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Low-shear TORVAD Ventricular Assist Device Preserves von Willebrand Factor in Chronic Ovine Model

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Study: The TORVAD is a positive-displacement ventricular assist device that synchronizes with the cardiac cycle to deliver full support to a failing heart with a 30 ml counterpulse ejection. Pumping is achieved by rotating two pistons within a toroidal chamber on ceramic hydrodynamic bearings. The design achieves low-shear by virtue of controlled gaps and low rotational speeds (60–140 rpm). Blood pressure is measured using motor currents. This chronic animal study was performed to assess long-term performance, automatic control of pumping parameters, hematologic effects, and thrombogenicity of the TORVAD.
Methods: Three sheep were implanted with the TORVAD with a target study duration of 60 days. Blood samples were taken throughout the study for analysis of plasma free hemoglobin (PFHg) and von Willebrand Factor (vWF). Hemodynamic and pump parameters were relayed by the controller to a server for continuous remote monitoring.
Results: Animals 1 and 2 were weaned off heparin and onto warfarin. All anticoagulation was stopped on postoperative day (POD) 8 due to excessive anticoagulation with bleeding complications. Animal 3 was weaned off of heparin on POD 3 and no anticoagulation was given for the remainder of the study. The first animal was terminated on POD 9 due to non-device-related internal bleeding; the other two animals were supported for 62 and 60 days. Following stabilization, PFHg averaged 5.2 ± 2.3, 7.4 ± 5.8, and 4.4 ± 3.6 mg/dL for each animal. No loss in high molecular weight vWF was observed. Grafts and inflow cannulas were free from thrombus except for the inflow graft of animal 3, likely due to contamination prior to implantation. Infarcts were observed in the kidneys of animals 2 and 3, which may have resulted from a thrombus in a torus inner seam gap caused by deflection from O-ring forces. This will be corrected by laser welding the seam before any future studies. All other blood-contacting surfaces of the pump were free from thrombi, including the pistons and hydrodynamic bearings.

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Thrombotic Depositions on Right Impeller of Double-ended Centrifugal Total Artificial Heart *in vivo*

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Study: The development of Cleveland Clinic continuous-flow total artificial heart (CFTAH) is a complex undertaking that includes chronic biocompatibility assessment of the device. In this study we evaluated the CFTAH for signs of thrombosis and biological material deposition in four animals that had achieved the intended 14-, 30-, or 90-day durations in each respective experiment.
Methods: Thrombotic depositions from four animals (Jersey calves; weight range, 79.5–89.5 kg) that had been implanted with a CFTAH and that had achieved the intended durations were analyzed. The analysis included macroscopic evaluation of pump depositions, histology and computational flow dynamics of the device impeller.
Results: Four animals achieved the intended durations of 14 (case 1), 30 (case 2), or 90 days (cases 3 and 4). Detailed analysis at explant revealed the rotor, stator bore, both (left and right) pump housings, and rotating assembly had remained free of thrombus or depositions in all cases. The left impeller was free of depositions and thrombus. The right impeller was found to have some depositions in all four cases. The shape, configuration, consistency of the thrombi varied in each case. Thrombus depositions in the right pump of the total artificial heart continue to represent an important clinical issue. The right depositions can have multiple contributing factors that will require further investigation. Improved wash and lower residence time within the right impeller, upstream sources for thrombus migration, and increased speed modulation can be potential solutions. More research is necessary to elucidate the implications of a particular impeller design on the susceptibility of the pump to migrating clots.