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A novel 3D additive manufacturing machine to biodegradable stents

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Abstract

Biodegradable stents offer the potential to improve long-term patency rates by providing support just long enough for the artery to heal. However, design a biodegradable structure for an intended period of support is rather difficult. Nowadays in the stent industry the manufacture process par excellence is the laser micro cutting. Nevertheless in the case of polymeric stents, the 3D additive manufacturing techniques could be a more economical solution.

This work aim to design and implement a novel 3D Additive Manufacturing Machine to Biodegradable Stent Manufacture. The effects of nozzle temperature, fluid flow, and printing speed over the polycaprolactone stent's precision is studied. Results have shown the strong influence of temperature and flow rate over the printing precision. Printing speed did not had a clear tendency. The results allow us to believe that the novel technology presented in this paper will be an interesting future research line.

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Keywords: Additive Manufacturing, Cylindrical, 3D Printing, Biodegradable Stent, Polymer

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1. Introduction

Although metallic stents are effective in preventing acute occlusion and reducing late restenosis after coronary angioplasty, many concern still remain. The role of stenting is temporary and is limited to the intervention and shortly thereafter, until healing and re-endothelialization are obtained. Bioresorbable stents (BRS) were introduced to overcome these limitations with important advantages: complete bioresorption, mechanical flexibility, does not produce imaging artefacts in non-invasive imaging modalities, etc. [1]

Biodegradable stents offer the potential to improve long-term patency rates by providing support just long enough for the artery to heal, offering the potential to establish a vibrant market. However, design a biodegradable structure for an intended period of support is rather difficult. Nowadays in the stent industry the manufacture process par

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excellence is the laser micro cutting. Nevertheless in the case of polymeric stents, the 3D additive manufacturing techniques could be a more economical solution [2].

Recently, three-dimensional (3D) printing, a specific technique in the biomedical field, has emerged as an alternative system for producing biomaterials. The 3D printing system, applied to rapid prototyping in structural fabrication can easily manufacture biomaterials, such as BRS, better than other devices. Additionally, 3D-printing offers a more efficient process for assembling all of the necessary components, such as the vascular artificial scaffold. For the past decade, biomedical stents have received much attention for their prevention of coronary thrombosis. Conventionally used BMS, such as stainless steel and titanium, can cause after effects, as they remain in situ even after vascular repair. Thus, there is a need for residue-free alternatives [2].

Some authors have been focused their research in the field of stent manufacture. Stepak et al. [3] presented the impact of the KrF excimer laser irradiation above the ablation threshold on physicochemical properties of biodegradable PLLA. It could be 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. [4] fabricated a polymer-based biodegradable stent using a CO2 laser.

Nevertheless, with the best author’s knowledge, the use of cylindrical 3D printing for stent purpose have been never reported before. This work aim to design and implement a novel 3D Additive Manufacturing Machine to Biodegradable Stent Manufacture. The effects of nozzle temperature, fluid flow, and printing speed over the stent's precision is studied and compared with the laser cutting technology.

2. Material and method

2.1. 3D Printer machine

The 3D Additive Manufacturing Machine developed is based in the Fused Filament Fabrication (FFF) and the 3-axis 3D printing technologies. The filament is melted into the extruder nozzle, which deposited the material onto a heated computer-controlled rotatory Cartesian platform (Fig. 1). The machine developed is based in the Fused Filament Fabrication (FFF) method and the 3-axis 3D printing technology. The filament is melted into the extruder nozzle, which deposited the material onto a computer-controlled rotatory platform. The machine provides a precision of 0.9375 µm in the X axis, 0.028125º in the W axis, 0.3125 in the Z axis, and 0.028125º in the extruder. The nozzle provides 0.4 mm of diameter.

