Design and Optimization of a Fontan Assist Device

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Objectives: About 1 in 3000 live births are affected by univentricular heart physiology. Treated by multi-stage surgeries (Fontan palliation), these patients typically suffer complications in the second decade of life (Fontan failure). Given the absence of an effective long-term therapy, we recently proposed a rotodynamic blood pump to alleviate Fontan failure by pumping blood from the caval veins into the pulmonary arteries. This study aimed to optimize our Fontan assist device through a series of investigations from computer via benchtop to animal studies.

Methods: Upon thorough numerical flow analysis, a first-generation prototype was manufactured to assess corresponding hydraulics, hemolysis (bovine blood, n=3), and electric power consumption in-vitro and to verify the hemodynamic benefit in-vivo (acute sheep model, n=6). This preclinical evaluation and follow-up numerical studies including virtual fitting (n=10), computational fluid dynamics, and finite element analysis, served the multi-objective optimization of the first-generation device accounting for size, hemocompatibility, and motor performance.

Results: The first-generation device indicated a broad range of operation (H=0-50mmHg, Q=0-10L/min) with a normalized index of hemolysis of 3.8±1.6mg/100L and an electric power consumption below 1W at typical settings (4L/min, 2500rpm) in-vitro and restored biventricular equivalency in terms of venous return in vivo. The animal trial and the virtual assessment of device fit for implantability in sheep and humans guided the redesign from double- to single-outflow configuration for enhanced versatility. The in-silico multi-objective optimization demonstrated the feasibility of downsizing the device by up to 20.3%, concomitant with a marginal enhancement of hemocompatibility performance by 1.9% and a reduction in motor losses by 2.4%.

Conclusions: The comprehensive preclinical evaluation of the Fontan assist device demonstrated promising results and informed the multi-objective device optimization for improved implantability in the chronic sheep model and enhanced versatility for the implantation in the heterogeneous Fontan population.