



Full length article

Fibre laser cutting of polycaprolactone sheet for stents manufacturing: A feasibility study

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ABSTRACT

The role of the stent is temporary and it is limited to the intervention and shortly thereafter. Bioresorbable polymer stents were introduced to overcome this problem, making the stent manufacturing process rather difficult considering the complexity of the material. The stent forecast sale makes constant technology development necessary on this field. The adaptation of the laser manufacturing industry to these new materials is costly, thus further studies employing different sorts of lasers are necessary. This paper aims to explore the feasibility of 1.08 μm wavelength fibre laser to cut *polycaprolactone sheet*, which is especially interesting for long-term implantable devices, such as stents. The laser cut samples were analysed by *Differential Scanning Calorimetry (DSC)*, *Tensile Stress Test*, and *Optical Microscopy* in order to study the effects of the laser process over the workpiece. The parameters measured were: taper angle, dimensional precision, material structure changes and mechanical properties changes. Results showed a dimensional precision above 95.75% with a taper angle lower than 0.033°. The laser ablation process has exhibited a minor influence upon material properties. Results exhibit the feasibility of fibre laser to cut *polycaprolactone*, making the fibre laser an alternative to manufacture stents.

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1. Introduction

Nowadays, stents are the main treatment modality for atherosclerosis. The coronary stent global market, primarily balloon-expanded, bare metal, and drug eluting stents (BMS and DES), was approximately \$7.5 billion in 2015 and forecast stent sales will grow at double digit rates as a result of constant innovations, increasing coronary atherosclerotic diseases, and emerging market update [1]. These facts, have made that many authors focus their research in this field, such as [2] whom studied the effect of a femtosecond (150 fs) laser machine on the surface and the characteristics of Nitinol to stent applications, or [3] whom studied the capability of picosecond laser micromachining of Nitinol and platinum-iridium alloy to improve the cut quality. Process parameters used in the process have achieved dross-free cut and minimum extent of Heat Affected Zone (HAZ).

Although metallic stents are effective in preventing acute occlusion and reducing late restenosis after coronary angioplasty, many concerns still remain. Nowadays, the major medical limitations of stents are thrombosis and restenosis [1]. Bioresorbable stents

(BRSs) were introduced to overcome these limitations with important advantages: complete bioresorption, mechanical flexibility, they do not produce imaging artefacts in non-invasive imaging modalities, etc. Several types of materials are currently been investigated: poly-L-lactic acid (PLLA) and magnesium have been the most promising materials [4]. Other polymers suggested as material for bioabsorbable stents include polyglycolic acid (PGA) and polycaprolactone (PCL) [5]. Biodegradable stents offer the potential of improving long-term patency rates by providing support just long enough for the artery to heal, offering the potential to establish a vibrant market. However, designing a biodegradable structure for an intended period of support is rather difficult, considering the complexity of the material, the stent geometries, the manufacturing process, etc.; making the application of biodegradable materials a particularly difficult challenge.

Nowadays the main efforts have been focused on analysing the mechanical and medical considerations of new biodegradable materials. Hideo Tamai et al. [6] evaluated the feasibility, safety, and efficacy of the PLLA stent in humans. Fifteen patients electively underwent PLLA Igaki-Tamai stent implantation for coronary artery stenosis. The results were promising. Unverdorben et al. [7] developed a polyhydroxybutyrate biodegradable stent and carried out preliminary experiments with rabbits. Zilberman et al. [8] focused their studies on the mechanical properties of bioresorbable

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fibres. PLLA, Polydioxanone (PDS) and poly (glycolide-co- ϵ -caprolactone) PGACL were studied in vitro. The three fibres combined a relatively high initial strength and modulus together, with sufficient ductility. Venkatraman et al. [9] reported, for the first time, the development of a fully biodegradable polymeric stent that can self-expand at body temperatures. Niels Grabow et al. [10] designed and produced a biodegradable slotted tube stent for rapid balloon-expansion. Based on PLLA and prolyl 4-hydroxylase (P4HB) polymers, carried out mechanical and degradation experiment. The results showed that the PLLA/P4HB stent allows rapid balloon-expansion and exhibited adequate mechanical scaffolding properties suitable for a broad range of vascular and nonvascular applications. Liang et al. [11] designed a biodegradable shape-memory block co-polymers (PCTBV-25) for fast self-expandable stents. The stent made from PCTBV-25 film showed nearly complete self-expansion at 37 °C within only 25 s. Vieira et al. [12] studied the evolution of mechanical properties during degradation based on experimental data. The decrease of tensile strength followed the same trend as the decrease of molecular weight.

