Fontan Assistive Device Concept

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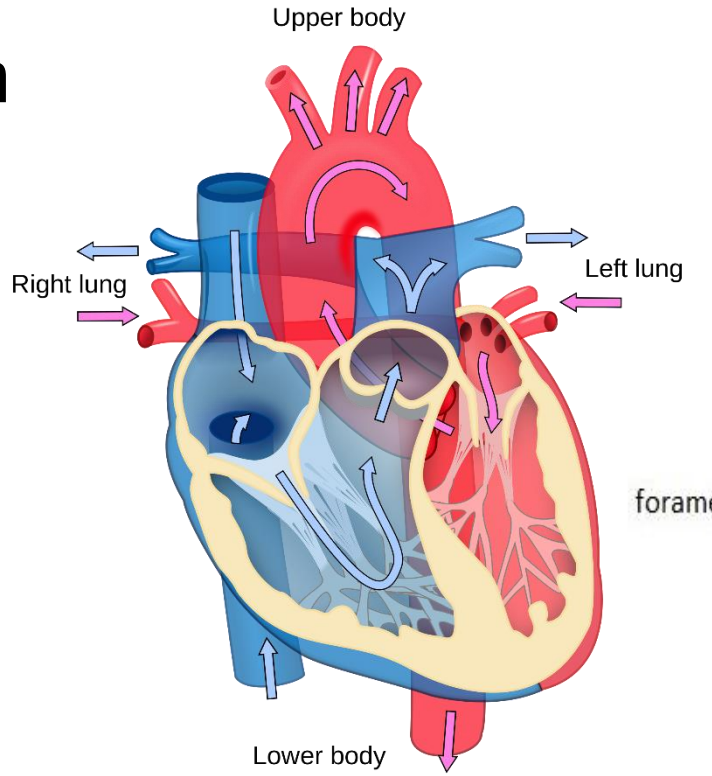
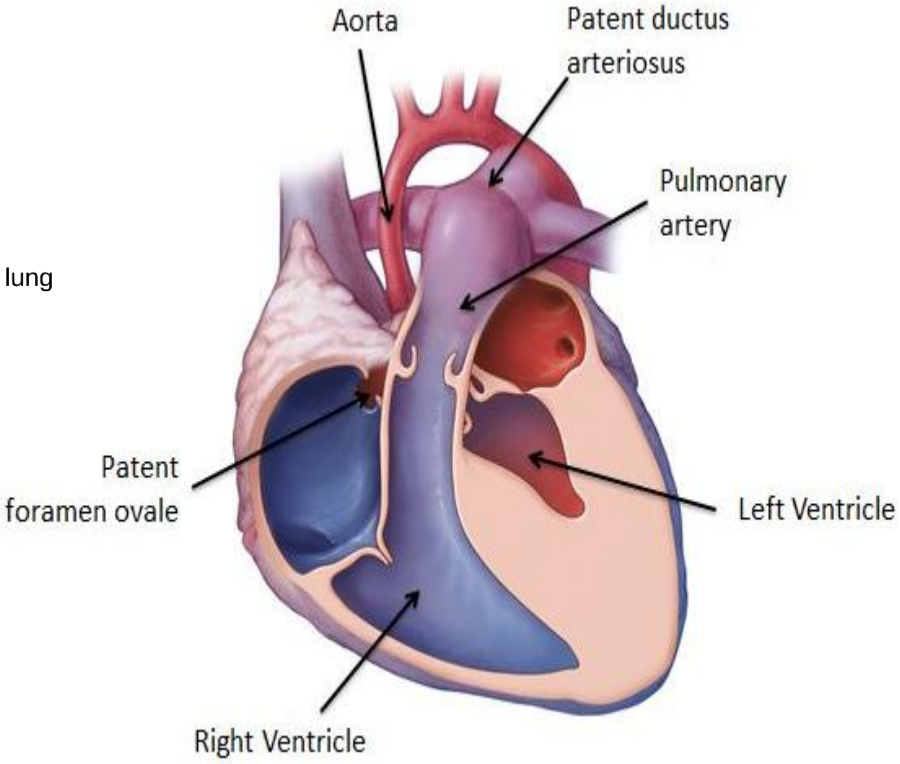
Agenda

- Hypoplastic Left Heart Syndrome (HLHS)
  - Background
- Concept Design
- Experiment
  - Setup
  - Results
- Limitations & Improvements
- Conclusions

