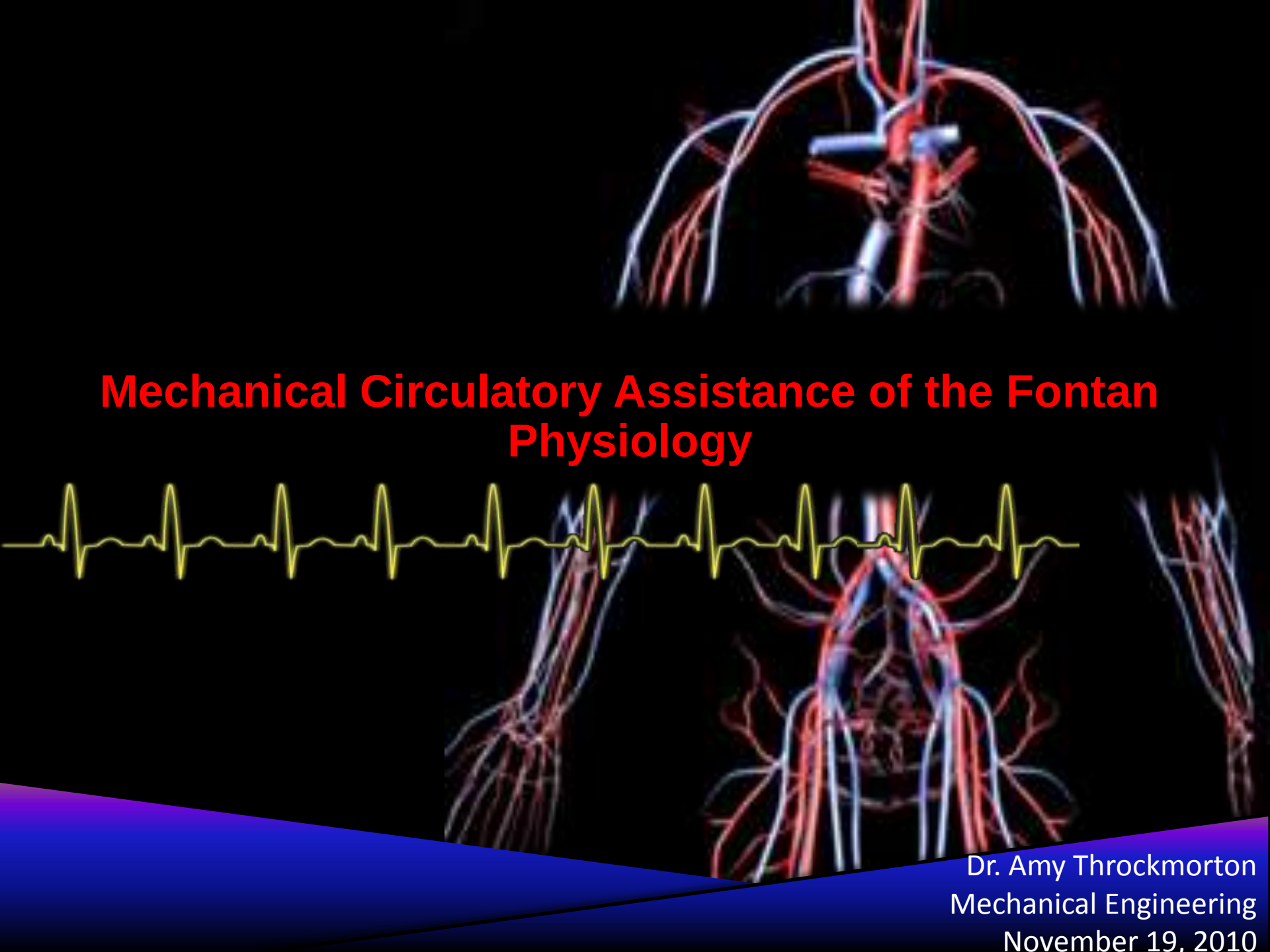
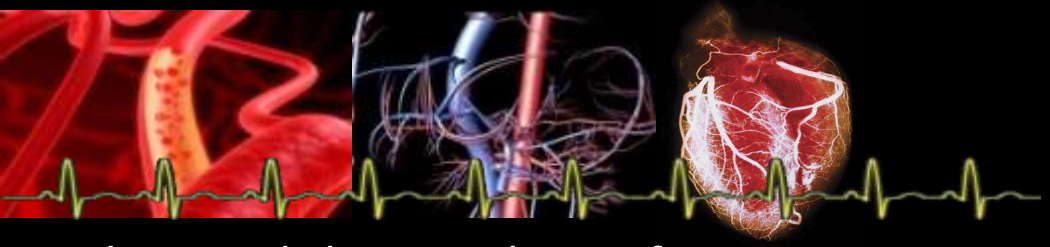


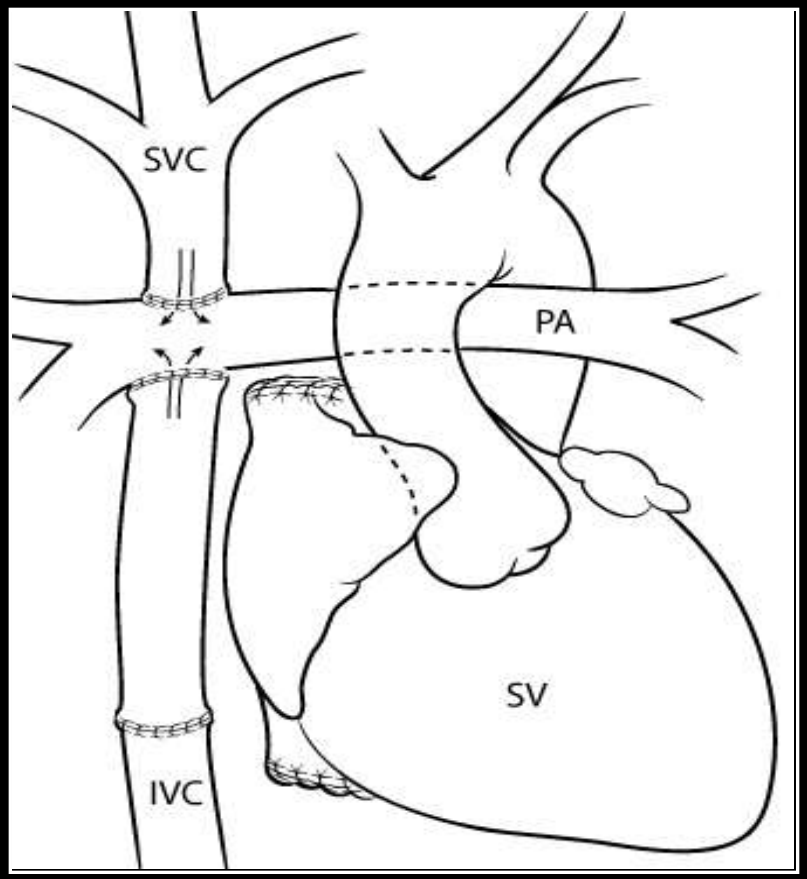
Mechanical Circulatory Assistance of the Fontan Physiology

Dr. Amy Throckmorton
Mechanical Engineering
November 19, 2010

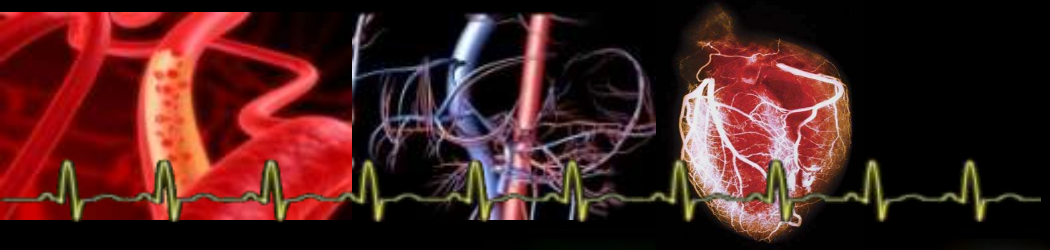
Congenital Heart Defects



- Thousands born with significant malformations of heart and vessels
- Must survive open-heart surgeries to correct or “repair” anomalies
- Single ventricle physiology
  - No right ventricle
  - Right sided flow: two inputs, two outputs
  - One pump doing workload of two pumps
- Fontan physiology – early decompensation to congestive heart failure.
- Other than a heart transplant, few if any therapeutic options exist.



