

Implantable Hemofilter: 32 day Patency in a Canine Surgical Model

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Background:

Transplantation offers the best treatment option in end stage renal disease in terms of cost, survival, and quality of life, but is limited by donor organ supply. An implantable artificial kidney using high-efficiency silicon nanopore membranes is in development to provide the benefits of transplantation to all dialysis patients. The major challenge in implementation of chronic blood-contacting devices is thrombosis. We report a successful 32-day device implant in a canine model without systemic anti-coagulation.

Methods:

A small-scale single-channel parallel-plate hemofilter (design membrane area ~2 cm²) was manufactured from medical grade polycarbonate. In order to understand the influence of the hemofilter blood path on hemolysis, thrombosis and long-term patency, two silicon chips coated with biocompatible polymer thin films (sulfobetaine methacrylate) were mounted in the hemofilter in lieu of the planned silicon nanopore membranes.

In regards to the operation, the retroperitoneal vasculature was exposed via a midline laparotomy. 6 mm Polytetrafluoroethylene (PTFE) grafts were anastomosed in standard fashion with a running 6-0 prolene suture to the common iliac artery and vein to be used as inflow and outflow conduits to the device. Therapeutic heparin (100U/kg) was administered intra-operatively. The dog was housed without restrictions post-operatively. The dog received lovenox (0.5mg/kg) once a day at a venous thromboembolic prophylactic dose, rather than a therapeutic dose to demonstrate device patency in the absence of full anticoagulation. Graft patency and flow velocity were serially assessed post-operatively with a pulse wave, color flow doppler ultrasound.

The device was explanted at Day 32.

Results:

On serial ultrasound evaluations, the inflow and outflow PTFE grafts showed patent, pulsatile flow throughout the 32 day experiment. Operative findings on device explant noted that the device was patent without thrombosis formation. The dog had no complications during the course of the experiment.

Conclusion:

The 32 day patency of the device in the absence of therapeutic anti-coagulation highlights successful surgical technique, non-thrombogenic blood flow conduit geometry, and the biocompatibility of the manufacturing techniques and materials which provides the foundation for further preclinical canine experiments.