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Mini Review

3D Printed Polymeric Composite Stent for Cardiovascular Application

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Abstract:

Biodegradable stents (BRS) offer enormous potential but first they must meet five specific requirements: (i) their manufacturing process must be precise; (ii) degradation should have minimal toxicity; (iii) the rate of degradation should match the recovery rate of vascular tissue; (iv) ideally, they should induce rapid endothelialization to restore the functions of vascular tissue, but at the same time reduce the risk of restenosis; and (v) their mechanical behavior should comply with medical requirements, namely, the flexibility required to facilitate placement but also sufficient radial rigidity to support the vessel. Although the first three requirements have been comprehensively studied, the last two have been overlooked. One possible way of addressing these issues would be to fabricate composite stents using materials that have different mechanical, biological, or medical properties, for instance, Polylactide Acid (PLA) or Polycaprolactone (PCL). However, fashioning such stents using the traditional stent manufacturing process known as laser cutting would be impossible.

Keywords: cardiovascular diseases

Introduction

Biodegradable stents (BRS) offer enormous potential but first they must meet five specific requirements: (i) their manufacturing process must be precise; (ii) degradation should have minimal toxicity; (iii) the rate of degradation should match the recovery rate of vascular tissue; (iv) ideally, they should induce rapid endothelialization to restore the functions of vascular tissue, but at the same time reduce the risk of restenosis; and (v) their mechanical behavior should comply with medical requirements, namely, the flexibility required to facilitate placement but also sufficient radial rigidity to support the vessel. Although the first three requirements have been comprehensively studied, the last two have been overlooked. One possible way of addressing these issues would be to fabricate composite stents using materials that have different mechanical, biological, or medical properties, for instance, Polylactide Acid (PLA) or Polycaprolactone (PCL). However, fashioning such stents using the traditional stent manufacturing process known as laser cutting would be impossible.

It is therefore, aims to produce PCL/PLA composite stents using a novel 3D tubular printer based on Fused Deposition Modelling (FDM). The cell geometry (shape and area) and the materials (PCL and PLA) of the stents were analyzed and correlated with 3T3 cell proliferation, degradation rates, dynamic mechanical and radial expansion tests to determine the best

parameters for a stent that will satisfy the five strict BRS requirements. Results proved that the 3D-printing process was highly suitable for producing composite stents (approximately 85–95% accuracy). Both PCL and PLA demonstrated their biocompatibility with PCL stents presenting an average cell proliferation of 12.46% and PLA 8.28% after only 3 days. Furthermore, the PCL/PLA composite stents demonstrated their potential in degradation, dynamic mechanical and expansion tests. Moreover, and regardless of the order of the layers, the composite stents showed (virtually) medium levels of degradation rates and mechanical modulus. Radially, they exhibited the virtues of PCL in the expansion step (elasticity) and those of PLA in the recoil step (rigidity). Results have clearly demonstrated that composite PCL/PLA stents are a highly promising solution to fulfilling the rigorous BRS requirements.

Biodegradable stents (BRS) were introduced to overcome the limitations of permanent stents and to offer significant advantages such as, among others, complete bioresorption and/or mechanical flexibility. [1]. BRS have the potential to improve long-term patency rates by providing support just long enough for the artery to heal. Ideally, BRS should meet some exacting requirements. A large number of authors have contributed to BRS research in recent years. For instance, in terms of manufacturing processes laser cutting and, more recently, additive manufacturing technologies have been at the center of many studies. Guerra et al. [2] studied the effects laser cutting has on the degradation rate of Polycaprolactone (PCL) stent subunits under dynamic and static conditions.

Although their results showed that laser cutting has a negligible effect on degradation, the degradation conditions showed that PCL degrades faster in body conditions (dynamics) than the data found in traditional literature had reported (statics). Meanwhile, Grabow et al. [3] studied the effects CO2 laser cutting and sterilization have on Poly-L-Lactide (PLLA). Their results revealed the enormous influence sterilization has on the mechanical properties of PLLA (i.e., 40% crystalline modification).

Using additive manufacturing, Park et al. [4] produced drug-coated BRS with Fused Deposition Modelling (FDM) and had very promising results in animals (20.7% restenosis). Guerra et al. [5,6] designed and implemented a novel 3D tubular printer that allows the rapid manufacture of BRS based on polymers. Their results suggest that this technology could be the future of BRS manufacturing as they managed to achieve up to 85% precision and manufacturing times under 5 min.

In terms of the abovementioned second (degradation should have minimal toxicity), third (the rate of degradation should match the recovery rate of vascular tissue), and fifth (mechanical behavior should meet medical stipulations) requirements, some authors have focused their studies on potentially suitable materials for producing BRS [7,8]. Hideo Tamai et al. [9] evaluated the feasibility, safety, and efficacy of PLLA stents in humans for coronary artery stenosis with promising results. Shen et al. [10]
studied the degradation of L-Lactide (LA) and 5-methyl-5-benzyloxycarbonate-1,3-dioxan-2-one (MBC) coated stents and cast films. Their results showed similar degradation behavior of the coating materials in in vivo conditions and negligible differences in extensive endothelialization or the expression of inflammation-associated proteins after 4 weeks post-stent implantation.

