PRECLINICAL ASSESSMENT OF A DOUBLE-INFLOW SINGLE-OUTFLOW CAVOPULMONARY ASSIST DEVICE

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Introduction

The Fontan circulation serves as a palliative treatment for patients with congenital univentricular heart disease. Established through a series of three surgeries, it reinstates functional blood oxygenation and improves survival rates. The Fontan circulation is, however, prone to progressive hemodynamic deterioration. Therefore, the development of novel mechanical circulatory support systems is of pivotal importance given the shortage of donor organs. Escher et al. [1] showcased promising preclinical results with a double-inflow double-outflow Cavopulmonary Assist Device (CPAD), moreover, revealing the potential to enhance implantability by transitioning the design to a single-outflow concept [2]. This study covers the preclinical in silico and in vitro evaluation of the updated single-outflow CPAD (Figure 1) regarding hydraulic performance and hemocompatibility over a broad range of caval inflow ratios (IRs). In addition, a flow estimator was developed to monitor hemodynamics in future chronic animal trials.

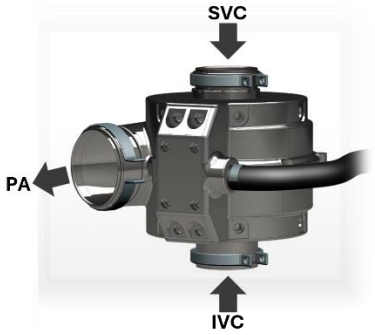

Figure 1: 2nd Generation CPAD with depiction of superior (SVC) and inferior vena cava (IVC) inflows and pulmonary artery (PA) outflow.

Materials & Methods

Numerical and experimental test setups were employed to assess hydraulic performance in terms of pressure-flow characteristics under varied IRs (IVC/SVC: 1/1; 2/1; 3/1; and 1/2) and operating conditions (rotational speed: 1500rpm – 3500rpm; and total flow: 0 – 10 L/min). Further, the current consumption of the CPAD was experimentally determined to establish a flow estimator based on current, rotational speed, and viscosity. The normalized index of hemolysis (NIH) over 30-min intervals was obtained experimentally at the nominal operating point (4 L/min, 2500 rpm) under two different IRs (IVC/SVC: 1/1 and 3/1) in a paired test setting using the same blood (hematocrit: 35%) per test (n=5). Moreover, the NIH was numerically computed for the same conditions utilizing a previously established methodology [3].

Results

Both in silico and in vitro analyses indicated a negligible impact of the analyzed IRs on hydraulic and hemolytic CPAD performance. Experimental analysis showed no significant influence ($p > 0.98$) on the current consumption and pressure head generated for all chosen operating conditions. Therefore, a flow estimator, independent of IR, was developed and cross-validated (RMSE < 0.13 L/min, R2 > 0.99). Further, the experimental NIH evaluation revealed a non-significant ($p = 0.79$) difference of 8.9% between both conditions (IR = 3/1: 8.5 mg/100L; IR = 1/1: 7.7 mg/100L), while numerical analysis showed a variation of 5.9% (IR = 3/1: 1.06 mg/100L; IR = 1/1: 0.99 mg/100L).

Discussion

The single-outflow CPAD meets hydraulic benchmarks set by its predecessor, while demonstrating a low hemolytic behavior (compared to clinically established blood pumps [3]). The updated design and the displayed robustness against different IRs further promote the implantability within the heterogenous Fontan patient population. The successfully developed flow estimator will be essential for pump control and monitoring in future pre-clinical in vivo trials.

References

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