BioCirc Research Lab at VCU

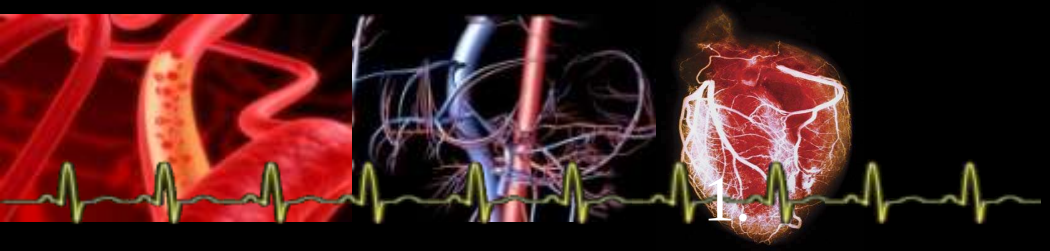


- Research Objective: Develop therapeutic treatment options to mechanically support adult and adolescent Fontan patients with heart failure or as a clinical management strategy.

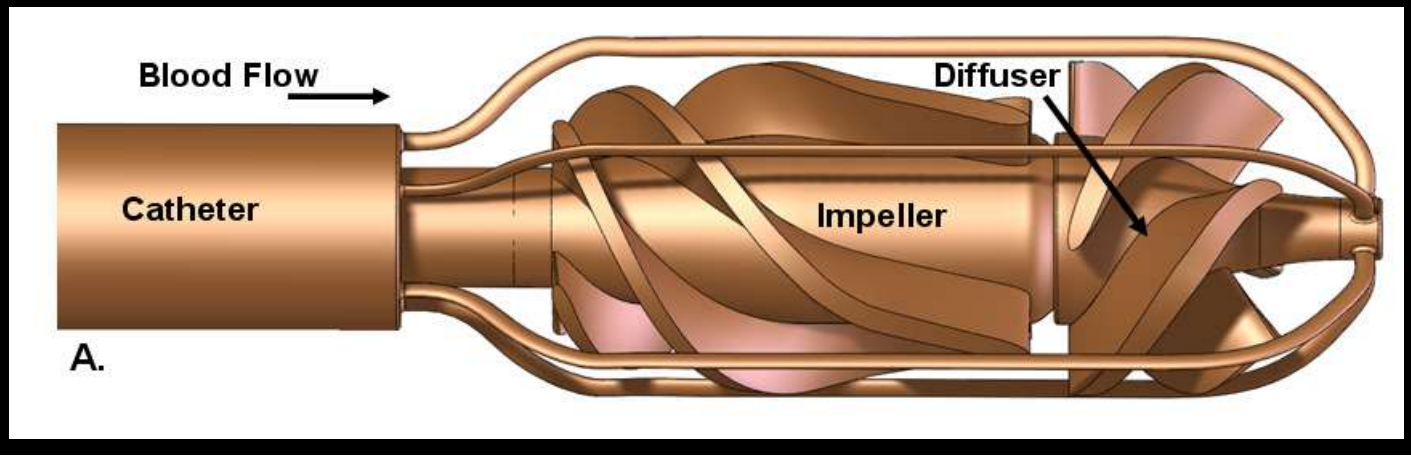
- Significance: Provide alternative support for bridge-to-transplant, bridge-to-recovery, or bridge-to-surgical reconstruction

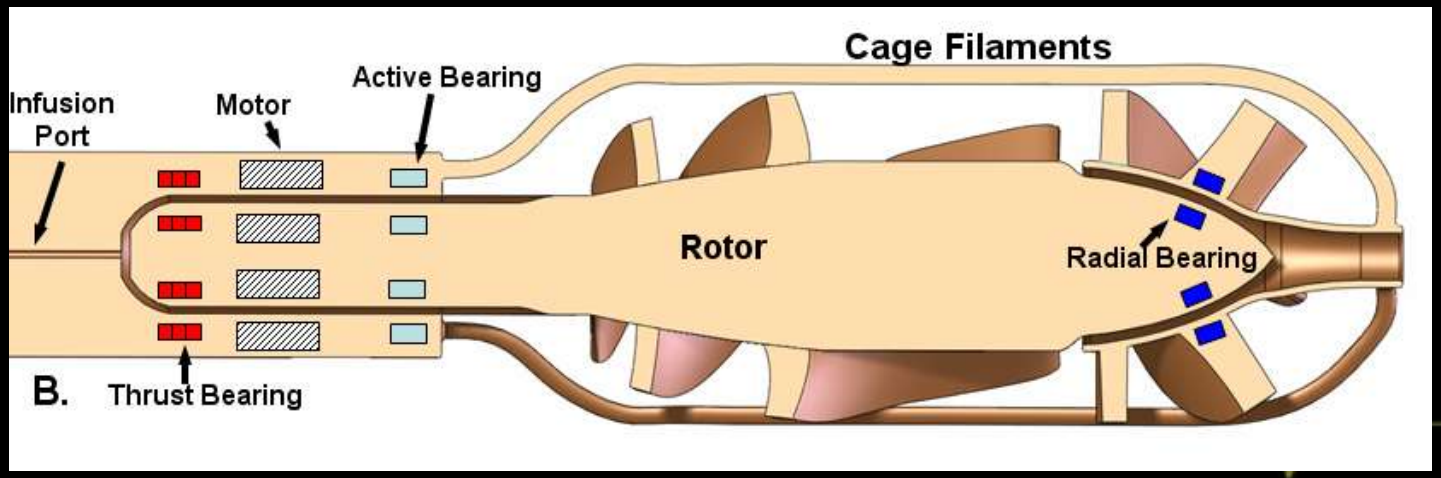
- Central Modality under Development:
    - Intravascular Axial Flow Blood Pump

Cavopulmonary Assist Device

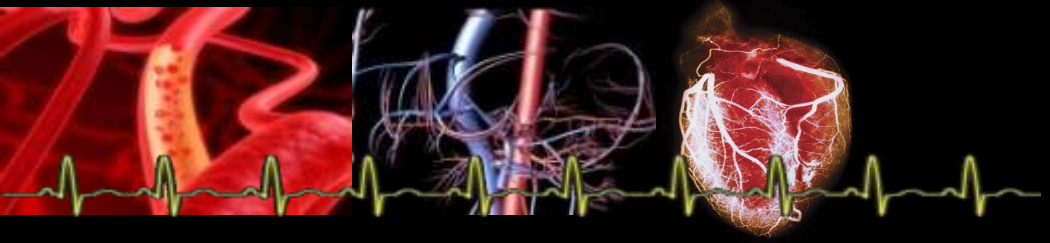


- Cantilever design
- Percutaneously-inserted
- Axial flow pump
- Magnets employed to levitate and rotate



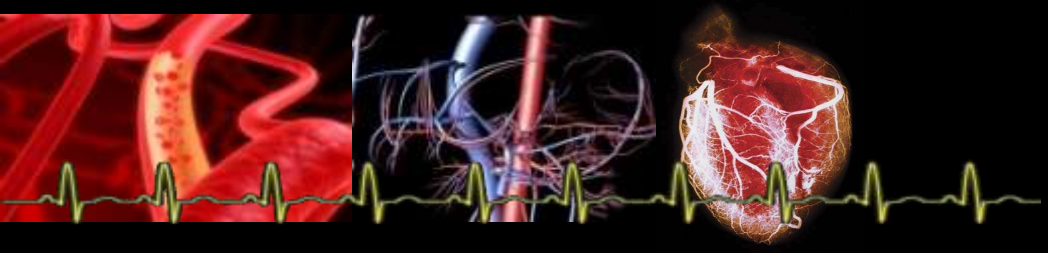


Development Methodology



- **Pump Design**
  - ✓ Numerical Modeling (CFD)
  - ✓ Prediction of Blood Damage and Clotting
  - ✓ Optimization / Iterations
- **Prototype Testing**
  - ✓ Hydraulic Performance
  - ✓ Laser Flow Measurements (PIV)
  - ✓ Mock Circulatory Loop
- **Animal Studies**
  - ✓ Pump's ability to support life
  - ✓ No clotting or blood damage
  - ✓ Implantability and operability

From MR Imaging Data to Numerical Model....

