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Development of a PSU Child Centrifugal Blood Pump

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PennState Health PennState College of Medicine

Objective

❑ Background

- ~14,000 pediatric heart failure-associated hospitalizations occur annually in the U.S. with the waiting list mortality of ~17% (Almond et al. Circulation. 2009).
- Ventricular assist devices (VADs):
  - Provide hemodynamic support in patients awaiting heart transplantation
  - More time to find a suitable donor and
  - Supports rehabilitation and improves transplant outcomes
- In pediatrics, VAD support is even more important:
  - Scarcity of donor hearts
  - Complications of congenital heart disease
  - ~1/3 of pediatric heart transplants are bridged by a VAD
- For larger children and adolescents (>30 kg), adult VADs can be successfully used:
  - Anatomic fit and pump outputs are not ideal.
- For infants (<10 kg), Berlin Heart EXCOR® (Berlin Heart GmbH)
  - Pulsatile Paracorporeal Pump
  - FDA approved for long-term support
  - Thromboembolism and Pump Failure (cf. adult devices)

https://www.berlinheart.de/en/mediaroom/press-releases/press-release/excorr-pediatric-receives-premarket-approval/

Objective - Cont'd

❑ Significance

- Design improvement in VADs over a decade.
- Yet, pediatric VAD support for young children is still severely limited:
  - Lack of devices suitable for young children (<10 years, 10 – 30 kg) for both short- and long-term support.
- Heartware HVAD (Medtronic)
  - Smallest approved adult VAD, had been used in pediatric patients (median age 12.9 years; median weight 41.8 kg).
  - Medtronic announced in June 2021 that the HVAD will no longer be available; elevated risk of stroke and pump stoppage.
- HeartMate 3 (Abbott Laboratories, Abbot Park, IL)
  - Larger than the HVAD
  - Limited to patients > 30 kg
- Currently, no long-term implantable devices for pediatric patients between 10 and 30 kg (waiting list mortality of ~17%).

Objective - Cont'd

Goal

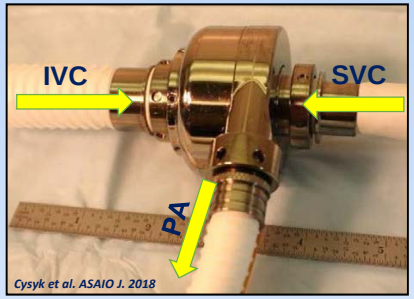
- Penn State Child Pump - small, durable, fully implantable
  - Continuous-flow Centrifugal blood pump
  - 10 - 30 kg, 1 - 8 years of age (BSA 0.5 - 1.2 m^2)
  - Mean cardiac output from 1.5 - 3.5 liters/min
  - Remove the risks of device size mismatch running at suboptimal operating conditions

Methods

- **Prototype PSU Child Pump**
  - To be designed/Built based on our previous experiences on adult ***cf-LVAD*** and ***cf-RVAD***
  - Advantages of a Centrifugal Pump (cf. axial pumps)
    - ***Higher pump efficiency*** – longer battery life
    - ***Relatively flat H-Q curve*** – less susceptible to pressure change over cardiac support; physiologically more stable
    - ***Low fluid stress*** – less blood trauma (hemolysis, thrombosis, bleeding)

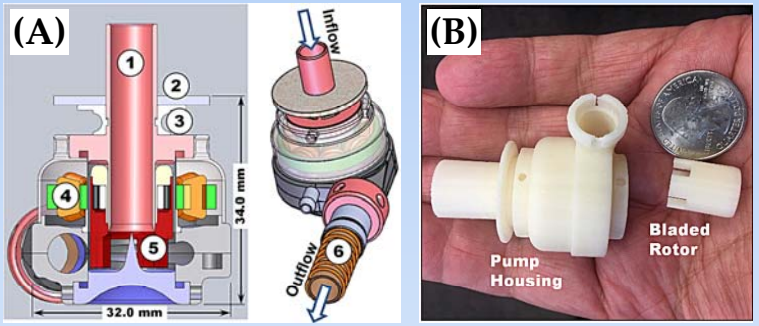
(A) Adult PSU cf-LVAD

(B) Adult PSU cf-RVAD



Methods - Cont'd

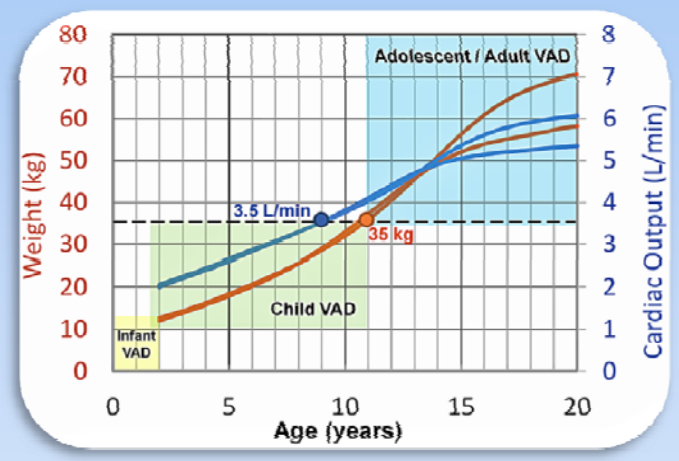
- **Virtual Fit Study**
  - Tailored to the Average Chest Size of Targeted Patient Population.
  - Pump STL model in Virtual Reality (VR) Space.