Although the mechanical and medical properties of the material are important, finding the best manufacture process to this kind of material has to be considered as well. Lasers appear to be the perfect tool for this purpose because of non-contact material removal and high precision. Therefore, some authors have been focusing their studies on the laser process of polymers. Grabow et al. [13] studied the effect of CO₂ laser cutting, and sterilization on PLLA. The results showed the dramatic influence of the sterilization procedure on the mechanical properties of the material. In 2008 Tiaw et al. [14] studied the effect of Nd:YAG laser on micro-drilling and micro-cutting of thin PCL films. The melting and tearing of the thin polymer film were not much of an issue for the thin spin-cast film, but a slight extent of melting was observed in the thickest biaxial drawn film. Choudhury and Shirley [15] employed CO₂ laser to cut three polymeric materials and developed a model equation regarding input process parameters with the output. Rocio Ortiz et al. [16] examined the picosecond laser ablation of PLLA as a function of laser fluence and degree of crystallinity. High quality micro-grooves were produced in amorphous PLLA, revealing the potential of the ultra-fast laser processing technique. Luigi et al. [17] modelled the evolution of PLA density under ultra-high pressure/temperature in the region of α relaxation. Azhikannickal et al. [18] characterized the magnitude and distribution of reflected light from thermoplastics as a function of thickness, laser incidence angle, and surface roughness. In 2013 Schneider and Petring [19]

employed a high power laser to cut fibre reinforced thermoplastic polymers with continuous and pulsed wavelength. The result shows that HAZ could be significantly reduced by multi-pass processing at high processing cutting speed. Leone et al. [20] employed a 30 W MOPA Q-switched short pulsed Yb:YAG with multi-passes to cut Carbon Fibre Reinforced Polymeric Composite (CFRP) thin Sheet. Their results pointed out that the main factors to obtain an effective cut were the scanning speed and pulse power. Stepak et al. [21] presented the impact of the KrF excimer laser irradiation above the ablation threshold on physicochemical properties of biodegradable PLLA. They concluded that usage of the 248 nm wavelength resulted in simultaneous ablation at the surface and photo degradation within the entire irradiated volume due to high penetration depth. Stepak et al. [5] fabricated a polymer-based biodegradable stent using a CO₂ laser. Tamrin et al. [22] determined an optimized set of cutting parameters for CO₂ laser for three different thermoplastics employing grey relational analysis. Genna et al. [23] assessed a simple procedure to determine the rates of absorbed, reflected, transmitted and scattered energy in the case of an unfilled High Density Polyethylene (HDPE) plate. Their results showed that about 47% of power was lost employing a 975 nm laser.

Although the effect of laser process over different polymers has been studied, nowadays, further studies about the laser cutting process of biodegradable materials are would be helpful to expand the laser stents manufacturing possibilities. The semi-transparent behaviour of most organic polymers at high wavelengths, hinders their manufacturing process with some sort of lasers, making the adaptation of this industry to these new materials costly. The use of fibre laser with high wavelength, short pulse laser with Galvano-mirror [20], among other, could open an interesting research line in the stent manufacturing field. This work shows experimental and parametrically the feasibility of 1.08 μ m wavelength fibre laser to cut *polycaprolactone*. The effects of peak pulse power, cutting speed, and number of passes upon dimensional and material properties is presented.

2. Material and methods

2.1. Cutting system

Experiments were carried out with a CNC Machine *KONDIA*. The laser employed was a *Fibre Laser RoFin FL x50s* that is able to provides a 1.08 μ m wavelength, a pulse width from 26 μ s to continu-

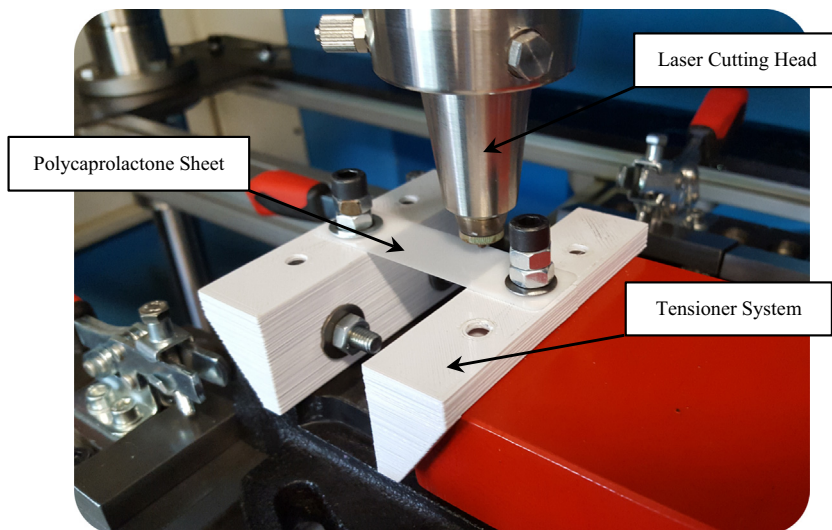


Fig. 1. Cutting system.

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