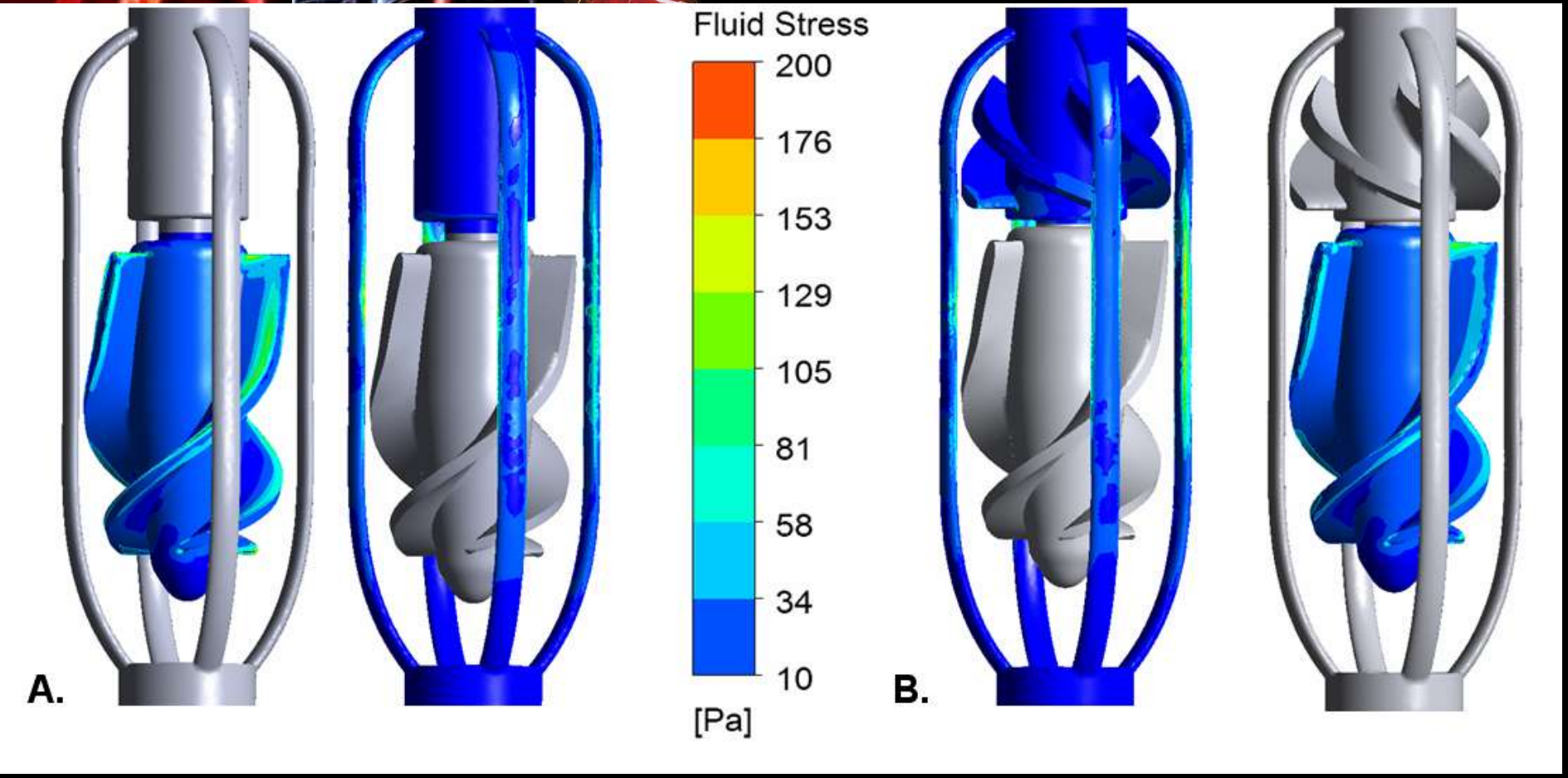


MIMICS (Materialise Inc.)

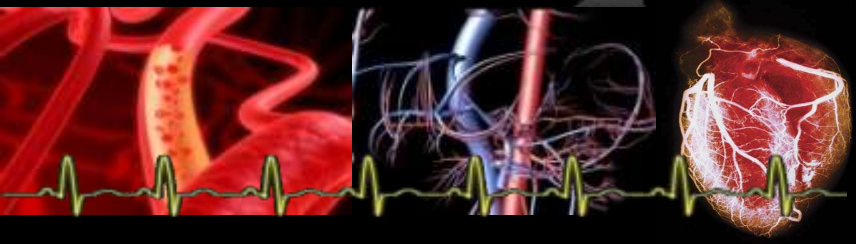
Cavopulmonary Physiology – Introduce Pump

