INFLUENCE OF CRIMPING PROCESS ON RADIAL STRENGTH OF VASCULAR STENT MADE OF VARIOUS BIORESORBABLE POLYMERS

Michał Sobota*, Mateusz Stojko, Jakub Włodarczyk, Katarzyna Jelonek, Joanna Jaworska, Monika Musiał-Kulik, Małgorzata Pastusiak, Piotr Dobrzyński, Janusz Kasperczyk

Centre of Polymer and Carbon Materials PAS, Zabrze, Poland
*e-mail: msobota@cmpw-pan.edu.pl

[Engineering of Biomaterials 163 (2021) 39]

Introduction

The World Health Organization estimated 17.9 million people died from Cardiovascular diseases in 2019, which is 32% of all deaths worldwide [1]. The scale of this problem affects the development of new technology in medicine cardiovascular area. Bioresorbable Scaffolds (BRS) are a promising medical tool for revascularization of a occlusive coronary artery disease. Basically, BRS are a scaffold for healing vassel which helps restoring vasomotive function and leaving no implant behind [2,3]. This advantage in comparison to metal vassculary stent is a driving force for developing bioresorbable stent technologies. Comperes metal and polymers stent production, the many differences could be found. Herein, we focused on crimping process of bioresorbable Poly(L-lactide)'s copolymers stent, on catheter which causes the significant change in radial strength whereas metal stent does not exhibit such phenomena [4].

Materials and Methods

The stents of Poly(L-lactide)'s (PLLA) copolymers and blends were manufactured using Micropowder 15 micro injection machine, made by Battenfeld. The radial force of stents was determined using radial force machine manufactured by Blockwise model RTU 124.

Results and Discussion

It was observed that final radial strength of opened biodegradable stent was lower after process of crimping on a balloon catheter. The changes in the value of radial strength were depended on Poly(L-lactide) contant in material and temperature of crimping. The observed changes are most likely due to the shape of the stent in which the bending point of the elbows enabling the stent to be packed to a diameter of 1.1 mm from 3mm or even 3.5mm diameter. During this process, deformation of the elbows(strut) undergoes more than 100%. As a result of such a deformation, the material may lose phase continuity which causes a decrease of material strength in span. In addition, PLLA is known for its high crystallization ability, which can affect the brittleness of the material during deformation. Therefore, stents made of materials with increased PLLA content lose the most radial strength after the crimping process.

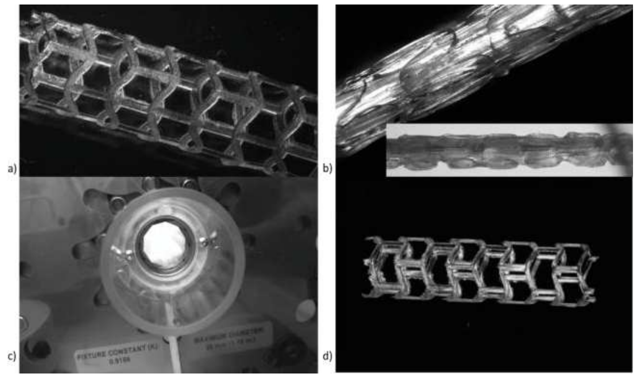

FIG. 1. Stent: a) before crimping process, b) crimped on balloon catheters, ready to implantation, c) crimper, d) opened after crimping (bright area-material tension)

Conclusions

The observed changes can be minimized by optimizing the shape of the stent, reducing the level of local deformation, in addition, it is important to adjust the material composition avoiding excessive amount of component with high crystallization tendency.

Acknowledgments

The research was carried out as part of project of The National Centre for Research and Development No. POIR.04.01.02-00-0105/17-00 “The technology for developing and obtaining the next generation of vascular stents through microinjection".

References

[1] http://www.who.int/mediacentre/factsheets/fs317/en/

[2] Kereiakes DJ, Onuma Y, Serruys PW, Stone GW. Bioresorbable Vascular Scaffolds for Coronary Revascularization. Circulation 2016;134:168-82.

[3] Ali ZA, Gao R, Kimura T, et al. Three-Year Outcomes With the Absorb Bioresorbable Scaffold: Individual-Patient-Data Meta-Analysis From the ABSORB Randomized Trials. Circulation 2018;137:464-79.

[4] B. Feng GJ, M. Rui, Y. Chunjie. Polylactic acid: synthesis, properties, and applications. Encyclopedia of Biomedical Polymers and Polymeric Biomaterials: Taylor & Francis; 2015.