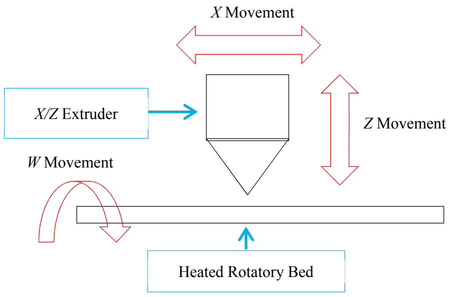

Fig. 1. 3D Machine methodology.

2.2. Material and geometry

Polycaprolactone (PCL) Capa 6500® supplied by Perstorp was used as material. PCL is a biodegradable polyester with a low melting point (60ºC) and a glass transition of -60ºC. PCL degradation is produced by hydrolysis of its ester linkages in physiological conditions and has therefore received a great deal of attention for using it as an implantable biomaterial, such stents, because of their properties (Table 1).

Table 1. Polycaprolactone (PCL) Capa 6500 properties.

Molecular Weight	Young Modulus	Strain at Break	Degradation Time
50000 g/mol	470 MPa	700 %	> 24 Months

The stent model used for the experiments was a diamond-cells stent. The stent parameters were the following: inner diameter ($I_ø$), stent thickness (S_T), number of circumferential cells (N_C), width and length of the cell (W_C, L_C), strut width (S_W) (Fig. 2). These parameters determine the behavior of the stent, the correct adjustment of them is crucial for calibrating the stent to the particular needs of each patient.

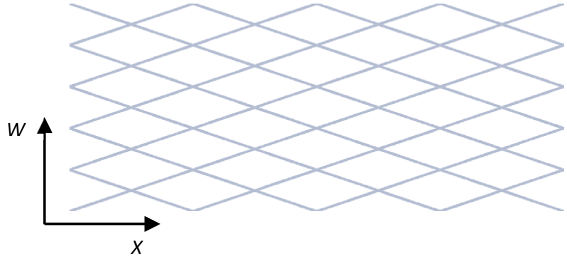

Fig. 2. Experiment geometry.

2.3. Design of experiment

Screening experiment were carried out to find the correct process parameters level to achieve a complete stents. The process parameter studied were; of nozzle temperature (NT^a: 80/250ºC), fluid flow rate (FR%: 75/200%), printing speed (PS: 200/1440 mm/min). Based on the screening results we selected the experiment parameters (Table 2).

Table 2.Design of experiments.

Parameter	Low Level	High Level
Printer Speed (mm/min)	480	880
Printer Temperature (ºC)	200	250
Fluid Flow Rate (%)	100	200

2.4. Characterization

Dimensional features (S_T, W_C, L_C, and S_W) of each of the 60 samples were analyzed by the Optical Microscope Nikon SMZ – 745T attached to a digital camera CT3 ProgRes. Image J® was used to process the images and collect the data. Micrometer Micromar 40EWV was used to measure S_T.

3. Results and discussion

The results have shown the strong influence of flow rate and temperature over the strut width while speed did not had a clear tendency. Temperature results have showed the influence over the dimensional features. At highest temperatures, the viscosity decreases according to the equation below [5]:

$$\mu(T) = \mu_0 \exp(-bT) \quad (1)$$

Where T is the temperature and μ_o and b are coefficients. That fact makes that PCL flow better by the nozzle which originates a mayor strut width (Fig. 3a).

The effect of the speed did not show a clear tendency (Fig. 3b). It seems that the combinations of speed-flow (Fig. 4a) or speed-temperature (Fig. 4b) are influential. The printing speed affect over the material accumulations and the axis micro-vibrations. At higher speeds the filament flows faster through the nozzle, acquiring more inertia and reducing the filament torsion when it is deposited on the bed of the printer. The increase of printing speed also derives in a reduction of PCLs cooling rate, the heated nozzle leaves faster the printer-off point and heat can be dissipated more effectively. This fact will change the material properties.

