A COMPREHENSIVE STUDY OF THE ACCELERATED AND REAL-TIME DEGRADATION BEHAVIOUR OF BIORESORBABLE BRAIDED STENTS

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Introduction

Poly-L-lactic acid (PLLA) is a polymer commonly employed for the manufacturing of bioresorbable stents since it offers a good balance between favourable mechanical properties and degradation time [1]. While different studies have characterized the behaviour of PLLA wire-braided stents prior degradation [2], the long-term properties have been poorly characterized, with a limited number of studies available. Most studies investigated the degradation behaviour of PLLA laser-cut stents in accelerated conditions [3,4] based on the hypothesis that there is a 4-fold factor between real-time and accelerated conditions [5]. However, this hypothesis has never been proved for PLLA wires and wire-braided stents.

This study aims at giving a comprehensive description of the degradation properties (physical, thermal and mechanical) of bioresorbable PLLA wires and wire-braided stents. The investigation has been performed in both accelerated and real-time degradation conditions to compare the former methodology with realistic degradation times.

Methods

PLLA wires and in-house manufactured stents were degraded according to the ISO 13781. Samples were put in phosphate-buffered solution (PBS) and placed in the oven at T=37°C (real-time degradation, RD) and T=50°C (accelerated degradation, AD) for a total of 272 days and 114 days, respectively. At each observation point (Table 1), samples were removed from the oven and assessed in their physical, thermal and mechanical properties. Molecular weight, thermal properties and material spectra were evaluated with gel permeation chromatography (GPC), differential scanning calorimetry (DSC), Fourier-transform infrared spectroscopy (FTIR), respectively. Young's modulus, tensile strength and ultimate strain were extracted from tensile tests on single wires, whereas radial force curves were obtained from crimping tests on stents. Optical microscopy and scanning electron microscopy (SEM) allowed for visual characterization at different time points. The outcomes from the two protocols (RD, AD) were compared to obtain the relation between the two conditions.

Results

The PLLA molecular weight sharply decreased between 36 and 50 days in AD while it showed a constant decrease in RD (Figure 1a). The mechanical properties of PLLA wires kept constant until day 50, then a sharp decrease was found until the wires were no more testable (day 114). In RD the wires showed constant mechanical properties as in AD until day 272 (Figure 1b). The visual inspection revealed a change in the colour of the stent upon degradation, turning from white to transparent (Figure 1c).

T [°C]	Timepoint [days]
37	0, 13, 30, 44, 75, 105, 121, 154, 183, 212, 232, 272
50	0, 1, 3, 6, 13, 21, 36, 50, 74, 90, 114

Table 1: Overview of observation timepoints

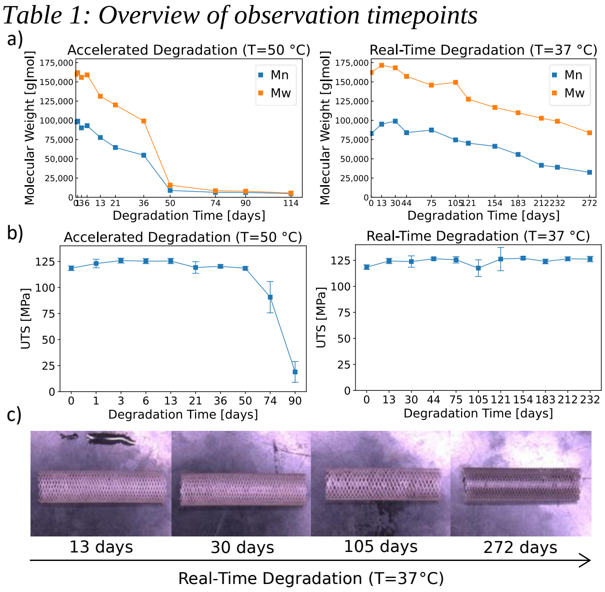

Figure 1: a) Molecular weight; b) PLLA wires ultimate tensile strength (UTS); c) PLLA stents microscopy.

Discussion

This study provides a comprehensive investigation on the physical, thermal and mechanical behaviour of new PLLA wire-braided stents under two different degradation conditions that was never presented before. From the results it arises that an at least 6-fold factor should be introduced when performing accelerated degradation to match the properties obtained at realistic conditions (T=37°C), differently to what has been suggested in literature for PLLA dogbones.

References

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