Artificial Tricuspid Aortic Valve

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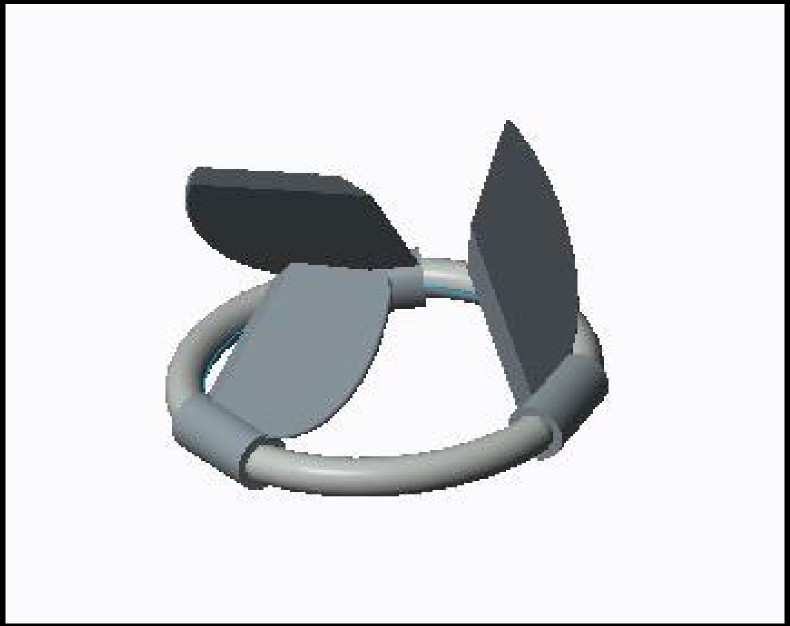
Design Motivation



- Better valve mechanics
  - Less stress on blood cells
  - Higher wear resistance
  - Minimum backflow (regurgitation)
- More naturalistic
  - Improved hemodynamics
    - Less shear stress on the wall of the aorta
  - Minimal transvalvular pressure gradient
- Less thrombogenic
  - Decreased risk of thrombi formation, which could result in blood clotting

Patient Benefits

- Longer-lasting device
- Less stress on blood cells
  - Decreased risk of coagulation
  - Plasma-free hemoglobin
- Biocompatible
- Tissue ingrowth
- No metal-on-metal contact
  - Avoids galvanic corrosion and the production of wear particles

Procedure Statistics

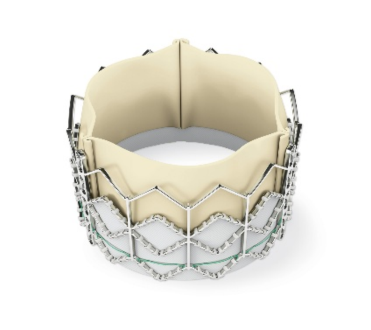
- 85,000 aortic valve replacements performed per year in the U.S.
- Approximately 50% of patients with aortic valve stenosis (narrowing of the aortic valve) will not survive for more than an average of 2 years after symptom onset without an aortic valve replacement
- Mostly biological valves are used in the U.S. and Europe
- Mechanically valves are more typically used in Asia and Latin America

Design Rationale

- A trileaflet valve creates more naturalistic hemodynamics
  - Less stress on blood and the device itself
  - Decreased risk of blood clotting because of lower transvalvular pressure
- Durable
  - Can withstand more stress than bioprosthetic heart valves and won't need to be replaced as frequently
- Manufacturability
  - Individual components can be easily modeled; good reproducibility

“Gold Standard” Models

- Mechanical
  - Typically used in younger patients
  - Increased durability
  - Higher stresses
  - More prone to blood clotting
  - Sorin-Carbomedics Valve
    - Disc comprised of carbon fiber
    - Housing made of carbon fiber or titanium
    - Housing surrounding by Dacron (polyethylene terephthalate) for tissue ingrowth
- Biological
  - Decreased durability
  - Higher biocompatibility
  - Sorin Valve
    - Porcine tissue valves
    - Titanium stent
    - Some models utilize Dacron for tissue ingrowth
- Minimally-invasive Transcatheter Implants
  - For patients who are not eligible for surgery or have high surgical risk
  - Polyethylene valves with stents
  - Biological valves with stents



Existing Designs/Devices

- Mechanical
  - Caged-Ball Valve (Starr-Edwards)
  - Tilting-Disc Valve (Medtronic-Hall)
  - Bileaflet Valve (Medtronic Open Pivot)
- Biological
  - Porcine Valve (St. Jude Toronto Stentless)
  - Pericardial Valve (Carpentier-Edwards)
  - Homograft (Human Aortic Valve)
  - Pulmonary Homograft (Human Pulmonary Valve)

