PILOT STUDIES OF BIODEGRADABLE IRON-BASED 3D SYSTEMS – FOR THE NEEDS OF MODERN CARDIOLOGY

ALEKSANDRA RADTKE*, JONASZ SZCZEPAŃSKI, PIOTR PISZCZEK

FACULTY OF CHEMISTRY, NICOLAUS COPERNICUS UNIVERSITY IN TORUŃ, POLAND
*E-MAIL: ARADTKE@UMK.PL

[ENGINEERING OF BIOMATERIALS 158 (2020) 26]

Introduction

The current stent technology is based on the use of permanent stent made from 316L stainless steel, nitinol and cobalt-chromium alloy, which are corrosion-resistant systems [1]. The implantation of bare metal stents has shown tremendous superior effects in various kinds of clinical situations, especially in the field of percutaneous coronary intervention, however they have specific properties, which limit their more widespread use. Since the major effect of stent implantation is provided by its scaffolding effect, it is required to last 6-12 months during which arterial remodeling and healing is achieved. After this period, the presence of stents within the body cannot provide any beneficial effects [2]. Thus the development of biodegradable stents, which can fulfill the mission and step away, is the logical approach. A near two decades long investigations into bioabsorbable stent materials have included both polymeric and metallic materials. Poly-L-lactic acid (PLLA) has been shown to possess acceptable biocompatibility, but a polymeric stent requires a greater strut thickness than most metal stents because of the polymer's lower ultimate tensile strength [3]. In the case of metals, their degradability is closely related to their susceptibility to corrosion. And although corrosion is generally considered as a failure in metallurgy, the corrodibility of certain metals can be an advantage for their application as degradable implants. The candidate metallic biodegradable materials for such application should have mechanical properties ideally close to those of 316L stainless steel, in order to provide mechanical support to diseased arteries. Non-toxicity of the metal itself and its degradation products is another requirement as blood and cells absorb the material. Based on the mentioned requirements, magnesium-based and iron-based alloys have been investigated as candidates for biodegradable stents [4]. Unfortunately, magnesium alloys show a relatively high rate of degradation (they can dissolve within 60-90 days from implantation, which is premature for vascular stenting applications) and associated evolution of hydrogen gas, which has raised concerns cytotoxicity and systematic toxicity. Instead, the results of first iron stent implantation showed no significant evidence of either the inflammatory response or neointimal proliferation, and organ examination did not reveal any systematic toxicity. Iron is also interesting because of its mechanical properties (high radial strength, high elastic modulus, and high ductility), which let to maintain during the implantation without any failure. However, its faster degradation rate is desired. Various techniques have been used recently on pure iron, to enhance its physical and biological properties maintaining their mechanical properties.

Materials and Methods

The iron systems have been obtained by the replica method where the polyurethane (PU) foam template was impregnated with suspension of pure iron made of metallic powder, ethyl alcohol and polyvinyl alcohol (PVA) solution, which was used to increase a suspension viscosity. The PU foam has been cut in the form of cube and it was immersed into abovementioned Fe-suspension, to allow suspension to completely impregnate the PU foam surface. The excess suspension has been removed to prevent the blocking of the pores and to obtain a uniform coating. In order to adjust the sintering process of iron foam, the course of the thermal decomposition PU foam has been investigated using differential thermal analysis (DTA) and thermogravimetric analysis (TGA). Preliminary tests showed that for pure iron system slow heating rate (1-2°C/min) to 600°C should be applied to prevent the structure collapsing during the burnout of the PU foam and other organic matter. Subsequently, a heating rate of 5°C/min should be applied to the final sintering temperature of 950°C. After the furnace cooling, the consolidated iron foam, which was the replica of the PU foam template, has been obtained. The samples thus obtained were subjected directly to all necessary structural and morphological tests, such as IR spectroscopy, Raman spectroscopy, X-ray diffraction (XRD), and scanning electron microscopy (SEM). Analysis of physico-chemical properties, such as wettability and free surface energy of obtained iron-based materials has been carried out. Moreover, the static immersion and potentiodynamic polarization tests have been used as *in vitro* experiments to assess the biodegradation behavior of samples in a modified Hanks' solution, which ionic composition and concentration are close to those of human blood plasma. The sample for the static immersion has been cleaned with ethanol, dried and weighed. Then it was suspended in Hanks' solution at a temperature of 37°C for 14 days, after which, it was removed from Hanks' solution, dried and weighed. The average corrosion rate (ACR) has been calculated based on the mass loss using equation from *ASTM G31 Standard*:

$$ACR = 8.76 \times 10^4 \frac{W}{A.t.p}$$

where ACR is the average corrosion rate in millimetre per year (mm/year), W is the mass loss (g), A is the exposed surface area (cm^2), t is the time of exposure in hours (h) and q is the density of Fe - 7.87 g/cm^3.

Results and Discussion

Optimizing the synthesis parameters, it was possible to obtain iron 3D materials, which show the porosity on micrometric level, as it is visible on SEM images (FIG. 1).

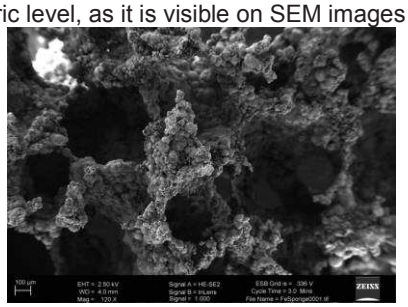

FIG. 1. SEM images of iron 3D porous systems.

The results of biodegradation behavior of sample will be presented during the conference.

Acknowledgments

Aleksandra Radtke would like to acknowledge Nicolaus Copernicus University in Toruń for financial support of studies within the project "Excellence Initiative – Debuts"

References

[1] P.K.Bowen,et al. *Adv. Healt. Mat.* 5(2016),1121-1140
[2] R. Waksman *J Invas. Card.*, 18(2006), 70-74
[3] C.M.Bunger et al.*J. Endovasc Ther*, 14(2007),725-733
[4] Moravej M., Mantovani D., *Int. J. Mol. Sci*, 12(2011), 4250-4270