HLHS - Background

- Congenital Heart Disease
  - 2 in 10,000 live births
  - Cause still unknown
- Underdevelopment
  - Left Side of Heart
    - Aorta
    - Left Ventricle
    - Mitral Vales



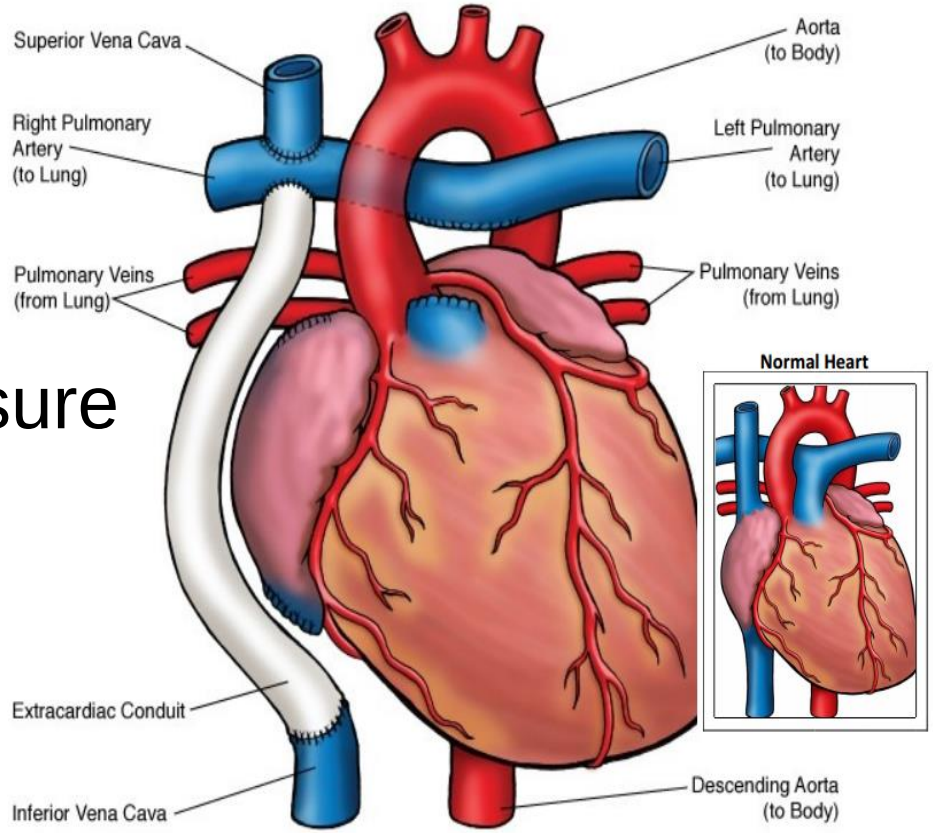


HLHS - Treatments

- Curative
  - Heart Transplant
    - Lack of availability
    - Not offered in many countries
- Palliative
  - 3 Surgical Operations
    - Norwood procedure (Immediately after Birth)
    - Bi-Directional Glenn shunt procedure (4 – 6 months)
    - Fontan Procedure (4- 6 Years)
      - Extracardiac Fontan

