A COMPARATIVE STUDY OF THE MECHANICAL PERFORMANCE OF NITI AND BIORESORBABLE PLLA BRAIDED STENTS

Agnese Lucchetti (1), Ted J. Vaughan (2), Thomas Gries (1)

1. Institut für Textiltechnik, RWTH Aachen University, Aachen, Germany; 2. Biomechanics Research Centre (BMEC), School of Engineering, National University of Ireland Galway, Ireland

Introduction

Despite advances in stent development over the past decades, issues such as thrombosis, in-stent restenosis and vessel remodeling impairment are still associated with permanent metallic stents [1]. Bioresorbable scaffolds (BRSs) have the potential to overcome these drawbacks, staying in the patient just for the time needed. Braiding is a well-established technology in the stent manufacturing and brings advantages especially in terms of a superior device flexibility and a major conformability to the anatomic shape of the lesion [2]. In this study, a comparison of the performance of a Nitinol (NiTi) and bioresorbable Poly-L-Lactic Acid (PLLA) braided stents was carried out by means of *in vitro* bench testing with the aim to have a clear understanding of how the performance of the polymeric devices differ from the one of their metallic counterpart.

Materials and Methods

The PLLA stents were manufactured in-house using a Steeger Braiding Machine (Körting Nachfolger Wilhelm Steeger GmbH & Co., Wuppertal, Germany). Firstly, five devices resembling the same geometrical features of the NiTi stent characterized by McKenna et al. [3] were produced. More specifically, the stents were composed of 24 monofilaments with a 100-µm diameter (ϑ), braided in a 1:1-1 pattern (labeled as PLLA/100/24). The diameter and the length of the stents were 5 mm and 20 mm, respectively. Then, two others configurations were manufactured using a 150-µm filament (PLLA/150/24) and increasing the wire count to 48 (PLLA/100/48). The braiding angle (α), defined as the angle formed by the filament with the longitudinal axis of the stent, was set at 45°, 60° and 70°. For the 150-µm filament stent, the highest braiding angle was not producible due to process limitations. The proper heat set conditions to fix the structure were found to be 140 °C and 10 min. The stents were characterized by means of a radial force test, performed according to DIN EN ISO standard 25539-2-2012. More specifically, all the stents were tested at a constant temperature of 37 °C and crimped to 50% of their initial diameter.

Results

Figure 1 shows that the radial behavior of the stents with lower braiding angle is far from the one of the NiTi stent. However, the gap is narrowed for an increased braid angle, a bigger filament diameter and a higher number of wires. As reported in Table 1, the PLLA stents show for three configurations higher values of initial radial stiffness (RS), radial resistive force (RRF) and chronic outward force (COF) in comparison with the NiTi device.

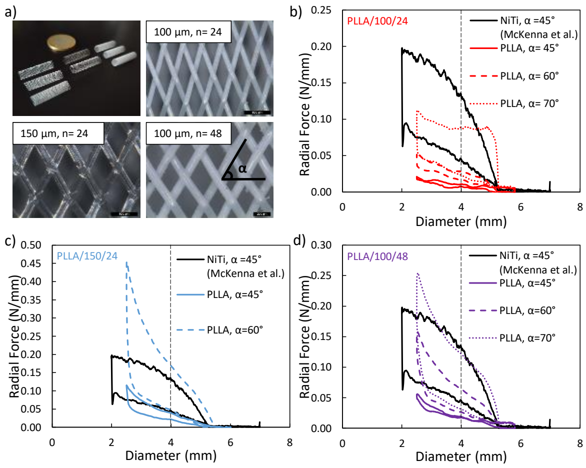

Figure 1: (a) Example of manufactured stents and detail of the braiding patterns. Comparison of NiTi and PLLA performance from the radial test for an increasing braiding angle: (b) PLLA/100/24; (c) PLLA/150/24; (d) PLLA/100/48.

Stent	RS (N/mm^2)	RRF (N/mm)	COF (N/mm)
NiTi	0.12	0.13	0.044
PLLA/100/24/70	0.55	0.09	0.024
PLLA/150/24/60	0.14	0.17	0.047
PLLA/100/48/70	0.14	0.12	0.031

Table 1: Radial stiffness (RS), radial resistive force (RRF) and chronic outward force (COF) of the three most meaningful PLLA cases in comparison to NiTi.

Discussion

This study showed that the mechanical performance of PLLA braided devices subdued to a radial load is in a similar range to the one of the NiTi stent for specific braided configurations. Further mechanical testing (i.e. tensile test and bending test) will be carried out with the aim of gaining a comprehensive insight into polymeric braided stents deformation modes. The ultimate aim is the *ad hoc* optimization of the device (e.g. by finding the right combination of braiding parameters and pattern) to further bridge the gap between permanent and bioresorbable devices.

References

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Acknowledgements

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 813869. This publication reflects only the author's view and the REA is not responsible for any use that may be made of the information it contains. The authors would like also to thank Boston Scientific Ltd., Co. Galway, Ireland for their support and collaboration on this work.