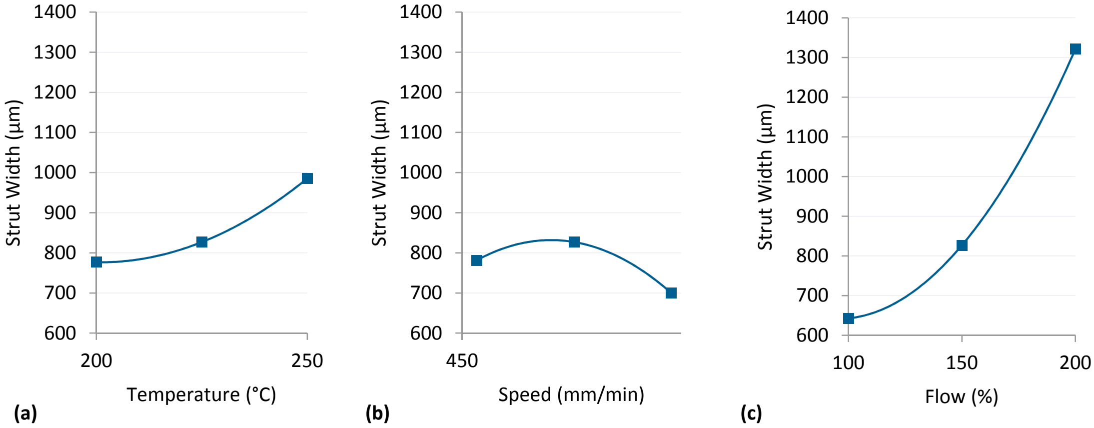

Fig. 3. Main effect plot for strut width (a) Temperature effects; (b) Printer speed effects; (c) Fluid flow rate effects.

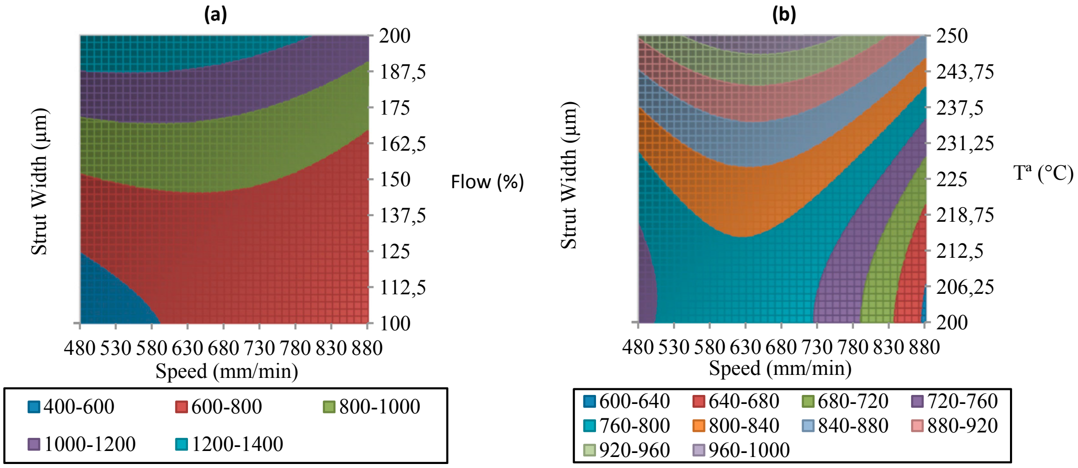

Fig. 4. Surface plots (a) Printer speed vs fluid flow rate; (b) Printer speed vs printer Tª.

Regards to the flow rate, has shown a growth nearly linear behavior of the strut width according to it increases. It is observed that the stents printed with highest flow rates had a top flat face (Fig. 5). This fact is due to an excessive stream of material thus squashing the filament as the nozzle is moving, increasing its diameter (Fig. 3c).

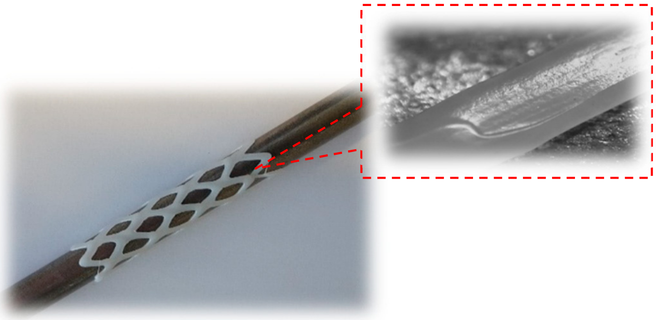

Fig. 5. Effect of the over fluid flow rate over the stent's top face.

