Surgical Considerations for an Implantable Renal Replacement System

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Background:

Silicon nanopore membranes are key to the construction of a pumpless implantable renal replacement system. Through the development of an early-stage implantable prototype and subsequent preclinical feasibility testing in a large animal-model, we have attempted to examine key surgical and clinical factors.

Methods:

An iterative proof-of-concept study was designed to develop the implantation procedure and to evaluate the blood-flow characteristics of the prototype. A swine model was selected because of the comparably sized vasculature and hematologic similarities with humans.

Results:

A prototype was fabricated with a 3mm inlet and outlet, which was divided into three 1mm high blood channels defined by silicon parallel plates. The titanium-based device was 9.3cm x 5.7cm x 1.4cm with a dry weight of 189g. Autoclave was used for sterilization. Dacron (polyester) grafts with titanium connectors served as the blood conduits. Initial implantations were unsuccessful due to thrombosis. The Dacron grafts were not structurally rigid enough to prevent kinking. Moreover, inadequate anchoring and subsequent device shifting subjected the grafts to additional extrinsic forces. Iterative changes included replacing Dacron with a ringed two-layered graft (Polytetrafluoroethylene (PTFE) bonded to polyester) and reinforced with a silicone strain-relieving sleeve. Sections of the titanium exoskeleton were replaced with Polyether ether ketone (PEEK), which reduced movement of the implant and resulted in a 40% dry-weight reduction. The anticoagulation regimen was modified to include Coumadin with a lovenox-bridge. These changes, along with refinement of the surgical procedure, allowed for successful implantation of the prototype with flow and patency confirmed via fluoroscopy on post-operative day 3.