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A Cavopulmonary Assist Device for Long-Term Therapy of Fontan Patients

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Introduction: Patients with univentricular heart physiology are typically palliated by staged surgical corrections to direct blood from the caval veins to the pulmonary arteries without intermediary right ventricle (Fontan circulation) [1]. This lack of subpulmonary pressure source is frequently causing progressively deteriorating hemodynamics with eventual circulatory failure (Failing Fontan) [2] and is yet left without effective medical solution. We seek to address this unmet medical need with a novel cavopulmonary assist device (CPAD) applied in cavopulmonary position pumping blood from the caval veins into the pulmonary arteries. The aim of this study was the preclinical evaluation of this CPAD regarding its potential for (i) inclusive cavopulmonary support, (ii) low-traumatic operation, (iii) low electric power consumption, (iv) implantability and (v) hemodynamic efficacy. Methods: The CPAD was designed as a rotodynamic blood pump (RBP) and manufactured based on hemocompatible titanium components with ceramic bearings for impeller suspension. Device actuation was realized by redundant electric motor configuration with corresponding drive unit. Hydraulic properties (pressure-flow characteristics) and hemocompatibility features (hemolysis) were evaluated across a broad range of operation in-silico (computational fluid dynamics) and validated in-vitro (hydraulics: water-glycerol; hemolysis: bovine blood). In-vitro benchtop analysis furthermore included the monitoring of the CPAD's electric power consumption. Feasibility of device implantation and hemodynamic support was evaluated in acute animal experiments (sheep, n=2, 48.75±4.6kg) with a speed ramp protocol to investigate the relationship between speed and hemodynamic parameters. Results: The CPAD delivered pressure step-ups across a wide range of pump operation (0-50mmHg, 0-10L/min) with speeds below 3900rpm. The device indicated a normalized index of hemolysis of 3.8±1.6mg/100L when operated at design point settings (4L/min, 2500rpm) during in-vitro hemolysis experiments (n=3). Within this main operating range, pump operation was associated with electric power consumption below 1.5W. The acute in-vivo trial proofed feasibility to implant the CPAD in 2 sheep. Venous pressures declined linearly with increasing pump speed until suction occurred. Vice versa, cardiac output, pulmonary arterial pressures and left atrial pressure increased. The animal experiment was successfully terminated after 2h of pump support without any signs of thrombus formation. Discussion: The wide range of possible pump operation provides the potential for physiologically controlled destination therapy. Accordingly, this may indicate the capability of applying the CPAD in a heterogenous Fontan population including pediatric and adult patients at individual states of cardiovascular condition and physical activity. The low-traumatic operation of the CPAD point toward the applicability of RBP technologies in cavopulmonary position, while the low power consumption holds the potential for the future conception using transcutaneous energy transfer technologies. This would enable a fully implantable device design omitting the risk of driveline-infections. The acute animal trial indicated device implantability and showed hemodynamic efficacy in a sheep model, thus substantiating the further analysis of safety and efficacy in chronic animal experiments. Acknowledgements: References: [1] Gewillig M. The Fontan circulation. Heart. 2005;91(6):839-846. doi:10.1136/hrt.2004.051789 [2] Goldberg DJ, Shaddy RE, Ravishankar C, Rychik J. The failing Fontan: Etiology, diagnosis and management. Expert Rev Cardiovasc Ther. 2011;9(6):785-793. doi:10.1586/erc.11.75

Physical prototype of the CPAD designed to assist the Fontan circulation by pumping blood via GORE-TEX® vascular grafts from the caval veins (IVC: inferior vena cava; SVC: superior vena cava) into the pulmonary arteries (LPA: left pulmonary artery, RPA: right pulmonary artery). The red arrows indicate the direction of blood flow. The CPAD features a total volume of 17.3cm³ with the distal ends of the cannula in- and outlets being spaced by 34 mm and 40 mm, respectively.

Keywords: Fontan; Cavopulmonary Assistance; Rotodynamic Blood Pump; Preclinical Testing