Four Different Patient-Specific TCPC Models with 1 Glenn Configuration

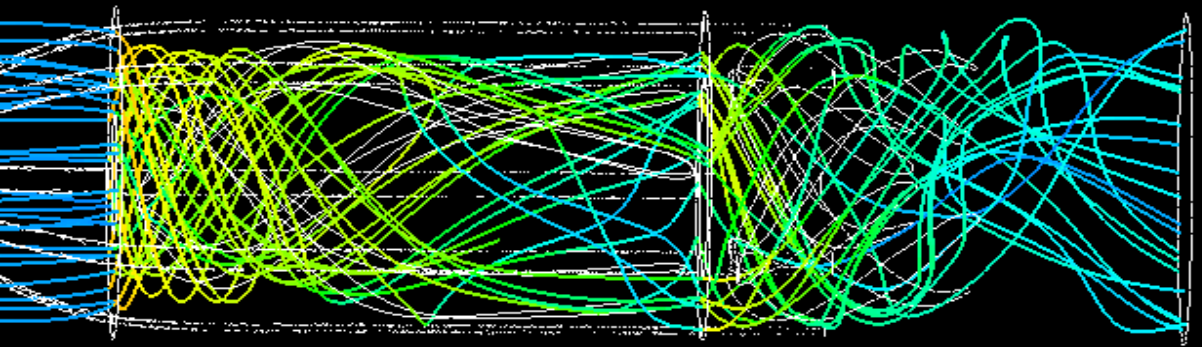
Numerical Estimations: Fluid Stress



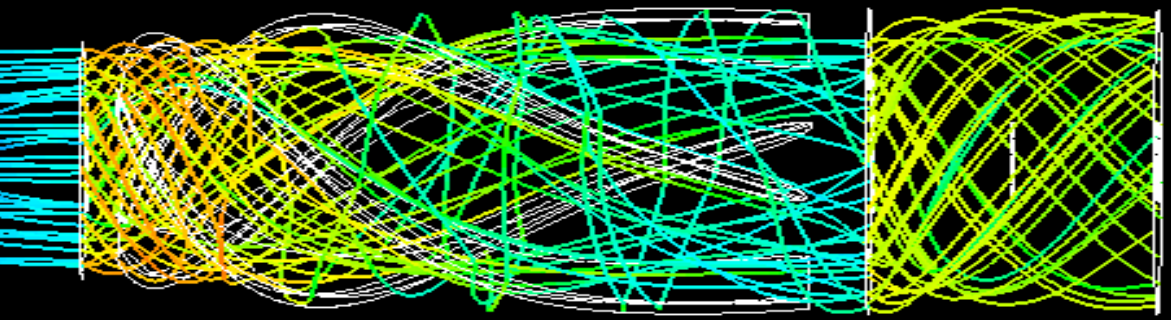
CFD Results



Diffuser Blades



Without Diffuser Blades



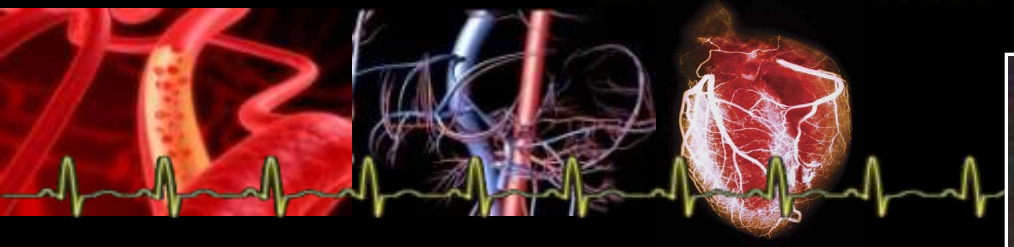
High Velocity

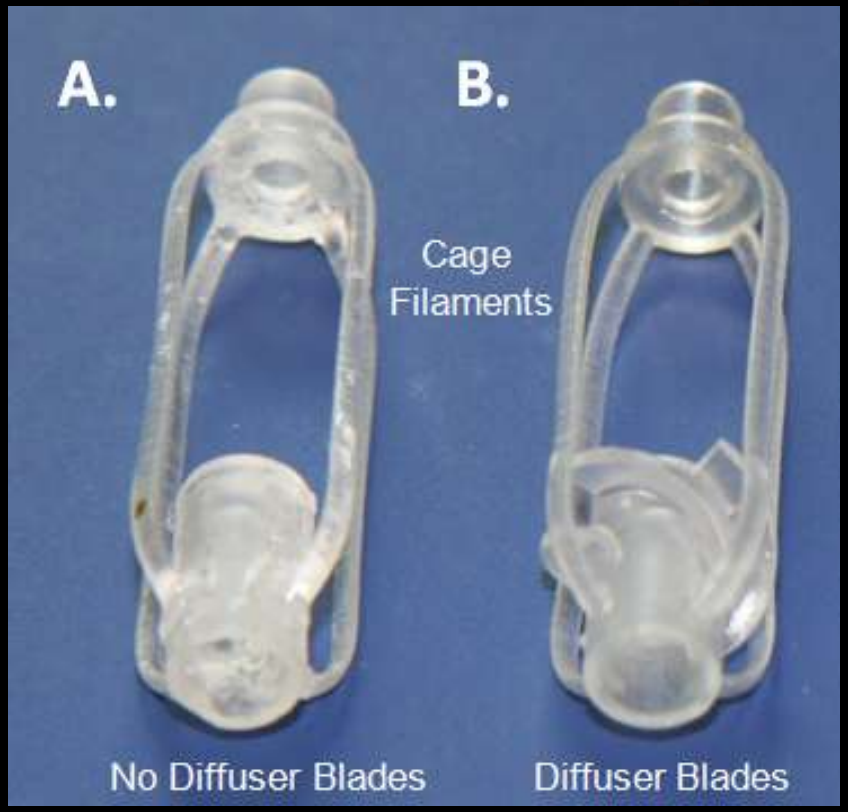
Low Velocity

Diffuser blades redirect flow at outlet and reduce vorticity

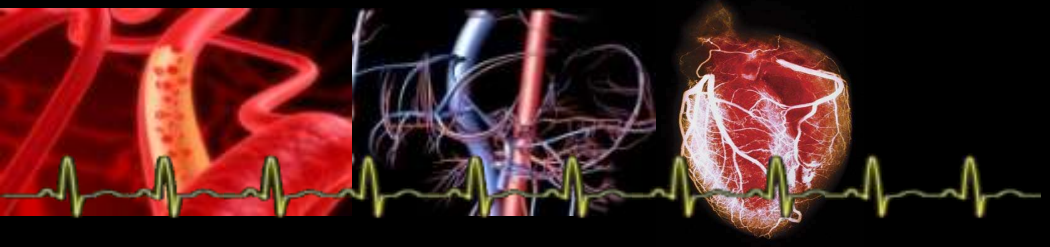
<u>Residence Times:</u>
Mean = 0.10sec
Maximum = 0.22sec
54% of particles < 0.005 sec

