A Novel Magnetically Levitated Axial Flow Left Ventricular Assist Device

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NEW MAGNETICALLY SUSPENDED LEV-VAD
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Scope of current NIH funded project

Design

Bench-top component testing

Full prototypes

Acute and chronic animal implants

Investigational Device Exemption (IDE) Application
Motivation

- ~ 5,000,000 people in US with congestive heart failure
  - Over 550,000 new cases of heart failure will be diagnosed in the next year.
  - responsible for more hospitalizations than all forms of cancer combined.

- <2,500 transplants available per year
  - 2,016 and 2,127 heart transplants were performed in the United States in 2004 and 2005, respectively.

- Many patients would benefit from a mechanical device:
  - Short term – ‘bridge-to transplant’ (BTT)
  - Long term – ‘destination therapy’
Left Ventricular Assist Device (LVAD)

- Pump assists native heart
- Proven short-term effectiveness
- Current devices have limited design life due to biocompatibility
  - Degradation of the artificial material
    Mechanical Wear
    - Blood damage caused by the device
      Hemolysis & Thrombosis
- Need for a long-term implant
  - Mechanical design life of 10+ years
  - Negligible effect on blood
Blood Damage

• **Hemolysis**
  – Red Blood cell membrane is torn, releasing cell contents
  – Caused by shear stress

• **Thrombosis**
  – Chemical and physical clotting cascade creates thrombus (clot)
  – Thrombus may detach and clog arteries
  – Encouraged by (among other things) turbulence, recirculation, stagnation
Evaluation and Prediction of Blood Damage

• Turbulent flow, shear, and stagnation are unavoidable

• Theory, empiricism, and Computational Fluid Dynamics (CFD) all have limitations in this miniature pump

Quantitative modeling and measurement of flow are required
History - “1\textsuperscript{st} generation” LVADs

HeartMate\textsuperscript{TM} LVAS - Thoratec
History - “2nd generation” LVADs
Rotary Pumps

Medtronic Biomedicus pump
Magnetically Suspended Rotary Blood Pumps

Requirements
- Long design life
- Negligible blood damage

Characteristics
- Fewer parts, no flexible materials, no moving contacting surfaces
- No valves, unobstructed pathway, and large clearances

CF4 – implanted in 5+ humans
Licensed to MedQuest Products, Inc.
Currently WorldHeart Levacor VAD

LEV-VAD1
Initial design under this BRP
• Eliminates:
  - Centrifugal
  - Axial
Axial Flow Pumps

Jarvik

Micromed/DeBakey

Thoratec

Berlin Heart
Eliminates:

- **Centrifugal**
  - Blade Tip Clearance
  - Back Clearance

- **Axial**
  - Blade Passage
  - Tip Clearance
LEV-VAD2
Current design
Sub-Systems

**Fluid System**
Pumping Performance, Blood damage

**Magnetic System**
Bearing, Motor, Sensing

**Peripheral systems**
Physiological Control, Cannula, Patient interface, Power, Monitoring

LEV-VAD2
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Hemolysis Thresholds

Shear Stress (Pa) vs. Exposure Time (seconds)

Giersiepen (1990)
Hemolysis Thresholds

[Graph showing hemolysis thresholds with various lines and points representing different studies.]

- Turbulent Stress
- Turbulent Stress - Reanalyzed
- Viscous Stress

Authors and years:
- Blackshear (1965)
- Blackshear - Jones (1995)
- Forstrom (1969)
- Forstrom - Jones (1995)
- Williams (1970)
- Rooney (1970)
- Bacher (1970)
- Keshavi (1970)
- Lovern (1972)
- Williams (1973)
- Sutera (1975)
- Hauser (1990)
- Sallam (1984)
- Sallam - Grigioni (1999)
- Sallam - Lu (2001)
- Wurzinger (1985)
- Blackshear (1987)
- Hashimoto (1989)
- Paul (2003)
Thrombosis

- Chemical and physical cascade creates thrombus (blood clot)
  - activation
  - amplification
  - adhesion
- Encouraged by fluid dynamics (among other factors)

1. High Shear $\rightarrow$ platelet activation
2. Recirculation $\rightarrow$ amplification
3. Stagnation $\rightarrow$ adhesion
Fluid Mechanics Contribute to Blood Damage

- Regions of turbulent flow, shear, and stagnation are unavoidable
- Must be designed to minimize blood damage
  
  **Avoid stagnation while maintaining acceptable stress levels**
  
- Design requires reliable techniques to predict and measure the flow
Computational Fluid Dynamics - CFD

- Commercial fluid solvers used for full 3-d Reynolds averaged Navier-Stokes equations.
  - Steady flow simulations using the frozen-rotor assumption and k-e or k-w turbulence model.
- Outflow pressure vs. flow curves determined over a range of rotational speeds.
- Used extensively in the design of blood pumps
- Limited accuracy:
  - Turbulence modeling
  - Rotating frames of reference
  - Limited grid resolution – 3D
- Results must be verified with experiments
Comparison of Experiment to CFD with k-ε and frozen rotor

- Accurate near design point
- Under-prediction at high flow
Experimental

Forces and torques on impeller

Oil streaking for wall shear stress

Pressure

Flow visualization and Velocimetry (PIV)
Instantaneous Measurement

Series of Instantaneous Measurements

Turbulence Statistics

Time Averaged (Mean) Velocity

Spatial Derivatives

Viscous Shear Stress

Vorticity
PIV Measurements within the Blood Pump
PIV Measurements within the Blood Pump
Transient Flow During Heartbeat

- **Inlet**
- **blade passage**
- **cut-water**

### Graph
- **Flow Rate (L/min)**
- **Phase**
  - $2\pi/10$
  - $4\pi/10$
  - $6\pi/10$
  - $8\pi/10$
  - $10\pi/10$
  - $12\pi/10$
  - $14\pi/10$
  - $16\pi/10$
  - $18\pi/10$

### Speed Colors
- 3.50
- 3.27
- 3.03
- 2.80
- 2.57
- 2.33
- 2.10
- 1.87
- 1.63
- 1.40
- 1.17
- 0.93
- 0.70
- 0.47
- 0.23
- 0.00
Sub-Systems

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LEV-VAD2
Current design
Magnetic Finite Element Analysis

- Determine magnetic fields and resulting magnetic forces
- Used for individual components and interactions of neighboring magnets
Magnetic Suspension Benchtop Testing

- All magnetic components can be located and held independently
- Useful for characterizing combined effect of individual magnets
- Development and testing of control laws
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Progress and Plans

✓ Paper design
✓ Computational modeling of subsystems
✓ Demonstration of manufacturability
✓ Bench-top validation of fluidic and magnetic subsystems
✓ Optimization of subsystems
✓ Prototype of complete pump
☐ Blood Testing
☐ Animal Testing
Current & Future Work

Investigation of Underlying Physics & Methodological
• Applying linked CFD & thrombosis models to pumps
• Effects of turbulence on red cells lysis and platelet activation
• Individual cell tracking
• Continued validation and refinement of computational methods
• Methods for measuring shear stress in pump

Design
• Design revision and optimization of current axial flow pump.
• Simplified designs that are smaller, cheaper, more efficient, manufacturable, etc.
• Other blood handling devices: catheters, stents, lungs, kidneys, etc.
RIT Team

Co-op students
Scott Carlson
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Graduate Students
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Carlos Cheek
Dave Gomez
Jim Cezo
Aditi Khare
Questions?
Measured Physiological Flow Conditions

- Continuous pump speed ≠ constant flow
- Need for measurements at:
  - ‘design’
  - off-design
  - pulsatile flow rates