- Transcatheter Aortic Valve Replacement (TAVR)
  - Medtronic CoreValve System
    - Trileaflet porcine pericardial tissue valve, more optimal blood flow but lower durability
  - Edwards-SAPIEN Valve
    - Trileaflet bovine pericardial tissue valve, similar characteristics to Medtronic CoreValve System

Necessities to Improve Quality of Life

- Diet
  - Fiber
  - Limited sugar and salt intake
  - Low cholesterol and saturated fat intake
- Exercise
  - Gradually increase exercise level after surgery
- Anticoagulant
  - Warfarin, common blood thinner

Anatomical Information

- Implant will replace the aortic valve of the heart
- Surrounding anatomy includes heart tissue, the aorta, and sinuses distal to the valve
- Blood flow through the device goes from left ventricle to the aorta
- Endothelial cells line the inner lumen of the aorta
  - Sensitive to shear stress
  - Can regenerate if damaged
  - Tendency to align in direction of shear stresses
- Natural valve leaflets are thin tissue with elastin and collagen as structural elements
  - Anisotropic

Device Function, Requirements, and Constraints

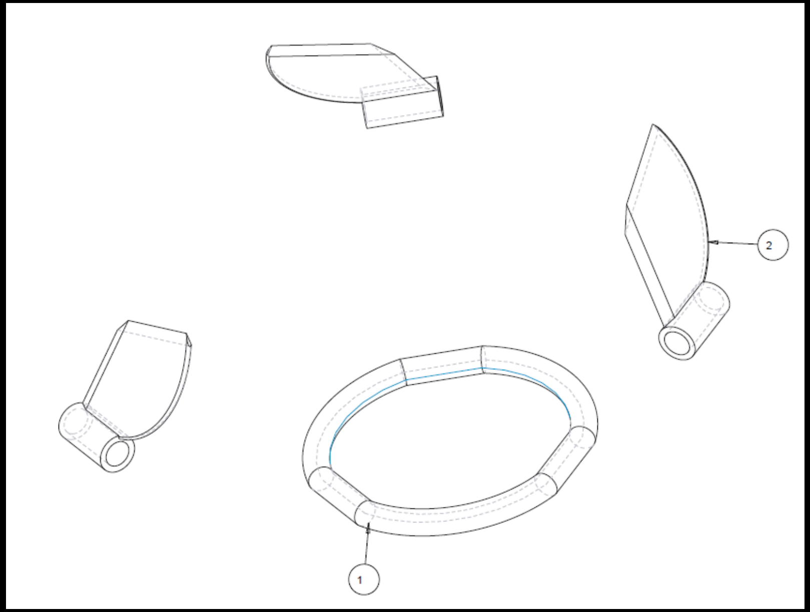
- Function
  - Create a more stable blood flow without coagulation and failure
- Requirements
  - Valves need to fully open
  - Valves need to open/close quickly
  - Valves/housing need to be risk-free of fatigue failure
- Constraints
  - Valves can only open one way; must not allow reverse blood flow

Basic Design and Materials

- Trileaflet artificial aortic valve
- Three separate components
  - Three discs
  - Housing
  - Cloth sewing ring surrounding
- Mimic biomechanics of natural aortic valve
- Disc/leaflets – UHMWPE
- Housing – Titanium
- Cloth surrounding – Dacron (polyethylene terephthalate), promotes tissue ingrowth

Device Aesthetics

- The artificial valve looks like a ring with three small leaflets attached to the ring on hinges
- Appearance is similar to that of a natural aortic valve



Similar Implant Aesthetics

- Other artificial aortic valves look similar, but the leaflets are attached to metal struts and have only one or two discs
- Biological replacement valves mimic the tricuspid appearance of a natural aortic valve
- Other device options
  - Transcatheter valves
    - Did not pursue because these devices are new and not as much information exists about them

Device's Interaction with Body

- The device will be implanted into the heart
- Will interact with cardiac muscle, endothelial cells, and blood
- Valves open when $P_{ventricle} > P_{aorta}$
- Valves close when $P_{ventricle} < P_{aorta}$
- Will allow for tissue ingrowth adjacent to the ring/housing due to the Dacron

Distinguishable Interaction

- No biocompatibility issues
- More naturalistic hemodynamics
- Lower trasnvalvular pressure
- Lower shear stresses
  - Less blood thinner is necessary
- Durable
  - Last around 25 years as opposed to 10-15 years for biological valves

