Packaging Considerations For An Implantable Hemofilter Based On Silicon Nanopore Membranes (SNM)

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Study: Silicon nanopore membranes (SNM) are being utilized to develop an implantable renal replacement device, which will consist of a tandem arrangement of a silicon hemofilter and renal cell bioreactor. Here we report the successful development of an implantable hemofilter using a scalable packaging method.

Methods: To significantly reduce prototyping time and cost, a small-scale version of the full-scale device was developed with 1/5 the number of blood channels. The small-scale hemofilter consists of a filtration cassette sealed into a biocompatible polycarbonate body. The filtration cassette is composed of several SNM plates covalently bonded in parallel fashion with intermediate silicone channel layers. FEA modelling of small and full-scale devices (with >2x physiological blood pressure loads) shows maximum stress and deformation values for the cassette components change by 7.14% and 0.46% respectively for the silicone layers, and 0.90% and 0.17% respectively for the SNM plates. All device components showed sub-critical stress values resulting in no significant difference in structural integrity between the small and full-scale devices. Additionally, in vitro small-scale device testing demon-strated structural integrity at blood pressures exceeding 350 mmHg. Based on comparative FEA results, the full-scale device is expected to successfully operate well above physiological blood pressure loads.

Results: In vitro filtration efficiency studies of the small-scale device showed urea transport of 129 ml/min/m^2 without the presence of albumin using the filtration cassette. Combined with the structural analysis, these results show that the filtration cassette assembly and packaging method can be used to create a clinically relevant full-scale implantable renal replacement device.