PRECLINICAL ASSESSMENT OF A NOVEL LINE OF LEFT ATRIAL DECOMPRESSION CATHETERS DESIGNED FOR USE IN PEDIATRIC VENOARTERIAL ECMO SUPPORT

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Background:

Extracorporeal membrane oxygenation (ECMO) remains a vital supportive measure for adult and pediatric patients suffering from acute cardiopulmonary failure. Patients with severe left ventricular systolic dysfunction can develop significant congestion within the left heart chambers. These patients require decompression of the LA/LV in order to prevent pulmonary hemorrhage, subendocardial ischemia, and resulting arrhythmias. LA/LV decompression in smaller pediatric patients remains a major challenge, and no specific device has been designed to accomplish this to date. We describe the preclinical development and testing results of a novel line of LA decompression catheters designed specifically for pediatric patients on VA ECMO for acute LV systolic dysfunction.

Methods:

Anthropometric data was obtained through a series of length measurements from the femoral vein to IVC, SVC, and mid LA on 70 patients undergoing cardiac catheterization. Previously performed cardiac MRI's were reviewed to determine optimal length and degree of curvature from IVC to mid LA on a variety of patients. A limited dataset of ECMO flows recorded on patients treated with VA ECMO who required LA decompression were compiled as reference points of typical flows necessary for adequate decompression. Computational fluid dynamic modeling was performed using boundary conditions established by the anthropometric data. MC3 InterSept™ catheter and transseptal introducer system prototypes (Figure 1) were manufactured at the longest (65 cm) and largest diameter (16 Fr O.D.) as predicted by the CFD analysis. Bench testing was performed, including flow characterization, insertion simulation, tensile strength, kink stability, leak testing and hemolysis rates. An in-vivo study following transseptal puncture was performed on a 60-kg anesthetized female swine, and pressure and flow data through the system was collected.

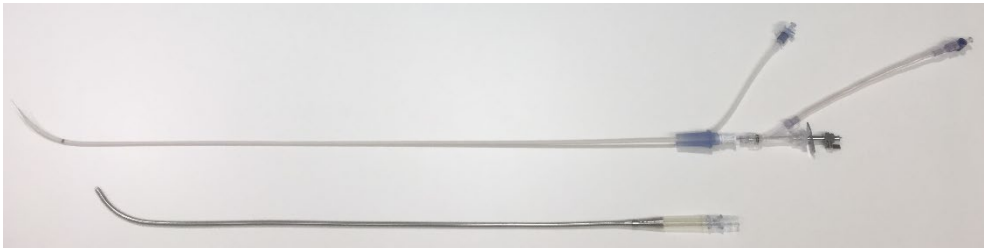

Figure 1

Results:

In-vitro testing for flow characterization and insertion simulation met the user requirements. Tensile strength testing showed that the lower tolerance limit (95/95 %C/%R) of the hub bond tensile strength was 124.1 (over 8x the requirement of ISO10555-1:2014). Kink stability testing showed a 95% upper tolerance below the industry standard of 72 mm at 46.5 mm. Leak testing and aspiration studies were negative. Hemolysis testing showed the MC3 InterSept™ catheter had similar hemolysis rates as the Bio-Medicus Venous Catheter and was well below FDA recommended limits (Figure 2). During In-vivo testing, one swine underwent placement of the MC3 InterSept™ catheter into the LA following intracardiac echo guided transseptal puncture. VA ECMO flow was maintained for 2 hours with flow rates obtained as high as 1.75 L/min without developing prohibitively negative pressure on the circuit.

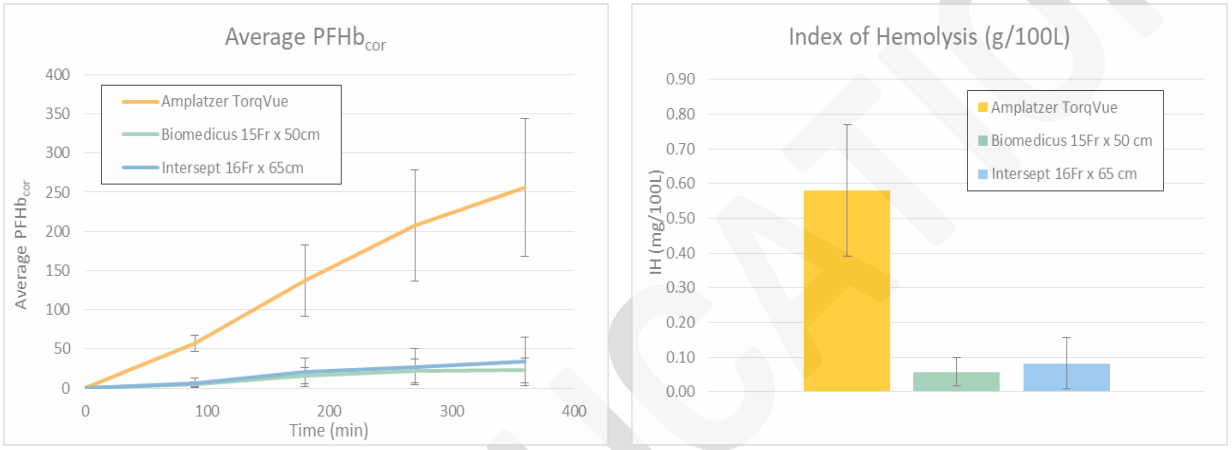

Figure 2

Conclusions:

Preclinical data on the MC3 InterSept™ catheter demonstrates the device to meet all pre-determined user requirements for in-vitro performance of flow characterization, insertion simulation, tensile strength, kink stability, leak testing and hemolysis. In-vivo testing showed catheter flow rates well within the range to provide adequate LA decompression. Additional testing is ongoing on smaller and shorter prototypes for use on smaller patients 5-10 kg and ages 6-12 months. This line of catheters may fill the unmet need for this small niche population with less than ideal methods currently available for LA decompression.