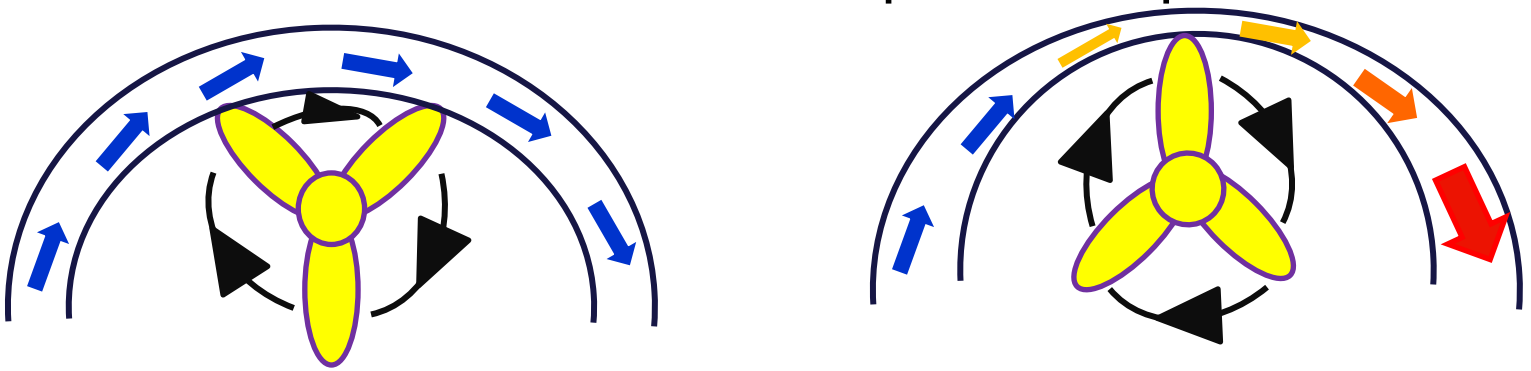
HLHS – EEC Fontan

- Venous Return
  - Disconnected from the heart
    - Flow diverted through a conduit
    - No pulsatile assist
  - Flowrate to lungs dependent on pressure
    - Position of Patient
    - Activity level
  - Assistive Device
    - Induce pulsatile venous return
    - Reduce side effects (Pleural Effusion)



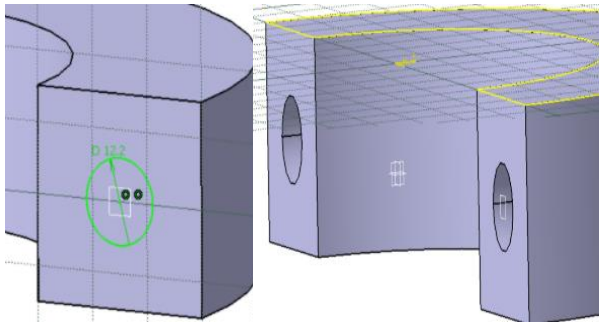
Concept Design

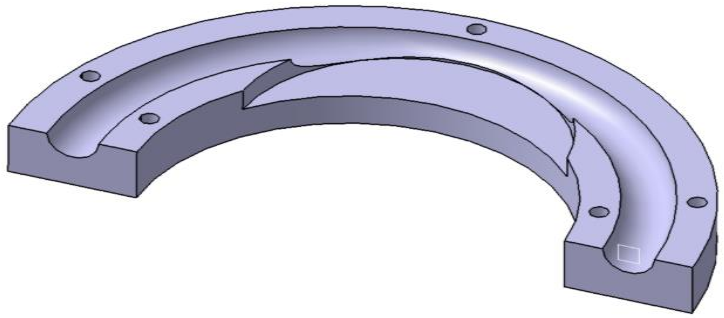
- Radial Pulsatile device
  - Semi-circular conduit Housing
  - Window exposing a conduit section
    - Progressively compressed and released
    - Tri-bladed rotor
    - 50% reduction in the diameter at peak compression



