A New Elastomeric Biomaterial for Arterial Diseases Applications

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Abstract
The covering of self-expandable stents (S-ESs) with elastic biocompatible membrane may avoid the atherosclerotic plaque prolapse between the stent struts into the lumen. In this work it is proposed a new elastomeric biomaterial, combined with a spray-technique, to realise a thin membrane for covering S-ESs. The membrane resulted adherent to metallic struts and able to follow stent deformation. The new biomaterial, an elastomeric silicone (polydimethylsiloxane PDMS) based poly(ether)urethane (PEtU/PDMS), deposited on the S-ESs by the spray-technique, showed *in vitro* good adhesion to metallic struts, even after deformation and recoil, and did not compromise its elastic behaviour. Capitalising on the good biocompatibility and low trombogenicity demonstrated by the material within previous studies it is expected that it can be used successfully for S-ESs covering for iliac-femoral applications.

Introduction
Peripheral occlusive artery disease (POD) is estimated to be present in 3% of the population of 40-59 years and in 20% of the population over 70 years. Traditional treatment is made by the surgical by-pass, but an alternative therapy is the interventional treatment that is less expensive, decreases the hospitalization time, does not require general anaesthesia, and induces less frequent and severe complications. In peripheral artery interventions, three main regions are distinguished based on differences in pathophysiology: the iliac, the femoro-popliteal and the infra-popliteal arteries. The use of a uniform elastic biocompatible membrane to cover the metallic meshes of the stents may prevent the atherosclerotic plaque from prolapsing into the lumen, avoiding the thrombotic material to embolize to distal circulation. Moreover covered stents may repair obstructive *flaps*, prevent elastic *recoil* and press the plaque effectively. The materials currently used for stent covering are not suitable for this applications since they don't possess adhesive properties respect to metallic struts and strongly limit stent deformation. Moreover the covering technology is inadequate and the observed material tendency to calcify, could cause the early failure of the re-vascularization.
The aim of this work was to cover iliac-femoral S-ESs with a membrane realized with a new PEtU-PDMS material processed with an original spray-technique. The material demonstrated to follow the struts elastic deformation during its delivery, and to minimally affect stent properties. Moreover previous *in vitro* and *in vivo* studies, showed its excellent biocompatibilty, allowing to assume that the proposed PEtU-PDMS covering could reduce the inflammatory response of the vessel wall following the procedure.

Materials and methods
The material proposed is an elastomeric PEtU/PDMS material processed by a spray-technique, based on the physical principle of phase-inversion. The spray technique allows the deposition of the material on a rotating mandrel generating structures with different properties in terms of morphology, biostability and mechanical properties, as a function of the chemical composition and of the fabrication parameters. The stents were mounted on PTFE® mandrels in a lightly stretched configuration; the membranes were realized spraying the polymeric solutions directly on the stents, during the mandrel rotation. The covered S-Ses, pulled off the mandrel, were dried in air at room temperature.

Results
The new PEtU-PDMS material demonstrated excellent biocompatibility and blood-compatibility by *in vitro* and *in vivo* tests. Preliminary results obtained covering S-ESs with different types of depositions evidenced the suitability of the technique to realize a uniform and resistant covering of the struts. The good attachment of the membranes to the metallic struts, realized without the use of suture thread or gluing agent, was demonstrated during cyclic crimping and expansion solicitation tests. Moreover it was evidenced that the extensibility of the S-ES was not compromised by the presence of the protective membrane.

Discussion
In this work it was investigated the possibility to realize a coating of S-ESs for iliac-femoral applications using a new elastomeric material associated to a phase-inversion process. The versatility of the spray technique and the good property of the material in terms of elasticity, adhesion respect to metallic struts, biocompatibility and emocompatibility, demonstrated the feasibility of the S-ESs covering with a uniform membrane, able to eliminate the risk of rupture of the atherosclerotic plaques. Fatigue tests are actually under preparation to establish the long-term behavior of the PEtU-PDMS coated S-ESs. Successive studies will regard the possibility to load drugs or bioactive molecules, within the membrane wall thickness, spraying drug-loaded nanoparticles suspended into solutions directly during the manufacturing process. In conclusion, a uniform covering of S-ESs with a PEtU-PDMS membrane could reduce the risk of restenosis, thrombotic occlusion and wall injury due to endovascular stenting procedure. The same materials and technique could be successfully adopted also for the covering of carotid self-expandable stents.