INTERLABORATORY MEASUREMENTS OF FLOW PARAMETERS FOR COMPARISON TO CFD SIMULATIONS OF FDA'S NOZZLE MODEL
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As part of FDA's Critical Path Initiative to assess the use of computational fluid dynamics (CFD) in the evaluation of medical devices, experimental data was obtained on a benchmark nozzle model for comparison with CFD simulation results. Particle image velocimetry (PIV) was performed at 3 independent laboratories over a range of nozzle-throat Reynolds numbers (Re) from 500 to 6500 to quantify measurement uncertainties. A standardized experimental procedure, fully developed flow was observed at the nozzle inlet for Re less than 6500, with the center-line velocities matching the theoretical values within ±8%. For laminar (Re=500) and turbulent flow conditions (Re=3500), the center-line velocities and peak shear stresses observed by the labs matched within ±15% and ±20% respectively, at all axial locations. However, for transitional flow (Re=2000), measurement uncertainties near the reattachment region were over 60% due to differences in jet reattachment lengths (caused by differences in flow perturbations at the model inlet). Besides providing benchmark data to be made publicly available, these experiments also helped to develop a protocol that reduces sources of measurement error during quantitative PIV evaluations of flow models (e.g., due to fluid property and flow rate fluctuations, peak locking, and large velocity gradients).

PRECLINICAL EVALUATION OF MITHIERTLVD

The MITIHeartLVAD, a rotary centrifugal blood pump with a low power magnetic bearing system, has been fully evaluated in pre-clinical tests. Constructed from titanium alloy, all blood-contacting surfaces have been treated with a unique biocompatible coating. In vitro testing has confirmed stable and reliable operation under a wide range of test conditions, producing 5 L/min of flow against 100 mmHg at approximately 5,000 rpm. Test results have confirmed low values of platelet adhesion on coated surfaces. Hemolysis testing in pulsatile and non-pulsatile conditions has demonstrated very low levels of hemolysis under all conditions with an average NIH of 0.002 mg/dl. The wearable control system that allows for 8 hours of operation before battery recharge has been validated in a series of in vitro and animal implant studies. A series of in vitro durability evaluations have been completed. A total of 2,000 hours of testing with calf animals models, including two successful thirty-day tests, have been performed at the Hershey Medical Center with the prototype pump.

A NEW FAILING FONTAN SHEEP MODEL
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The purpose of this study was to develop a new sheep model of a failing Fontan. Methods: Under general anesthesia, adult female sheep (35-44 kg, n=4) were instrumented for hemodynamic monitoring. Through a right lateral thoracotomy (the 4th intercostal space), the right pulmonary artery (RPA) was exposed and anastomosed to one end of an 18 mm Teflon graft. The other two ends of the graft were anastomosed to the inferior vena cava (IVC) and superior vena cava (SVC, end to side). Two complete clamps were applied on the IVC and SVC between anastomosis and right atrium to divert total venous blood from the vena cava to the RPA. Systolic blood pressure (SBP), central venous pressure (CVP), and mean pulmonary artery pressure (MPAP) were continuously monitored. Result: After total venous blood was diverted from vena cava to RPA, CVP increased from 6.25 to 10.75 mmHg, PAP dropped from 16 to 10.75 mmHg, and SBP decreased from 114.5 to 75.25 mmHg. With caval-pulmonary assist hemodynamic restore to normal range. Conclusion: A sheep model of Fontan pathology can be established through a right lateral thoracotomy. Our failing Fontan sheep model avoids a traumatic mid-sternotomy, eliminates the need for cardiopulmonary bypass, and is survivable with caval-pulmonary assist.

TURBULENCE MODELING AS A SOURCE OF ERROR IN FDA'S "CRITICAL PATH" INTERLABORATORY COMPUTATIONAL STUDY OF FLOW IN A NOZZLE MODEL
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Purpose: To determine factors affecting accuracy of computational fluid dynamics (CFD) in predicting flow in FDA's benchmark nozzle model. Methods: Results from an interlaboratory computational study performed by 28 groups were compared to velocity data from particle imaging velocimetry experiments performed at three independent laboratories in a nozzle model in which the throat Reynolds number (Re) varied from 300 to 6500. Results: All Re's, the largest discrepancies appeared downstream of the throat. At Re=500, laminar simulations agreed well with experimental data (figure), both using a k-omega shear stress transport (KOST) model. The other KOST models and all k-epsilon (KE) models performed poorly with premature breakthrough of the downstream jet. For Re=3500, the KE models grouped together, but were less accurate than the KOST models. At Re=6500, simulations were better grouped around the experimental data, particularly for the KOST models. While choice of turbulent model is one factor of many that affect simulation accuracy, analysis of results has helped us develop a suite of best practices (e.g., appropriate flow model, inlet/outlet length, maintaining mass conservation) for using CFD in medical device evaluations.