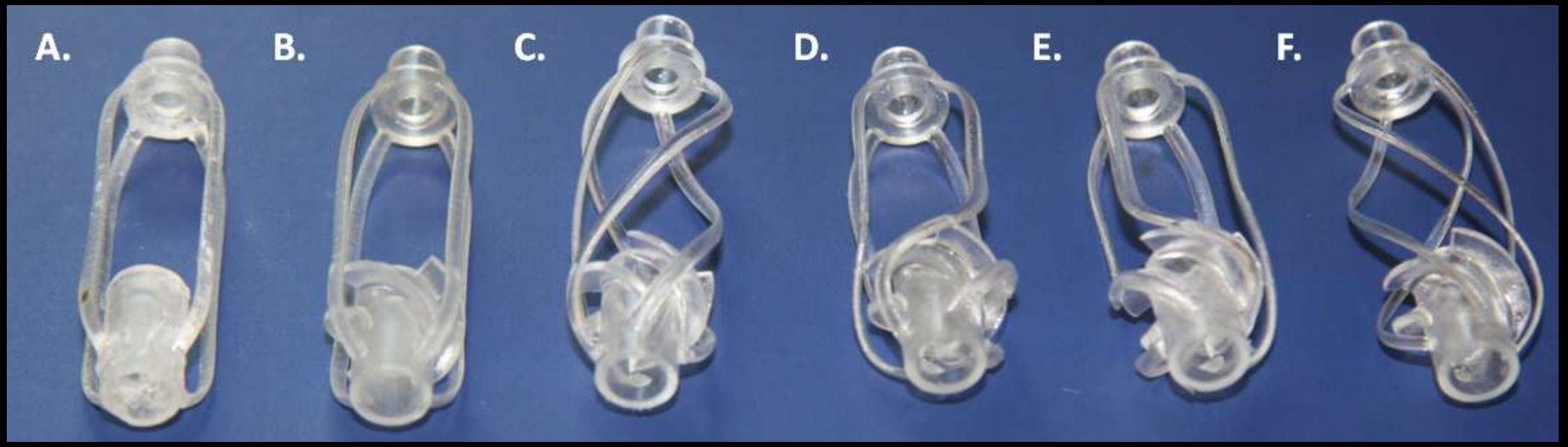
Prototype Design



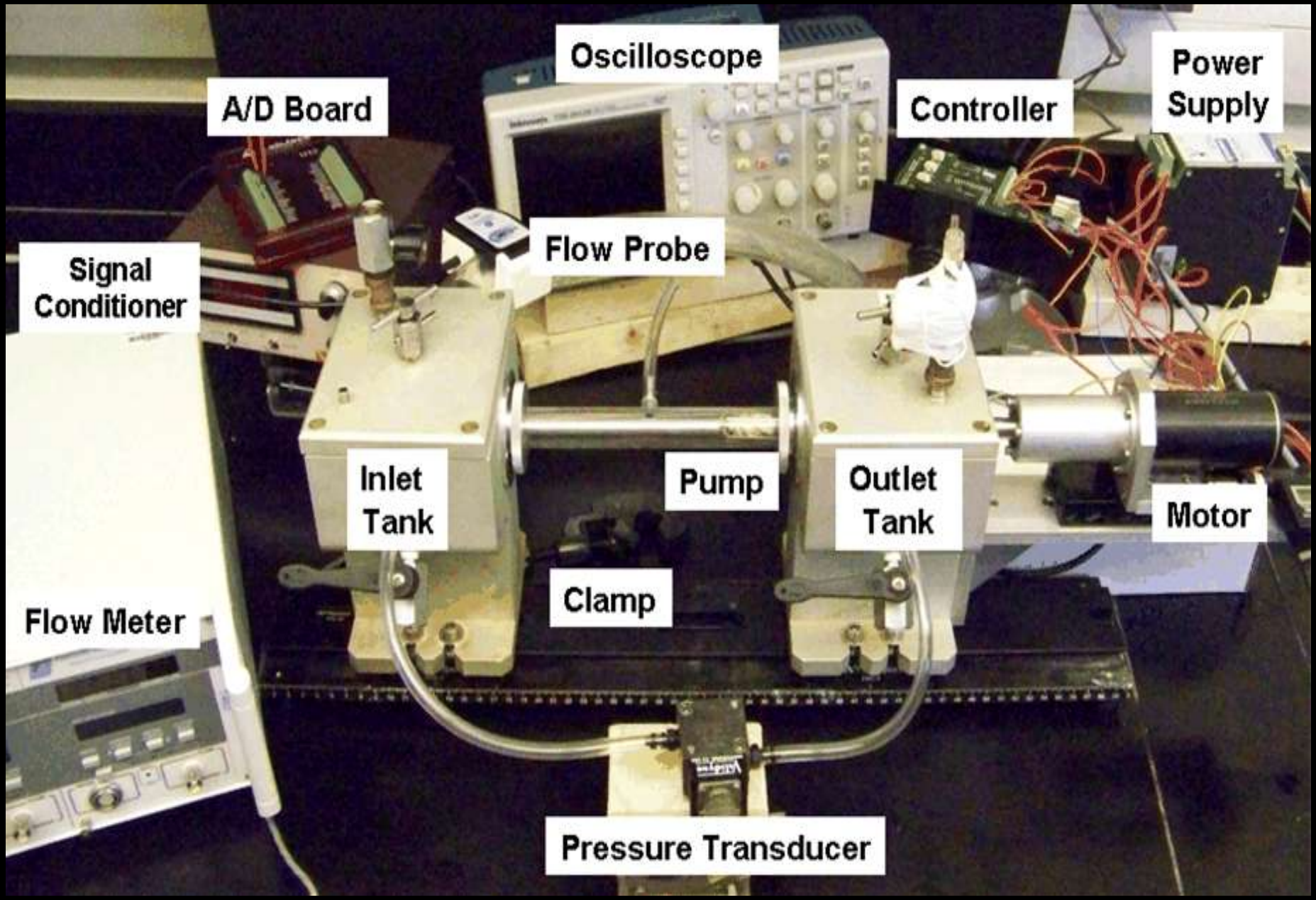


Axial Flow Pump with Protective Cage Designs

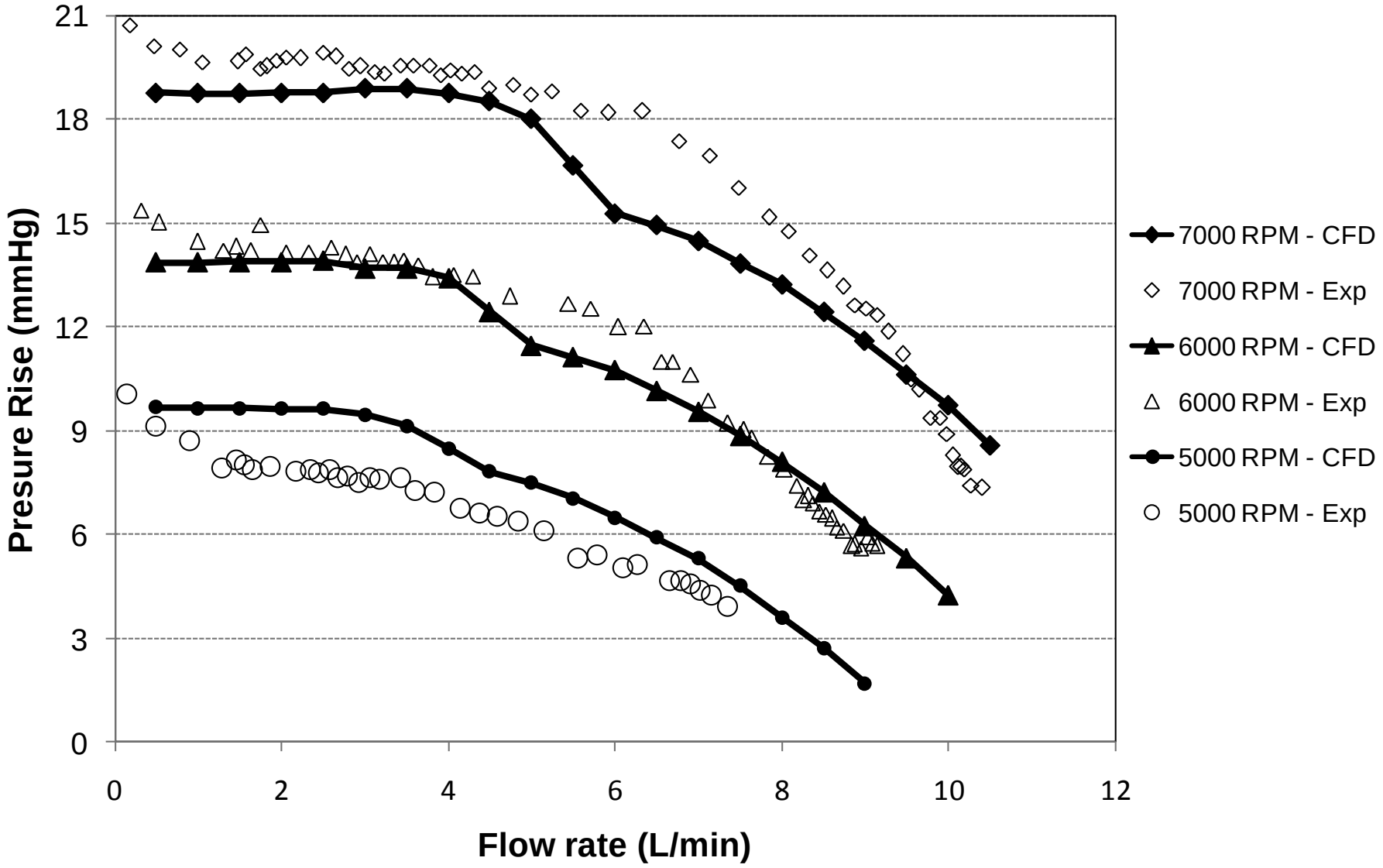




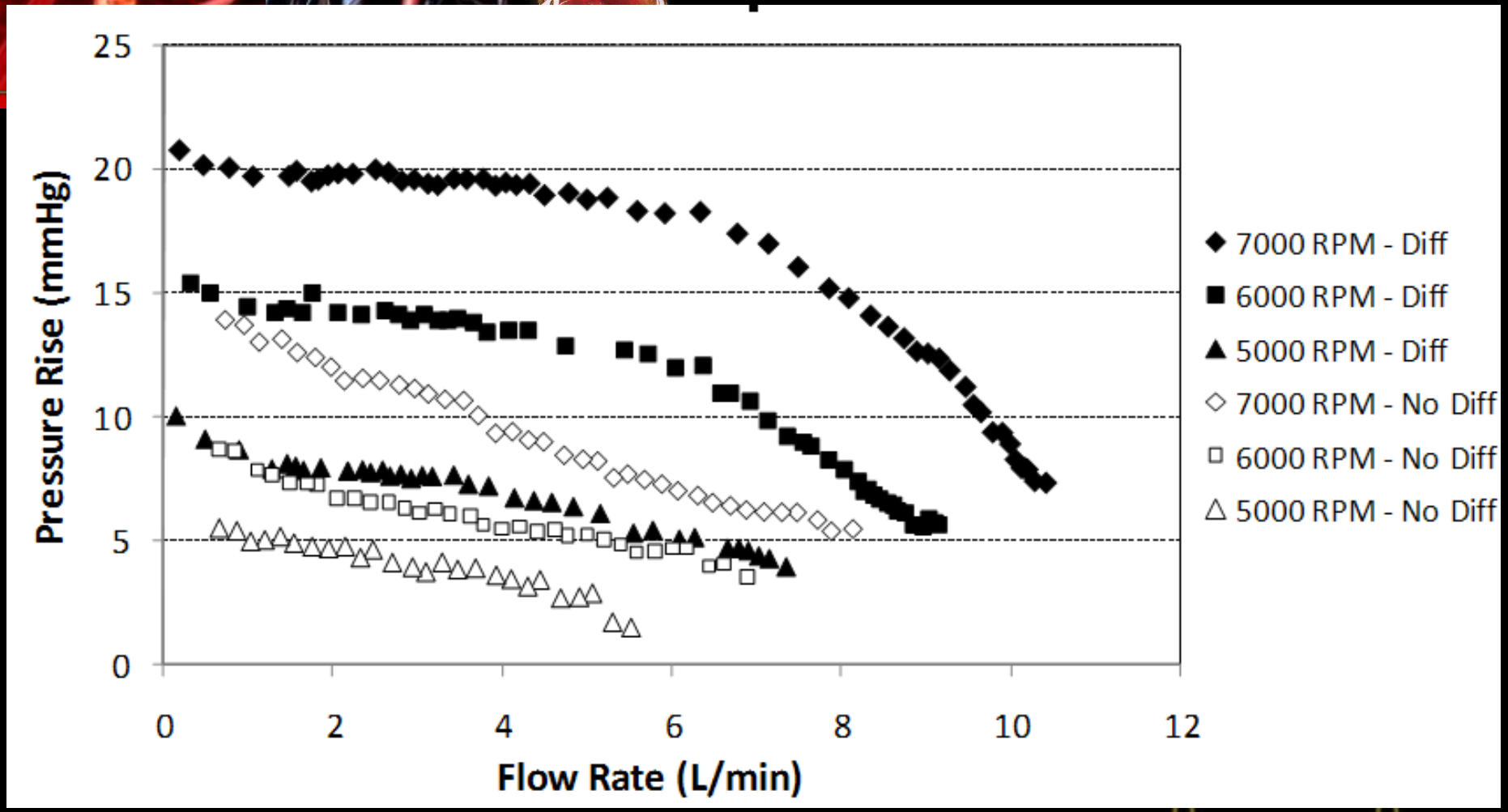
Hydraulic Performance Evaluation



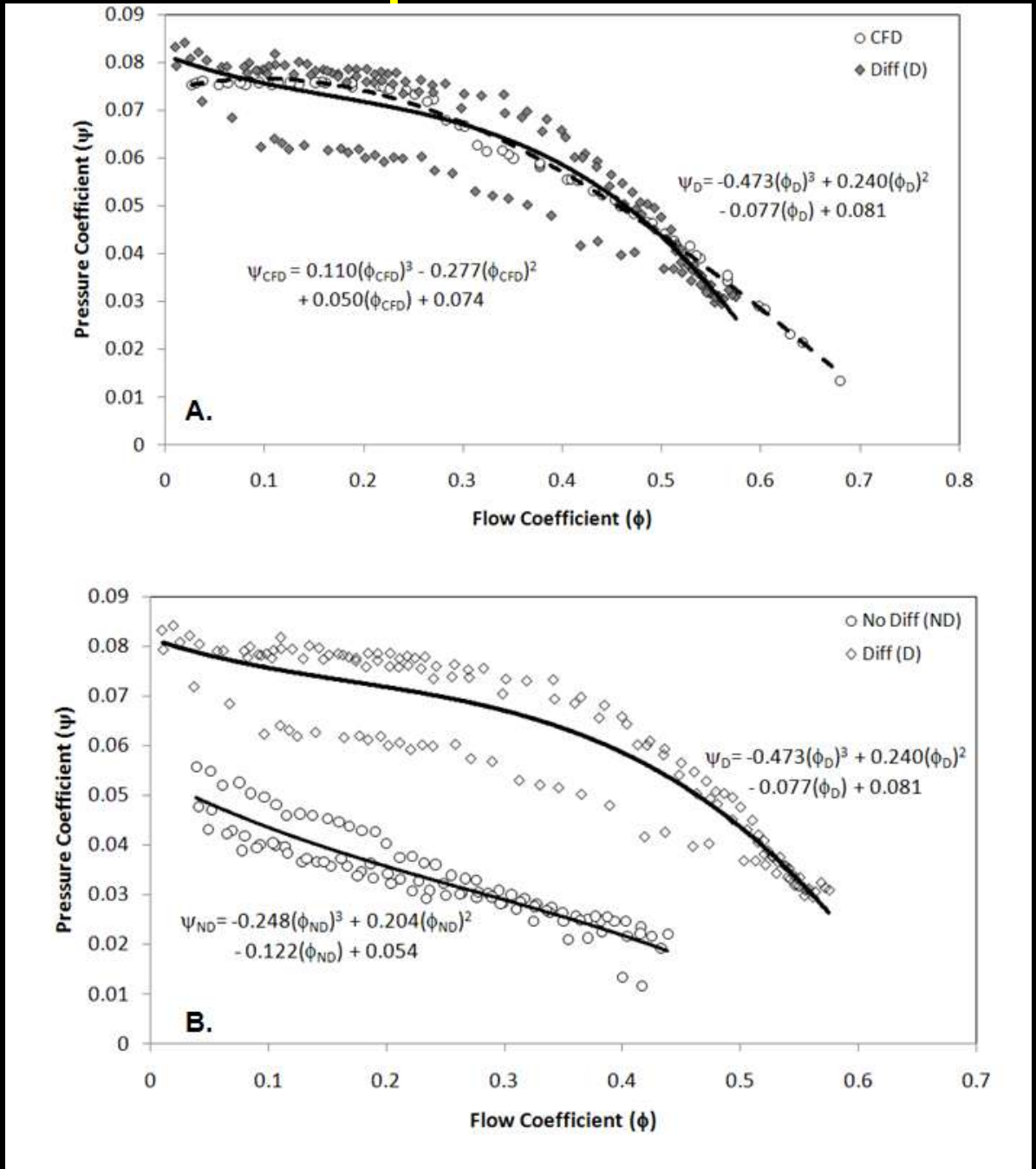
Axial Flow Pump with Protective Cage Designs



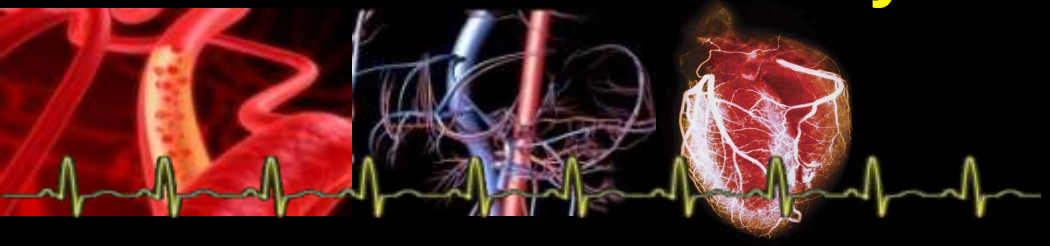
Axial Flow Pump with Protective Cage Designs



Quantitative Comparison – Nondimensional Analysis



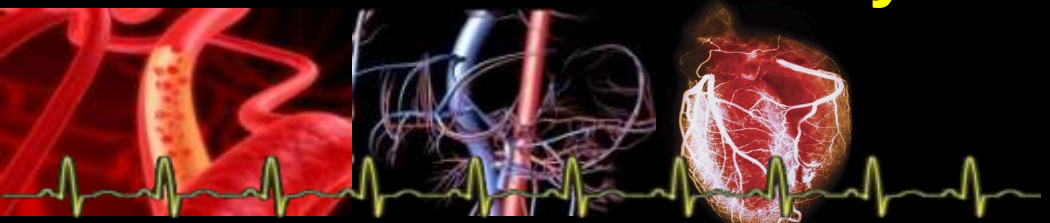
