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# Angiopermissive Foamed and Fibrillar Scaffolds for Vascular Graft Applications

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**Abstract :** Pre-seeding with autologous endothelial cells improves the long-term patency of synthetic vascular grafts levels obtained with autografts, but is limited to a single centre due to resource, time and other constraints. Spontaneous in vivo endothelialization would obviate the need for pre-seeding, but has been shown to be absent in man due to limited transanastomotic and fallout healing, and the lack of transmural ingrowth due to insufficient porosity. Two types of graft scaffolds with increased interconnected porosity for improved tissue ingrowth and healing are thus proposed and described. Foam-type polyurethane (PU) scaffolds with small, medium and large, interconnected pores were made by phase inversion and spherical porogen extraction, with and without additional surface modification with covalently attached heparin and subsequent loading with and delivery of growth factors. Fibrillar scaffolds were made either by standard electrospinning using degradable PU (Degrapol®), or by dual electrospinning using non-degradable PU. The latter process involves sacrificial fibres that are co-spun with structural fibres and subsequently removed to increased porosity and pore size. Degrapol samples were subjected to in vitro degradation, and all scaffold types were evaluated in vivo for tissue ingrowth and vascularization using rat subcutaneous model. The foam scaffolds were additionally evaluated in a circulatory (rat infrarenal aortic interposition) model that allows for the grafts to be anastomotically and/or ablumenally isolated to discern and determine endothelialization mode. Foam-type grafts with large (150 µm) pores showed improved subcutaneous healing in terms of vascularization and inflammatory response over smaller pore sizes (60 and 90µm), and vascularization of the large porosity scaffolds was significantly increased by more than 70% by heparin modification alone, and by 150% to 400% when combined with growth factors. In the circulatory model, extensive transmural endothelialization (95±10% at 12 w) was achieved. Fallout healing was shown to be sporadic and limited in groups that were ablumenally isolated to prevent transmural ingrowth (16±30% wrapped vs. 80±20% control; $p<0.002$). Heparinization and GF delivery improved both mural vascularization and lumenal endothelialization. Degrapol electrospun scaffolds showed decrease in molecular mass and corresponding tensile strength over the first 2 weeks, but very little decrease in mass over the 4w test period. Studies on the effect of tissue ingrowth with and without concomitant degradation of the scaffolds, are being used to develop material models for the finite element modelling. In the case of the dual-spun scaffolds, the PU fibre fraction could be controlled shown to vary linearly with porosity ($P = -0.18FF + 93.5$, $r2=0.91$), which in turn showed inverse linear correlation with tensile strength and elastic modulus ($r2 > 0.96$). Calculated compliance and burst pressures of the scaffolds increased with fibre fraction, and compliances matching the human popliteal artery (5-10 %/100 mmHg), and high burst pressures (> 2000 mmHg) could be achieved. Increasing porosity (76 to 82 and 90%) resulted in increased tissue ingrowth from 33±7 to 77±20 and 98±1% after 28d. Transmural endothelialization of highly porous foamed grafts is achievable in a circulatory model, and the enhancement of porosity and tissue ingrowth may hold the key the development of spontaneously endothelializing electrospun grafts.

**Keywords :** electrospinning, endothelialization, porosity, scaffold, vascular graft
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