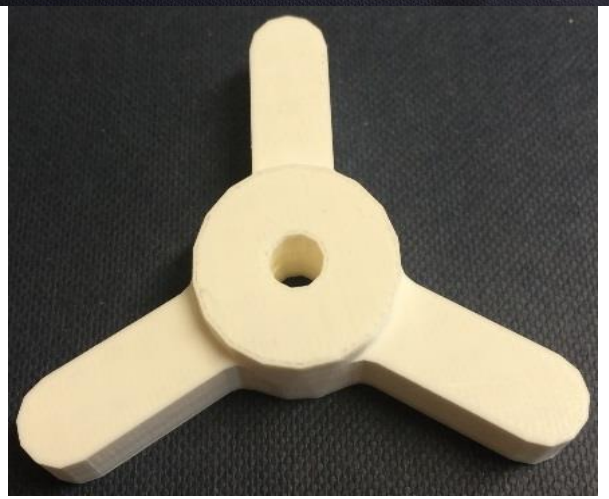
Concept Design

- Conduit Housing

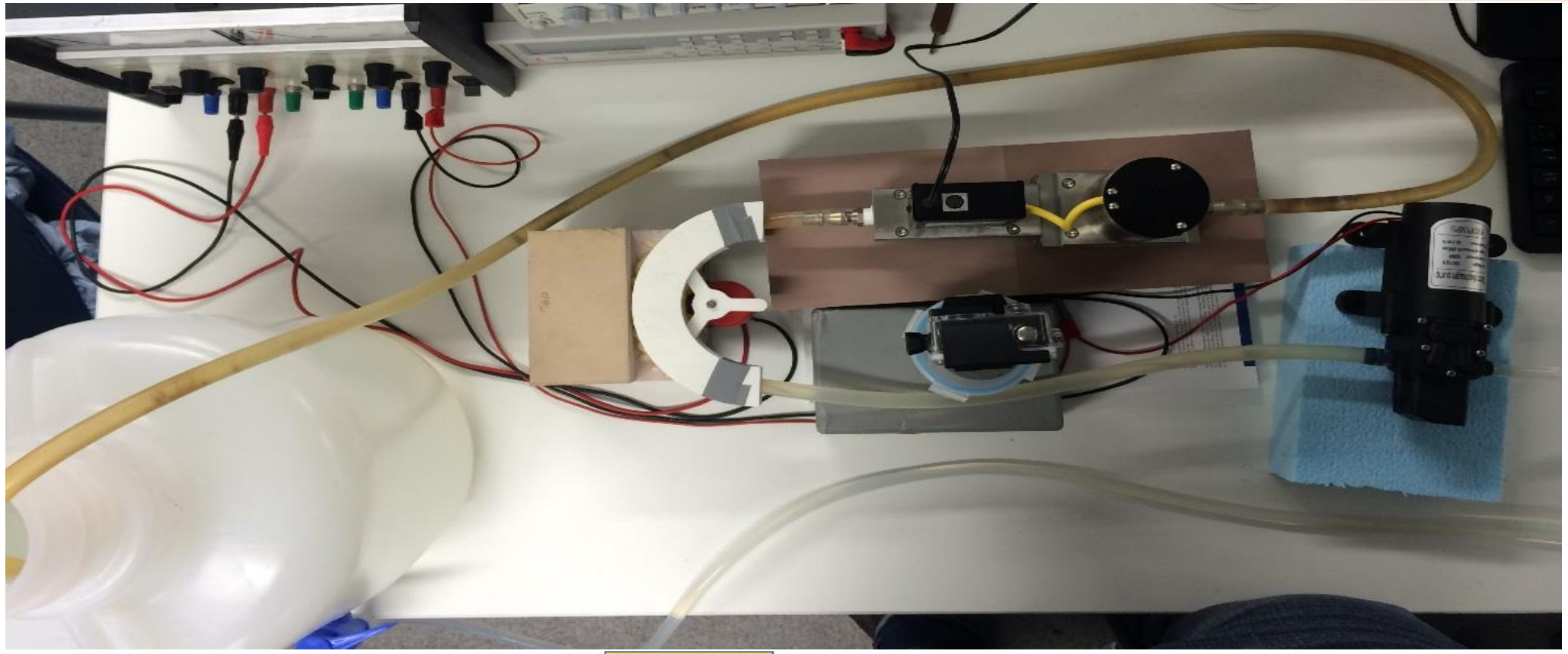


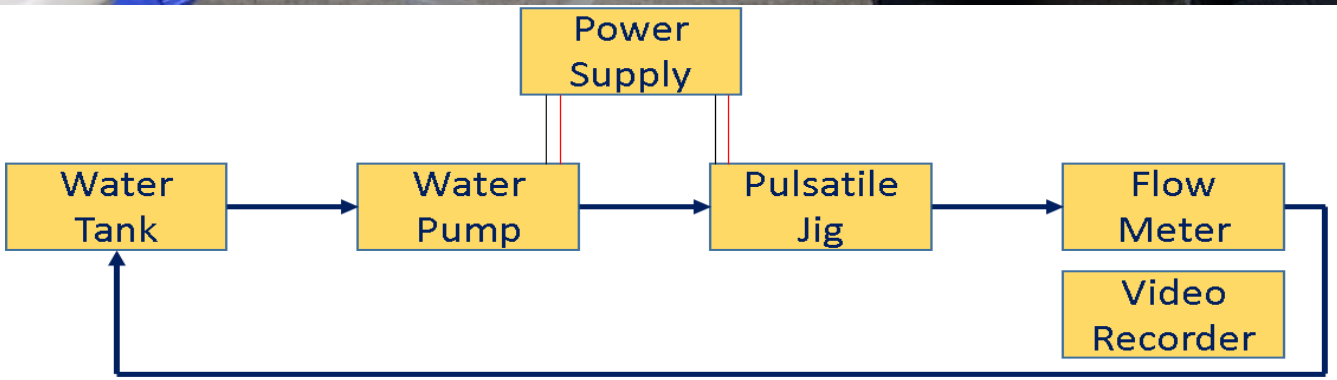


- Rotors
  - 3 Blades
  - Spaced at 120º apart
    - One point of restriction
- Size
  - Not relevant : theoretical testing
  - Tube groove designed to have no slack
- Manufacturing
  - 3D Printed
  - Two part design