However, there are fewer studies that consider the fourth requirement (BRS should induce rapid endothelialization to restore the functions of vascular tissue but, at the same time, reduce the risk of restenosis). Wang et al. [11] studied the cell adhesion of Human Umbilical Vein Endothelial Cells (HUVEC) on a stent coated with poly-L-lysine and fibronectin. Their work revealed that the metallic-coated stent significantly increased cell adhesion. Meanwhile, Xu et al. [12] developed strategies for improving stent endothelialization by employing a new polymer poly-1,8-octanediol-co-citric acid (POC), anti-CD34 antibody and a vascular endothelial growth factor.

Their method significantly improved the proliferation of endothelial progenitor cells (EPC) when
compared with PLLA stents. In 2015, Lutter et al. [13] studied the influence the microstructure of a stent's surface has on endothelialization and thrombogenicity using HUVEC and their results demonstrated that, compared to a smooth surface stent, flat cubic elevation improved endothelial cell adhesion. Additionally, Jiang et al. [14] analyzed four polymer coatings for controlling the degradation and HUVEC cell adhesion of Mg stents. Employing PLLA, poly-lactic-co-glycolic-acid (PLGA) (90:10), PLGA (50:50), and PCL, they evaluated surface and biological properties. Their results showed that PLGA (50:50) is a promising coating material for Mg stents. Finally, He et al. [15] studied how to design nanofiber mesh which would allow the attachment and phenotypic maintenance of human coronary artery endothelial cells. Similar work was carried out by Rubert M. et al. [16], who analyzed coaxial electrospun with PCL materials and added poly(ethylene oxide) (PEO) fibers containing basic fibroblast growth factor. The work also focused on fibroblast proliferation by combining cell culture and proliferation with additive manufacturing technologies.

However, many challenges still exist, such as evaluating and understanding the mechanical and biological properties of polymeric BRS. Previous work carried out by our groups [17] has proved that composite stents satisfy some of the requisites. However, composite stents cannot be created
easily with conventional laser cutting manufacturing processes [18]. Alternative manufacturing technologies, such as 3D-printing, need to be used. This work aims to develop PCL/PLA (Polylactide Acid) composite stents by employing 3D-printing based on FDM. Both the parameters of the stent, namely, its cell geometry (shape and area) and the materials (PCL and PLA), were analyzed. Stents were subjected to 3T3 cell proliferation, degradation, dynamic mechanical, and radial expansion tests to determine which parameters would best comply with the stringent BRS requirements.

This work presents a proof of concept for the viability of using composites stents in the treatment of cardiovascular disease. This is the first work to develop and present composite PCL/PLA stents using a 3D-printing process based on FDM. The effects the cell geometry (shape and area) and materials (PCL and PLA) exert were also analyzed. Samples were subjected to 3T3 cell proliferation, degradation, dynamic mechanical and radial expansion tests to determine the parameters that best meet the rigorous requirements for BRS.

The results have demonstrated the considerable influence the cell area and material of a stent have on 3T3 proliferation. That said, the cell shape of the stent did not show any significant influence at all. Our initial hypothesis was confirmed, i.e., the smaller the cell area of a stent, the better the cell proliferation rate. Meanwhile, as

a result of their different molecular weights, PCL demonstrated better cell proliferation than PLA.

The degradation rate results revealed the limitations of PLA for BRS purposes as a consequence

of its fast degradation rate, whereas PCL showed a better degradation rate. The composite PCL/PLA stents showed an almost medium degradation for all the layer configurations which was mainly due to PLA degradation. The faster PLA degradation rate would eventually leave a BRS made only of PCL. The differences in their degradation rates are produced by their different molecular weights, so employing PCL and PLA with similar molecular weights is a must to obtain a homogenous degradation of all the layers.

PCL showed a very low E' modulus in the dynamic mechanical results which, in turn, hinders

its sole applicability for stent purposes. On the other hand, PLA showed a high E' modulus and

good properties for supporting the artery vessel once in place but its properties hinder its placement.

Conversely, composite stents showed a middle E' modulus regardless of the order the layers were made up of. Finally, the radial behavior results have proved that composite PCL/PLA stents could be used to improve each material's separate limitations. For instance, PCL stents presented overly high recoil ratios but excellent expansion behavior, whereas PLA stents presented inadequate radial expansion, due to their rigidity, but excellent recoil ratio. Composite stents, either with PCL or PLA as the inner layer, demonstrated the virtues of PCL stents (i.e., their radial expansion) and PLA stents (i.e., their recoil ratio) that could be combined to provide a good solution for BRS. Furthermore, their good radial behavior (regardless of the order of the layers) makes composite stents a promising concept for cardiovascular problems. Based on the results presented here, we believe that polymer composite stents manufactured

with 3D-printing processes could be a highly effective solution to the current problems that stents made of polymers have. However, FDA rules currently limit the use of 3D-printed stents in real clinical applications and, although PCL and PLA are FDA-approved materials, there are still open challenges to be met before approval for 3D-printed implantable medical devices can be obtained This manuscript has presented a potential approach for future applications for stents.

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