***(A)** PSU Child VAD; 1: inlet cannula (7 mm), 2: sewing cuff (Dacron felt), 3: cuff clamp, 4: stator assembly, 5: 4-bladed rotor, 6: outlet GORE graft (8 mm). **(B)** 3D printed model.*

Methods - Cont'd

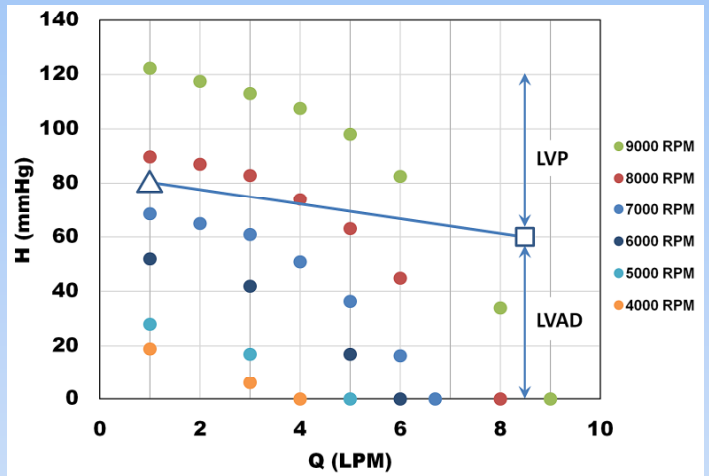
- **Physiologic Requirements**
  - *Implantable*
  - *Ambulation*
  - *Hospital discharge*



Bodyweight and cardiac output versus age based on 50th percentile data and cardiac output (Connell et al. ASAIO J. 2007). The curves diverge for males and females at approximately 14 years of age.

Methods - Cont'd

- **In-Silico Performance (H-Q)**
  - **Operating Requirements:**
    - **Normal Heart (no LVAD)**
      - Mean Diastolic and Systolic Flows ~ 0 - 10 LPM
    - **Heart Failure w/ LVAD**
      - Minimum – Maximum Flow of 1 – 8.5 LPM
    - **CFD simulations**
      - Large Eddy Simulations (LES)
      - Dynamic Smagorinsky SGS
      - 1 – 8.5 LPM: systolic and diastolic mean flows for the largest anticipated patients



CFD simulations of H-Q operating points at pump speeds of 4000 to 9000 rpm. The open triangle indicates the diastolic operating condition, and the open square indicates the systolic operating condition where the native LVP is assumed to generate 60 mmHg.

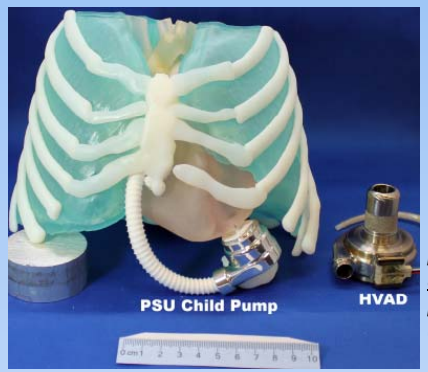
Methods - Cont'd

- **In-Vitro Testing on a Custom Mock Flow Loop**
  - In-vitro hemolysis was evaluated under four conditions:
    - Condition 1 - 8300 RPM, 3.5 LPM, ΔP = 60 mmHg
    - Condition 2 - 8200 RPM, 5.0 LPM, ΔP = 20 mmHg
    - Condition 3 - 8400 RPM, 3.2 LPM, ΔP = 70 mmHg
    - Condition 4 - 9850 RPM, 5.0 LPM, ΔP = 80 mmHg