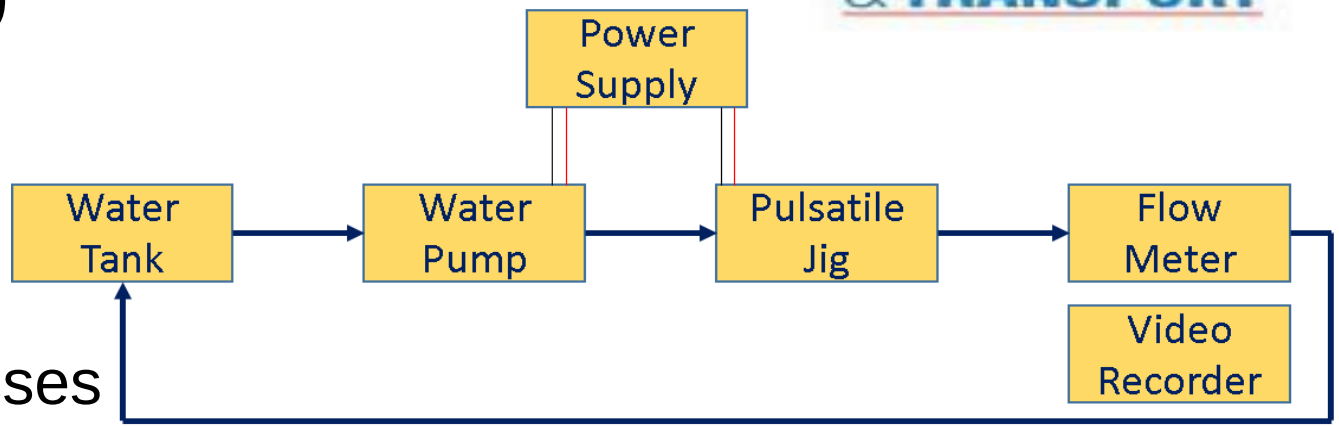
Experimental Setup

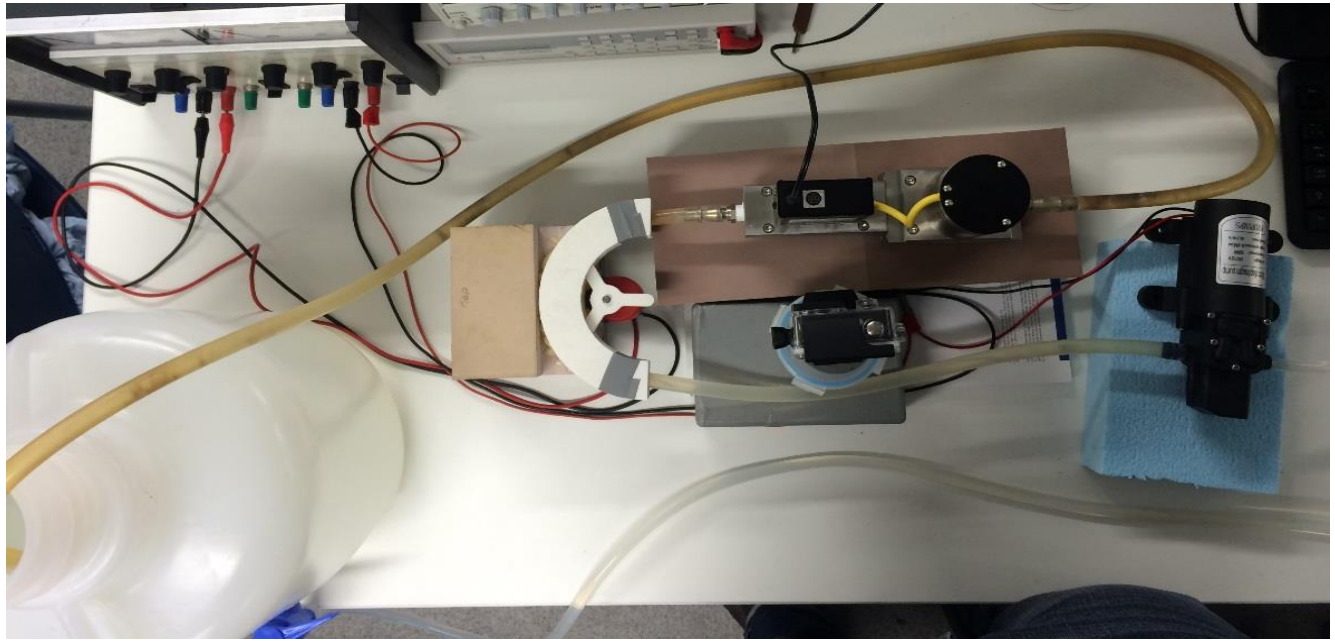




Experimental Setup

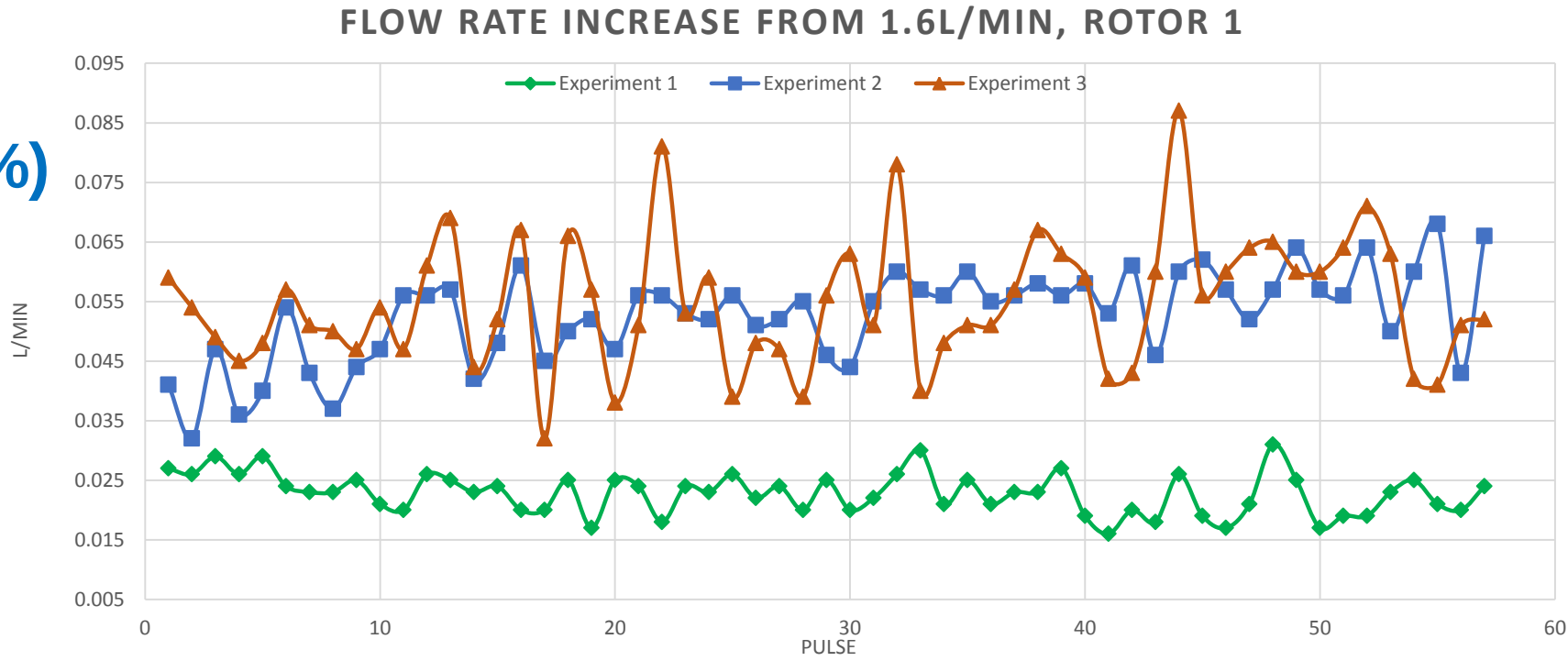
- Series Loop
- PVC Conduit
  - Positioned to reduce minor losses
- Jig Base
  - Housing glued on
  - Provides Support from rear
- Rotary motion
  - DC Motor
- Blood flow
  - Using water
  - 1.6 L/min