Hemolysis Testing

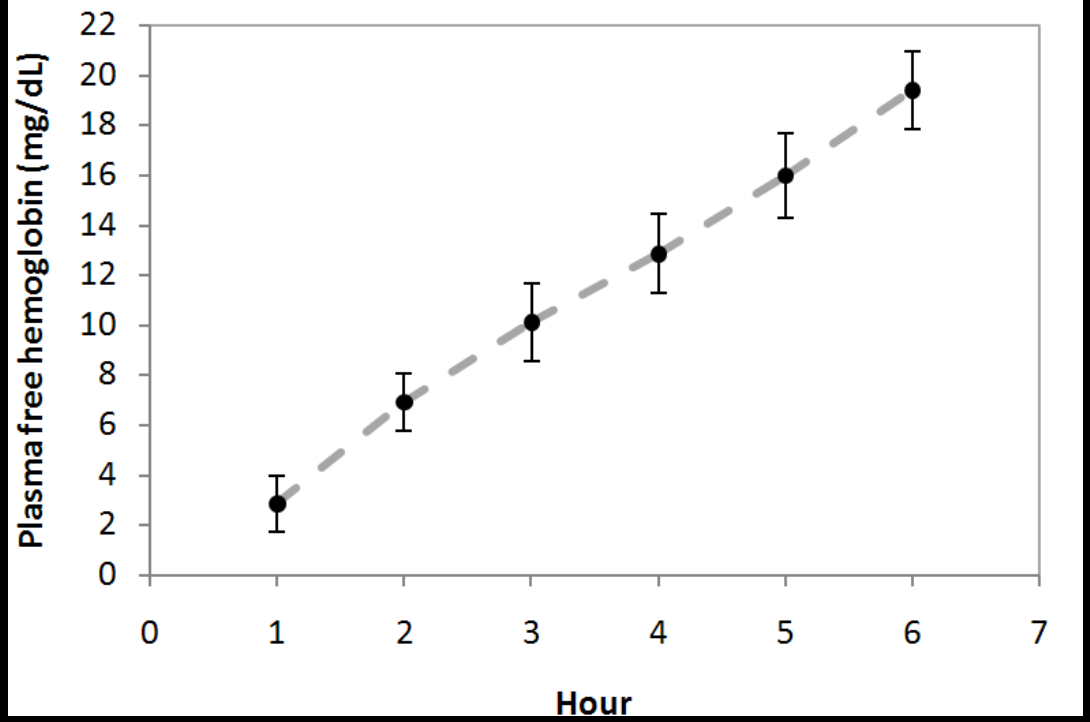


Cell damage caused by blood pump rupture and release hemoglobin into plasma

- Measurable evaluation of blood cell trauma caused by the pump
- ASTM Standards: F1841-97, F1830-97
- Local dairy farm – fresh bovine blood
- Hourly samples for centrifugation
  - Separated plasma layer from red cells
  - Determined *pfHb* and normalized index of hemolysis (N.I.H) level
  - Operating point: 3000 RPM at 3.5 LPM
  - Repeated Experiments: n=6
  - Design objective: N.I.H < 0.01 g/100L