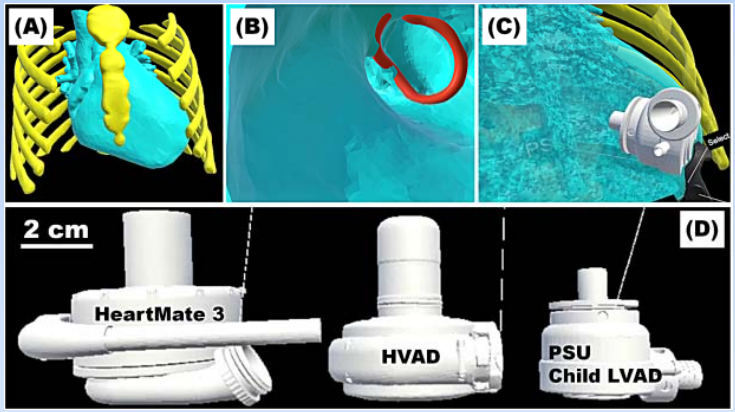
Results

❑ Virtual Fit Study

- **Fig 1**. PSU Child VAD Placement
  - 3D printed reconstruction of the chest
  - 5-year-old male, 19 kg, BSA 0.79 m^2
- **Fig 2**. Immersive Virtual Environment: HeartMate 3, Heartware HVAD, and PSU Child Pump.
  - ***Criteria for fit testing***: Inflow cannula that leaves enough distance from the AV valve annular plane to not to interfere with the chordal attachments.
- ~38% reduction in size compared to PSU adult cf-VAD



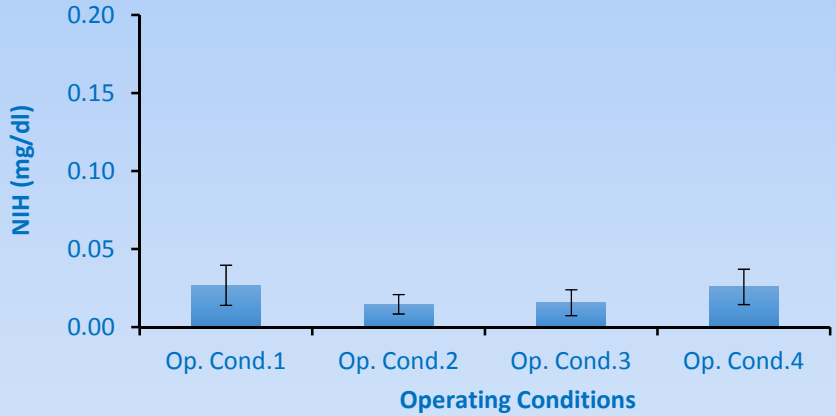
(1) The pump used for this preliminary fit testing is an actual-size replica of the pump. Note the size difference between our Child VAD and HVAD.



(2) VR fit testing; yellow - bones, blue - blood pool; (A) virtual construction of 19 kg child's chest, (B) AV valve annulus (red), (C) fitting with PSU Child LVAD; (D) fit testing was done with HeartMate 3 and HVAD as well.

Results - Cont'd

- **In-Vitro Testing on a Custom Mock Flow Loop**
  - Acceptable Hemolysis Range **≤ 0.03 mg/dl**



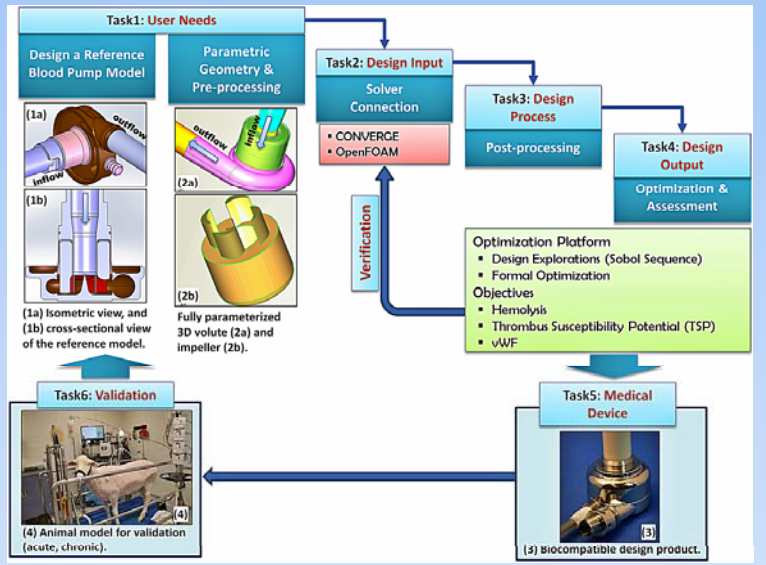
Conclusions

Summary

- A prototype of a PSU Child Pump was constructed and evaluated.
- Promising hemocompatibility (NIH_{mean} < 0.03 mg/dl)
- To date, the proposed PSU Child VAD is the first centrifugal pump designed for children.

Future Study

- Further Optimization
  - *Thrombus Formation*
  - *Hemolysis*
  - *Degradation of von Willebrand Factor*
  - *Efficiency*
- Chronic (30-Day) In-Vivo Study



A fully automatic design iteration procedure for adult cf-LVADs. Note that young sheep (20-40 kg) will be used for biocompatibility feedback for the PSU Child VAD.

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