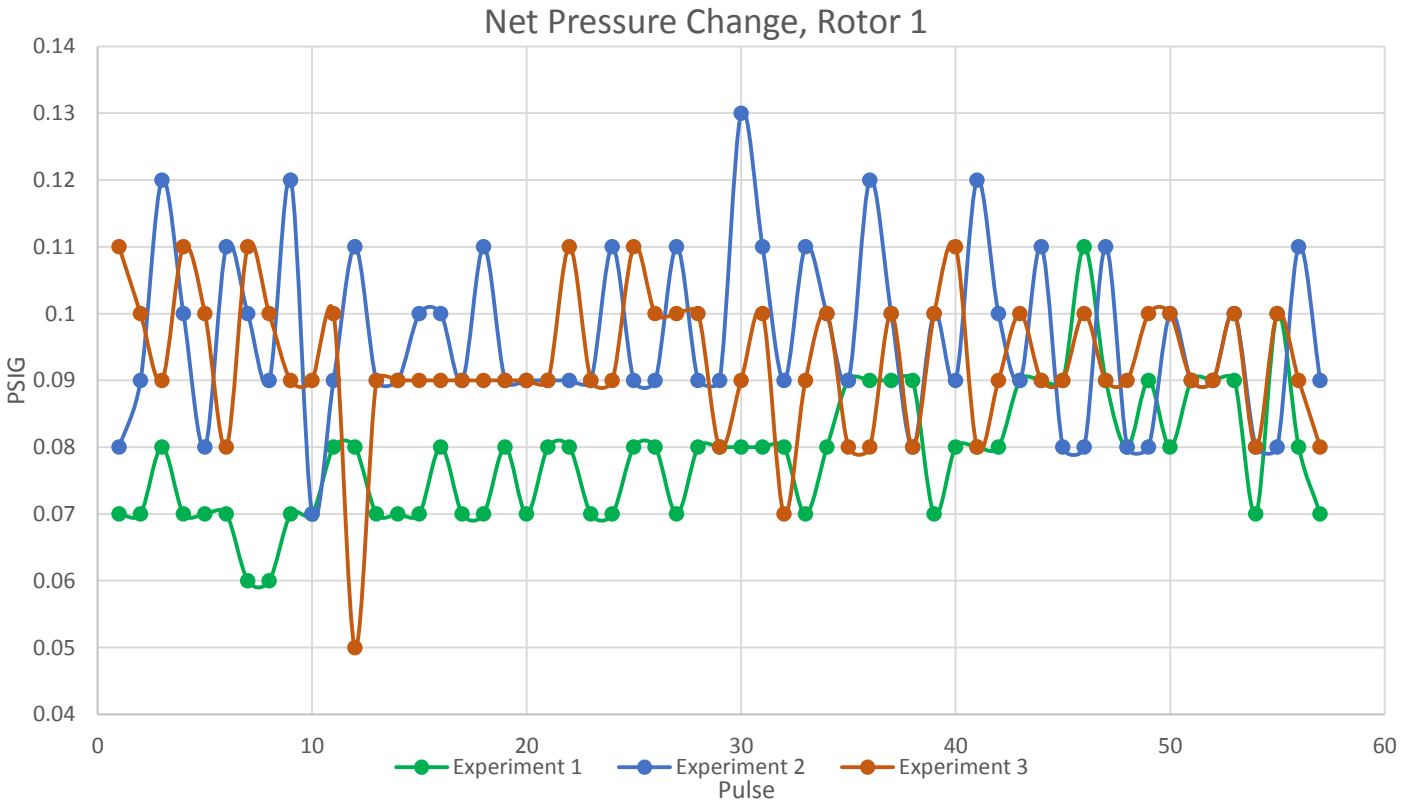
Experimental Results - Flow

- Data for 57 pulses
- Experiment 1 is an outlier
  - Conduit Compression moved the housing
- Flow Increase,
  - **0.054 L/min (3.4%)**
- No benchmark
- Previous development
  - Increase of 10mL/min
    - Shiraishi et al. 2011 and Yamada et al. 2013

