesh geometries and processable materials. The main results of this work are as follows:

- Laser microcutting with ns-pulsed fiber laser and oxygen as process gas produces the mesh geometry with high fidelity but also with high amount of dross.

- Chemical etching is required after laser microcutting as finishing operation. The solution attacks heat affected and oxidized zones removing dross and cleans the kerf. In the end, surface quality is improved. However, further electrochemical etching is required.
- Prototype stents in AISI 316L were produced with the novel mesh. The planar mesh was deployed to a tubular form, confirming the feasibility of the approach.
- The proposed method can be implemented to prototype stents with novel materials. The current mesh can provide comparative results between different materials in terms of mechanical and biological behavior.
- Mesh optimization, which has not been the main concern of this work, should involve the aspects regarding the stent insertion as well as the mechanical behavior in use.

Fig. 6. AISI 316L stent in semi-deployed configuration.

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