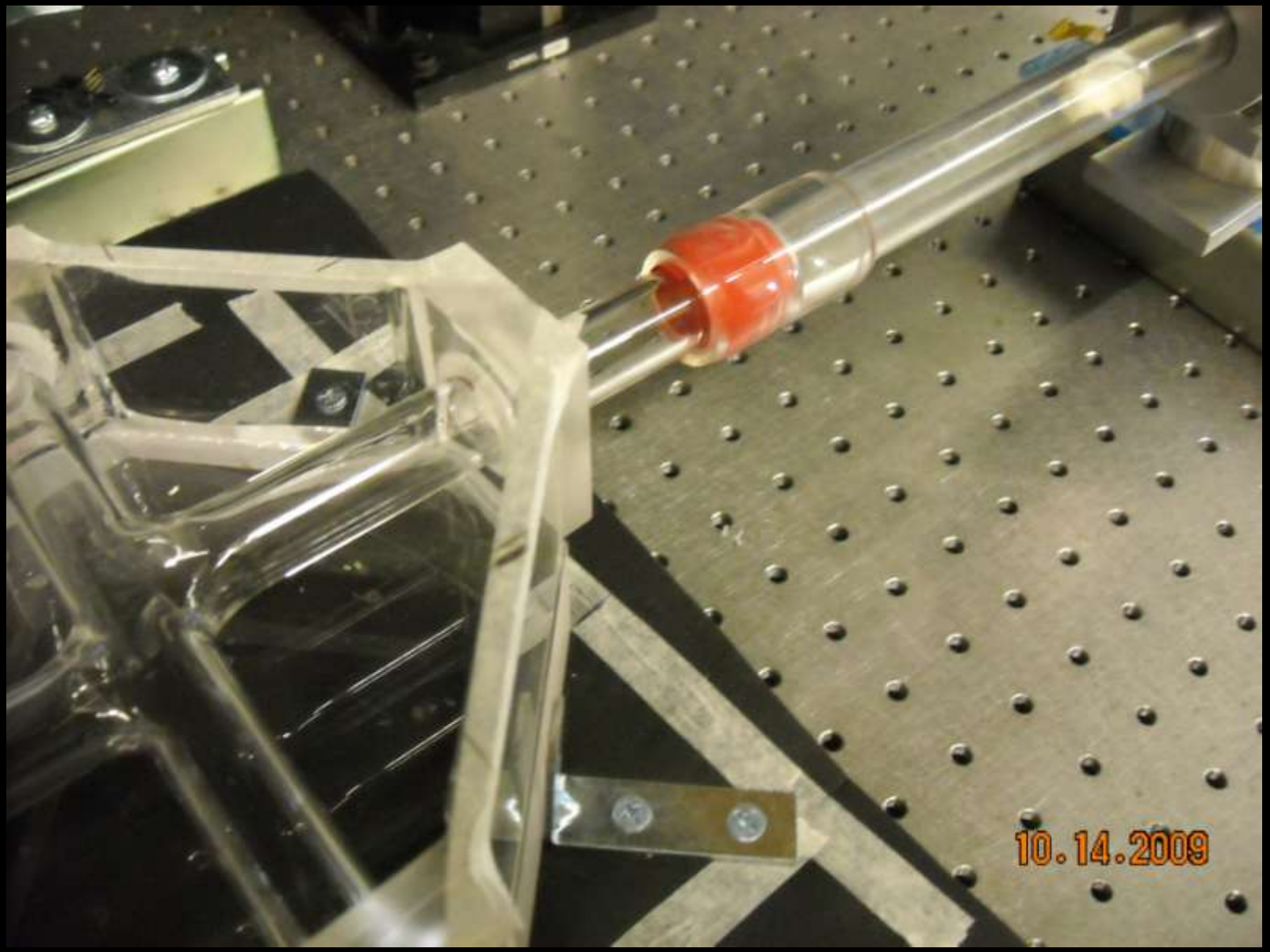
Hemolysis Testing



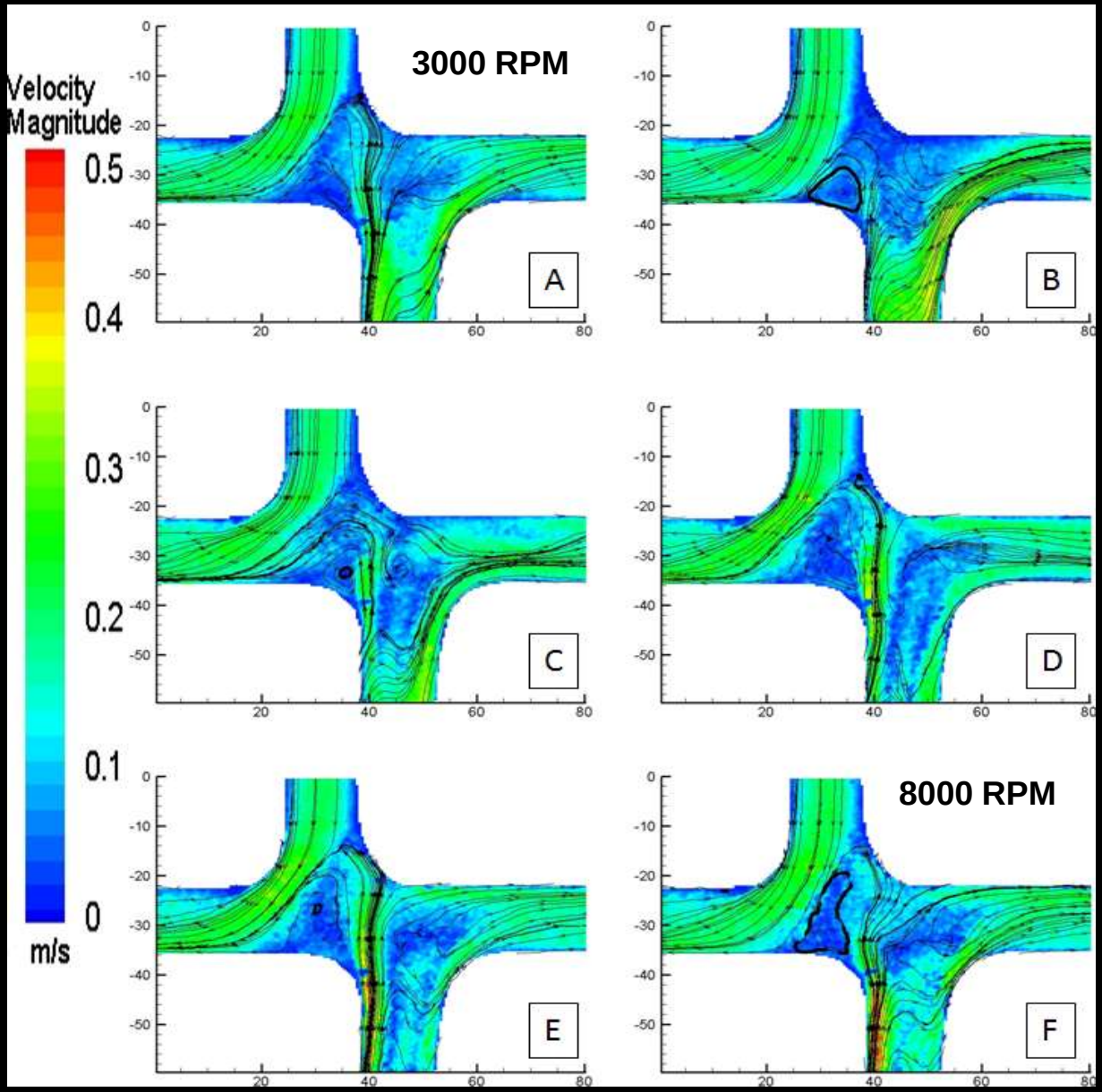


Experiment	N.I.H Value (g/100L)
1	0.0103
2	0.0084
3	0.0089
4	0.0093
5	0.0102
6	0.0099
7	0.0107
Average	0.0097
Maximum	0.0107