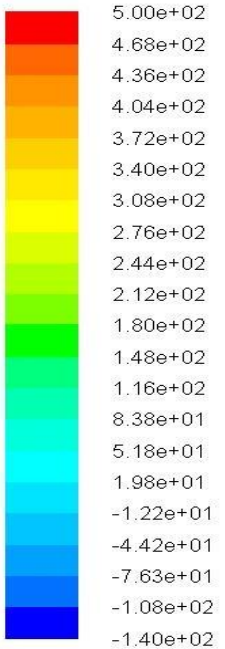


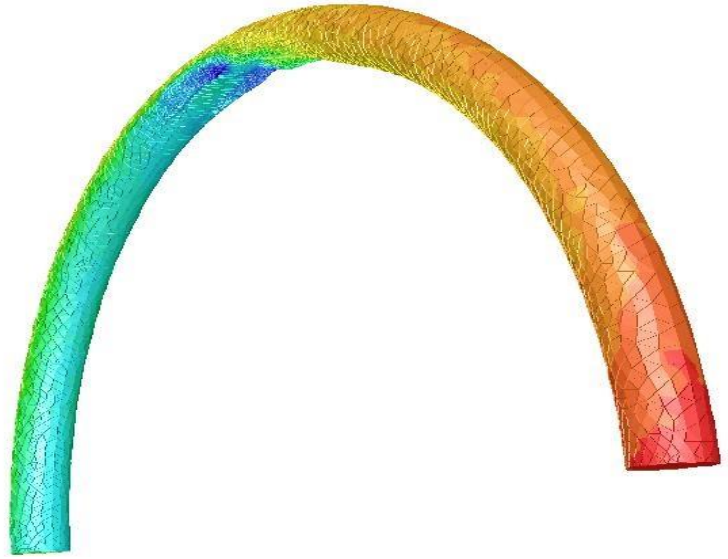
Experimental Results - Pressure

- Data for 57 pulses
- Experiment 1
  - Concurs to 2 & 3
  - Has to be ignored for fairness
- Net pressure increase
  - 0.0945psig (651.6 Pa [1 d.p])
- Current Benchmark
  - 2-5 mmHg (VanderPluym et al. 2014)
  - 651.6 Pa = 4.89 mmHg



Experimental Results - CFD

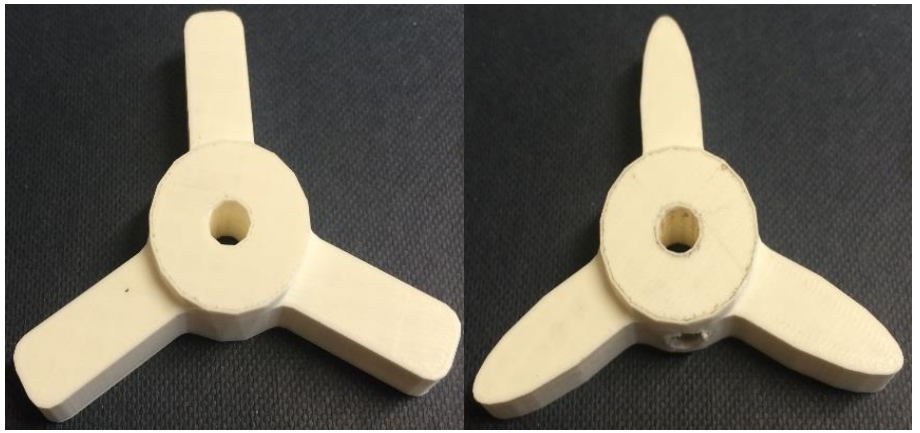




- CFD result comparison
  - Maximum pressure change
    - 500 Pa
  - Measured at the housing exit
- No Flow comparison
  - Steady State analysis
- Pressure variation of 151Pa
  - 23% difference to experiment
  - Can be attributed to flow meter inlet length (+68mm)
  - The model is not refined
- Jig can be validated
  - quasi-static, peak compression scenario

Limitations & Improvements

- Conduits
  - PVC tube used, Thick wall diameter
  - Use PTFE or Gore-Tex®, represents reality
- Theoretical test
  - Requires testing with smaller housing
  - Smaller motor
- Blade tip profile
  - Tested using a semi-circular profile.
  - Rate of change may vary with other profiles
- CFD
  - Diameter reduction set at exactly 50%
  - Compression profile was estimated
  - FSI : replicate the experiment
    - Modelling fluid interaction with conduit walls
    - Rotor interaction between the conduit



Conclusions

- Designed, Manufactured and Tested
  - Radial Pulsatile device
  - Observed positive effect on flow
- Concept at this moment in time
  - Further research required
    - Size
    - Synchronisation with heart
- Improve Quality of Life
  - Minimising side effects
  - Reducing mortality rates

Thank you!

any questions?