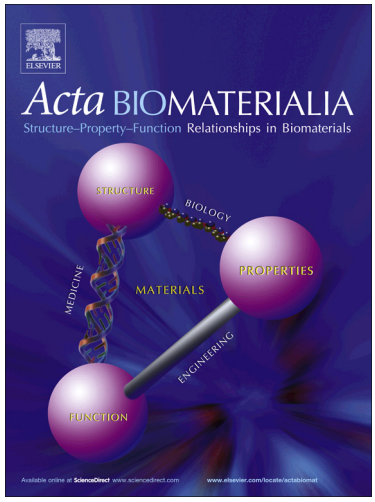

Tissue Processing Techniques for Fabrication of Covered Stents for Small-Diameter Vascular Intervention

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~~Novel~~ Tissue Processing Techniques for Fabrication of Covered Stents for Small-Diameter Vascular Intervention

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Abstract

Animal-derived pericardial tissue is a widely used biomaterial typically treated with glutaraldehyde (GA) to achieve immunological acceptance and long-term durability. However, GA fixation of biological tissue is associated with long-term failure due to degeneration and calcification. In this study, we evaluated two alternative tissue processing methods for the fabrication of pericardial tissue covered stents: detergent-based decellularization (decell) and limited exposure to GA (gentle-glut). Processed pericardial tissues were extensively characterized both in-vitro and in-vivo. Small-diameter covered stents were fabricated and the ability to seal perforation was evaluated in a flow circuit under physiological blood flow conditions. Results indicate that decell-treated tissue appeared with preserved architecture, tissue strength and stability. Gentle-glut tissue appeared with preserved architecture and increased tissue stability, compared to fresh, unprocessed tissue. Reduction of bioburden was demonstrated for both types of alternative treatments, as for GA fixation. Tensile testing demonstrated that both decell- and gentle-glut treated tissues respond better to low strain, as may occur during balloon inflation and stent deployment. Upon subcutaneous implantation in mice, gentle-glut and to a greater degree decell-treated tissue, elicit better host response, with evidence of active tissue remodeling and no detectable calcification, as compared with GA-treated tissue. Small-diameter stents covered with tissues from all groups successfully sealed perforation under physiological blood flow conditions in-vitro, without compromising flow. In summary, covered stents may perform better with pericardial tissue processed according to the methods described in this study. Adopting this methodology to other types of cardiovascular implants and tissues is also suggested.

Keywords: covered stents, pericardial tissue, cross-linking, glutaraldehyde, decellularization.