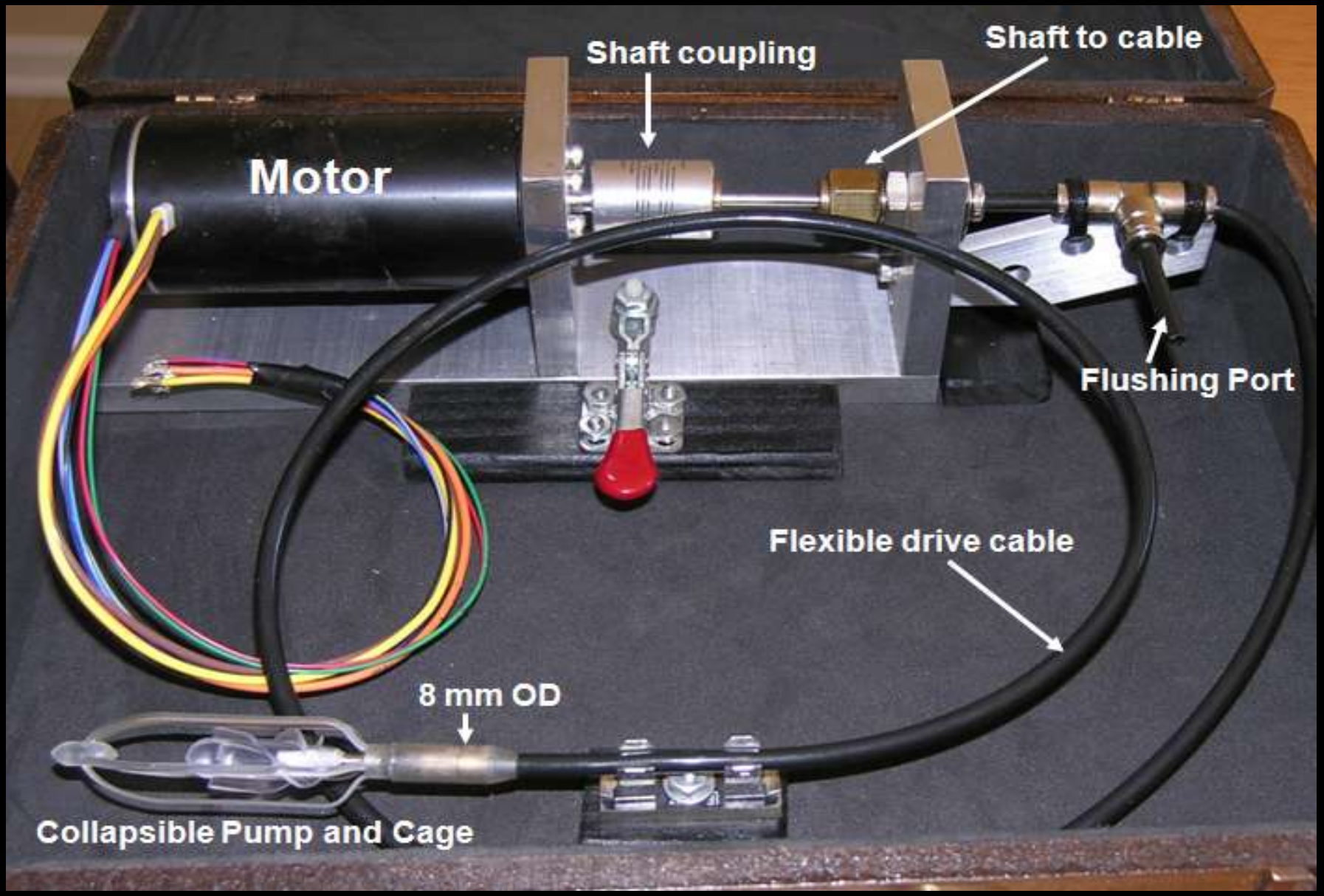
PIV Set-up with Pump in IVC



Experiments for 3 L/min, 40/60 flow split



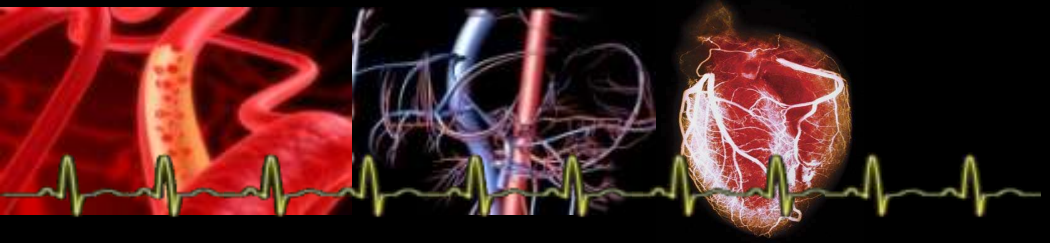
Axial Flow Pump for Acute Animal Studies



Axial Flow Pump for Acute Animal Studies

Parameter	1st Fontan baseline	2nd Fontan Baseline	3rd Fontan – pump fit	4th Fontan – baseline	4th Fontan with pump: 30-min.
Heart rate (bpm)	106	108	100	101	98.0
Systolic blood pressure (mmHg)	82.4	84.3	77.6	89.9	81.5
Diastolic blood pressure (mmHg)	48.8	51.8	40.2	47.4	35.2
Pulmonary arterial pressure (mmHg)	15.2	12.1	10.8	14.7	18.1
Left atrial pressure (mmHg)	6.3	5.2	4.1	5.4	5.9
Central venous pressure (mmHg)	14.8	16.1	14.3	21.3	20.9
Cardiac index (L/min/m^2)	2.66	2.89	2.78	2.52	3.43
Oxygen Saturation (%)	99.7	99.9	99.5	99.6	99.9
Hematocrit (%)	26.2	24.3	27.4	25.3	22.1
pH	7.35	7.44	7.32	7.38	7.26
P_{CO2} (mmHg)	39.2	36.9	42.0	36.3	38.0
P_{O2} (mmHg)	328	334	281	209.1	346
HCO_3- (mmol/L)	27.4	25.6	23.9	26.8	23.5
Base excess (mmol/L)	-0.6	0.3	-1.4	1.3	-1.1

BioCirc Research Lab at VCU



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Thank You
…questions?

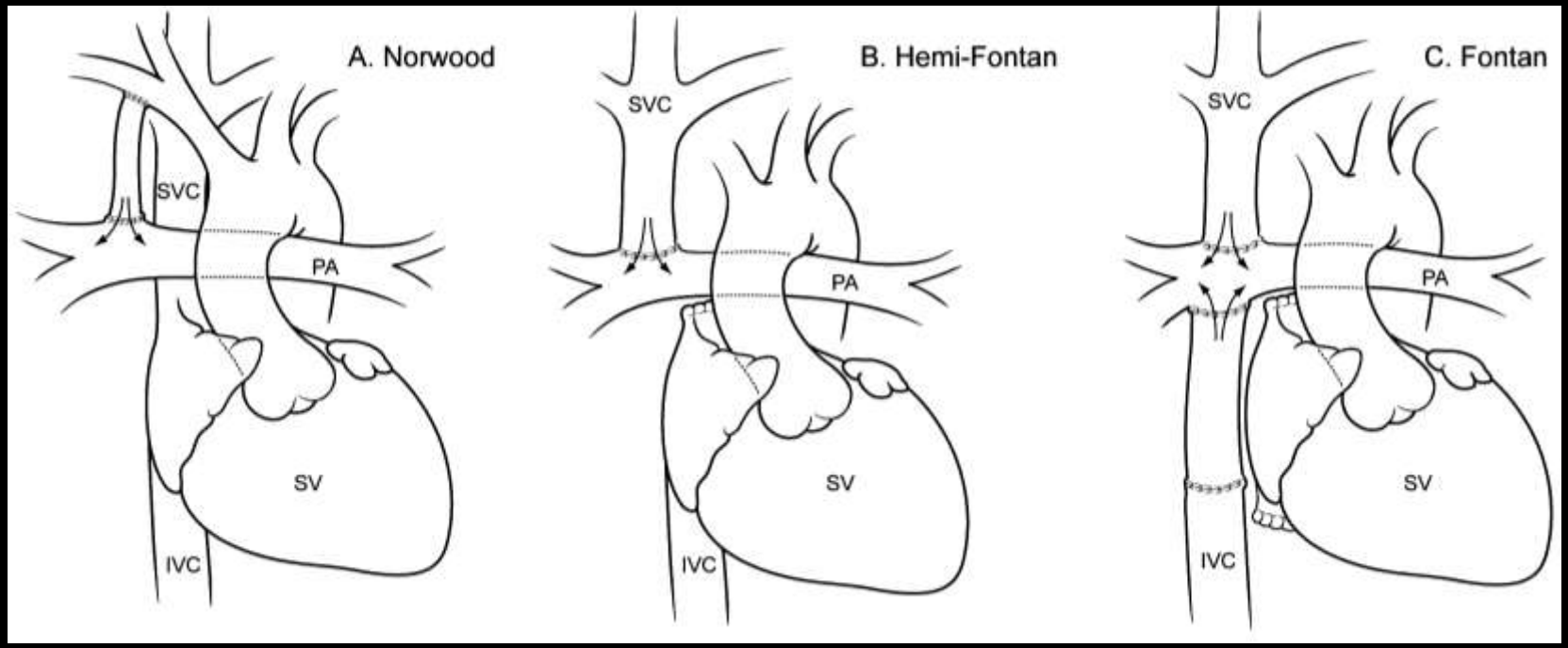

Figure 1. Staged surgical repair of functional single ventricle. **A.** Stage-1 Norwood repair. **B.** Stage-2 Hemi-Fontan repair. **C.** Stage-3 Fontan completion. **SV**, single ventricle; **PA**, pulmonary artery; **SVC**, superior vena cava; **IVC**, inferior vena cava