Preclinical Surgical Experience With An Intravascular Hemofilter For Organ Replacement Therapy

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Study: Intravascular bioartificial organs depend on high-efficiency hemofiltration for immune-privileged convective mass transfer. We sought to optimize a silicon nanopore membrane (SNM)-based hemofilter (HF) for renal and pancreatic islet replacement therapy.

Methods: We performed a proof-of-concept study to refine HF design and implantation considerations, enabling long-term HF patency. A swine model was chosen to approximate human vascular anatomy and thrombogenesis. HF prototypes housing SNM were implanted in arteriovenous fashion to the vasculature, enabling iterative assessment of HFcharacteristics: implantation technique, blood flow path, vessel-graft-device interface, and ultrafiltrate (UF) drainage. Patency was assessed by physical exam, Doppler ultrasound, and fluoroscopy.

Results: A HF was designed to eliminate high- and low-shear flow conditions using computational fluid dynamics (CFO) modeling, then constructed from polycarbonate and SNM (total silicon area 24 cm2). The prototype HF was attached via polycarbonate barbed connector to ePTFE vascular grafts anastomosed to swine vasculature. UFwas drained into a vein or externalized for collection or renal replacement. Initial patency was 50% (4/8). Subsequent alterations including: tunneled subcutaneous or retroperitoneal implantation, use of a stainless steel barbed graft connector, silicone reinforcement of ePTFEgrafts, and application of an anti-thrombotic UF catheter resulted in improved HFfunctionality, and

80% patency (8/10) up to 26 days' duration. In summary, refinement of HFcomponents and surgical technique may improve HF patency and function, establishing a platform for development of hemofiltration-based bioartificial organs.