A Novel Dual Chamber Perfusion Stent Graft Using a Smart Nitinol and Highly Stretchable ePTFE to Isolate Blood Flow in Donation after Cardiac Death

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Statement of Purpose: Shortage of healthy donors' organs has appeared as one of the main challenges for organ transplantation. This study focuses on the novel endovascular device development to increase the number of available organs from cardiac death donors. The primary objective of this study is the design validation of a newly developed stent graft for the abdominal organ perfusion with cardiac blood flow isolation. The effectiveness of the device design has been validated via the assessment of the device performance both *in vitro* and *in vivo*.

Methods: The device consists of two primary materials: 0.005 inch thick highly-stretchable expandable polytetrafluoroethylene (ePTFE) tube (ZEUS, Inc., Orangeburg, SC) and 0.015 inch diameter superelastic nitinol wire (Confluent Medical, Fremont, CA). A metallic backbone structure in the prototype was fabricated using superelastic nitinol wire. The wire was cold drawn and mechanically polished. The elastic modulus of the Nitinol wire has a range between 41 and 57GPa with the ultimate tensile strength of 1070MPa. The transformation temperature (i.e., Austenite finish temperature) is in the range of 25- 30°C, which is suitable for implementing a self-expanding behavior in the human body. Nickel to Titanium ratio is 55.8wt.% and 44.2wt.%.

Results: A functional prototype stent graft has been developed via device design iteration process of the nitinol backbone and ePTFE membrane. Both *in vitro* and *in vivo* study results have demonstrated the device's performance on the flow separation within the anatomical silicone model and animal (here, swine model). Figure 1A shows the fabricated prototype used *in vitro* and *in vivo* studies. A dual chamber nitinol backbone was fabricated via a low-energy laser joining process followed by the attachment of a highly stretchable expandable polytetrafluoroethylene (ePTFE) to create a fully collapsible stent graft with two chambers and one docking zone. Figure 1B and C show the flow dynamic study results on the relationship between the flow rates and perfusion sheath size, as well as between the flow rate and perfusion outlet locations showing the optimal design of the device. Figure 1D through F demonstrates the performance of the stent graft in the porcine model. Baseline angiography of a branched segment of aorta. Following placement of the dual chamber stent is shown in A, the center lumen excludes the branches shown in B, whereas the outer chamber isolates perfusion of the branches from a perfusion lumen (C) extending outside the body (Arrowhead).

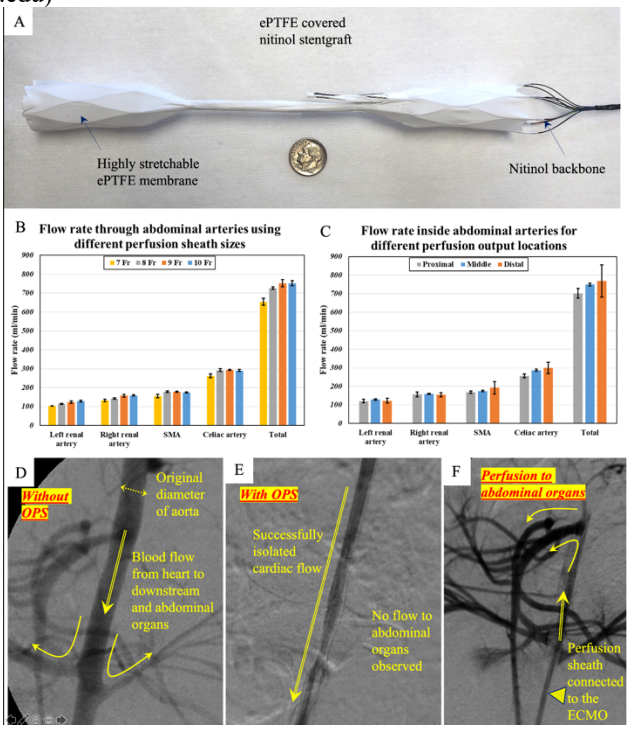

Figure 1. Study results on the development of a novel stent graft used to isolate blood flow; (A) prototype, (B) flow rate vs. perfusion sheath sizes, (C) flow rate vs. the outlet location, and D-F) *in vivo* test results using angiographical analysis.

Conclusions: A new stent graft has been successfully developed and tested both *in vitro* and *in vivo* demonstrating its feasibility through a rigorous design validation process. The cardiac flow dropped by at least 30% after the device deployment in the *in vitro* anatomical aorta model. The perfusion sheath influenced the perfusion flow rate, to be maximum at 9Fr. sheath. The perfusion flow rate was maximum at 50mm perfusion length when the perfusion outlet was located distal to the heart. The new stent graft successfully isolated the cardiac flow from the branches to major abdominal organs. This new stent graft could substantially increase the number of available organs from the cardiac death donors minimizing potential organ ischemic complications.

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