Furthermore, the area results have been corroborated the previous results. As is to be expected, when the filament diameter increases the area gets smaller (Fig. 6 and Fig. 7).

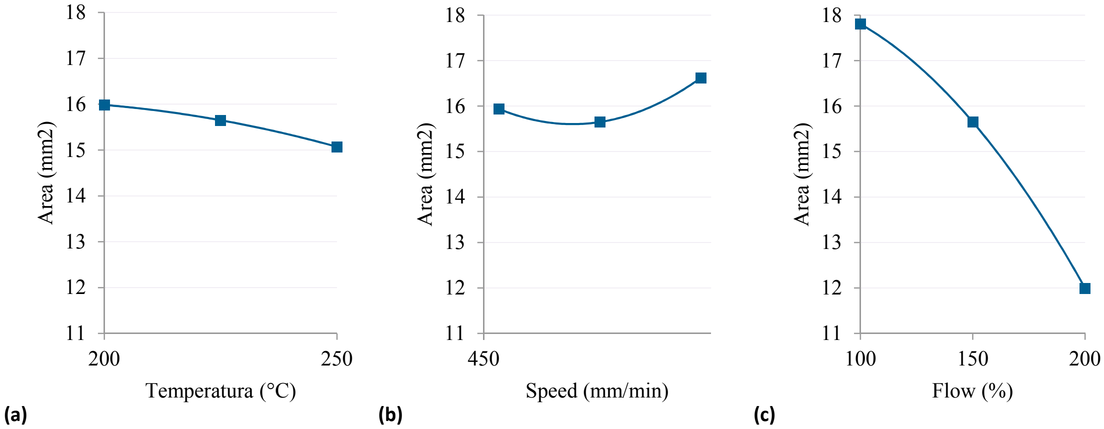

Fig. 6. Main effect plot for area (a) Printer Tª effects; (b) Printer speed effects; (c) Fluid flow rate effects.

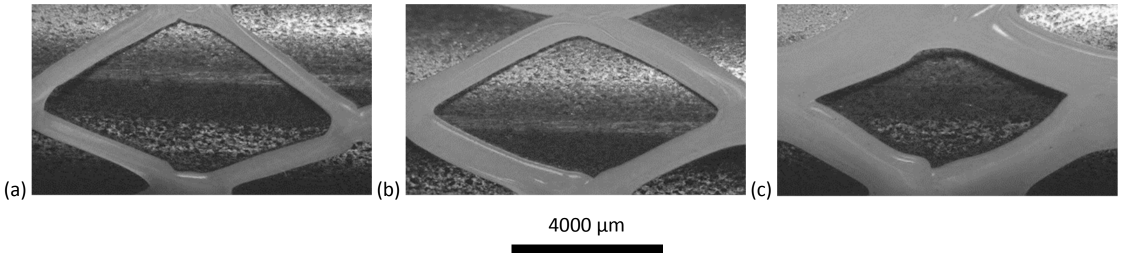

Fig. 7. Optical images of printer samples (a) 100 % Fluid flow rate; (b) 150% Fluid flow rate; (c) 200 % Fluid flow rate.

4. Conclusion

This work has demonstrated the feasibility of cylindrical 3D printing technology to the polymer stent manufacture. The effect of temperature, printing speed, and polymer flow rate have been reported. The strong influence of temperature and flow rate over the printing precision has been shown. The potential of cylindrical 3D printing on the micro medical devices manufacture, such as stents, have been introduced. Further studies about the effect of other printing parameters, materials, etc., would be interesting. The results allow us to believe that the novel technology presented in this paper will be an interesting future research line.

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