Effect of Material

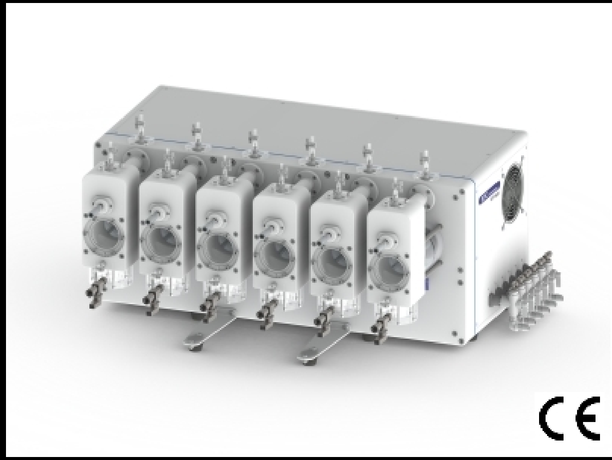
- Materials should be wear-resistant (UHMWPE discs) and biocompatible
- Dacron cloth will facilitate tissue ingrowth adjacent to endothelial cells
- Titanium housing may be vulnerable to fatigue

Medical Indications and Contra-Indications

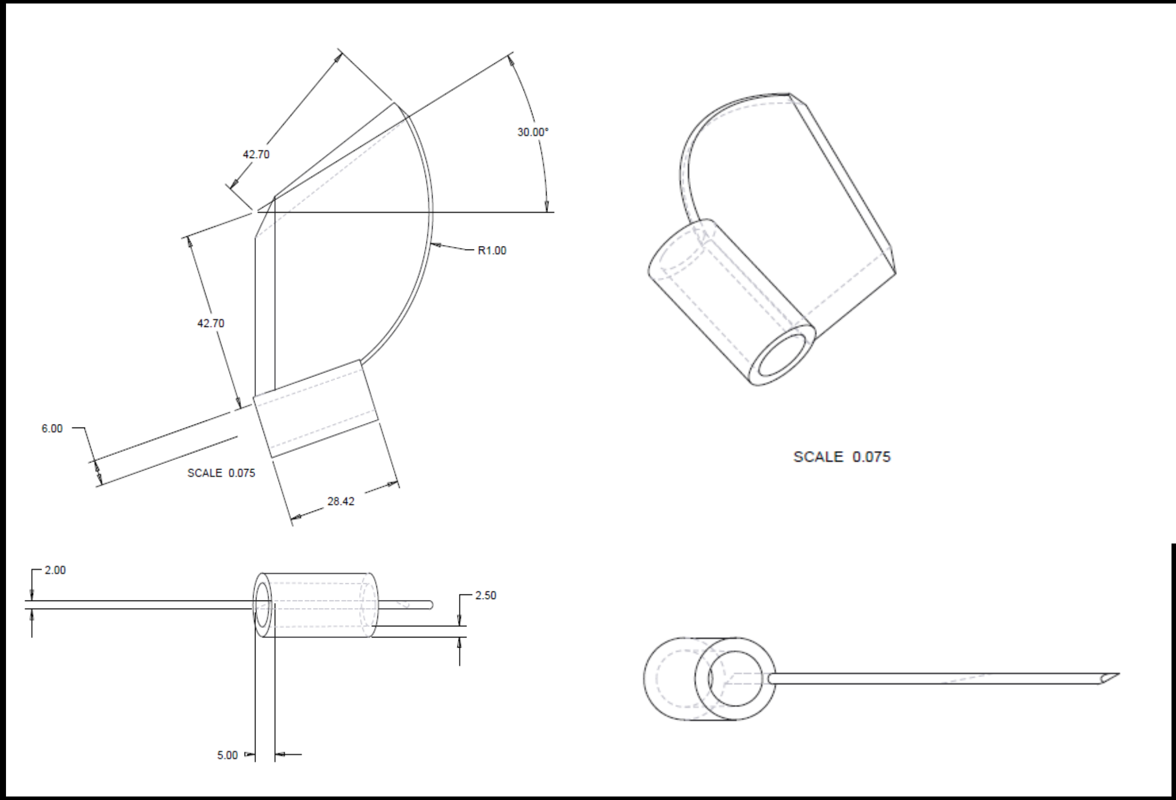
- Indications
  - Aortic stenosis (AS)
    - Narrowing of the aortic valve
  - Valvular incompetence
    - Incomplete valve closure
- Contra-Indications
  - Risk of open-heart surgery
    - Patients with cirrhosis (end-stage liver disease)
    - Possible acute episode of cardiac dysfunction

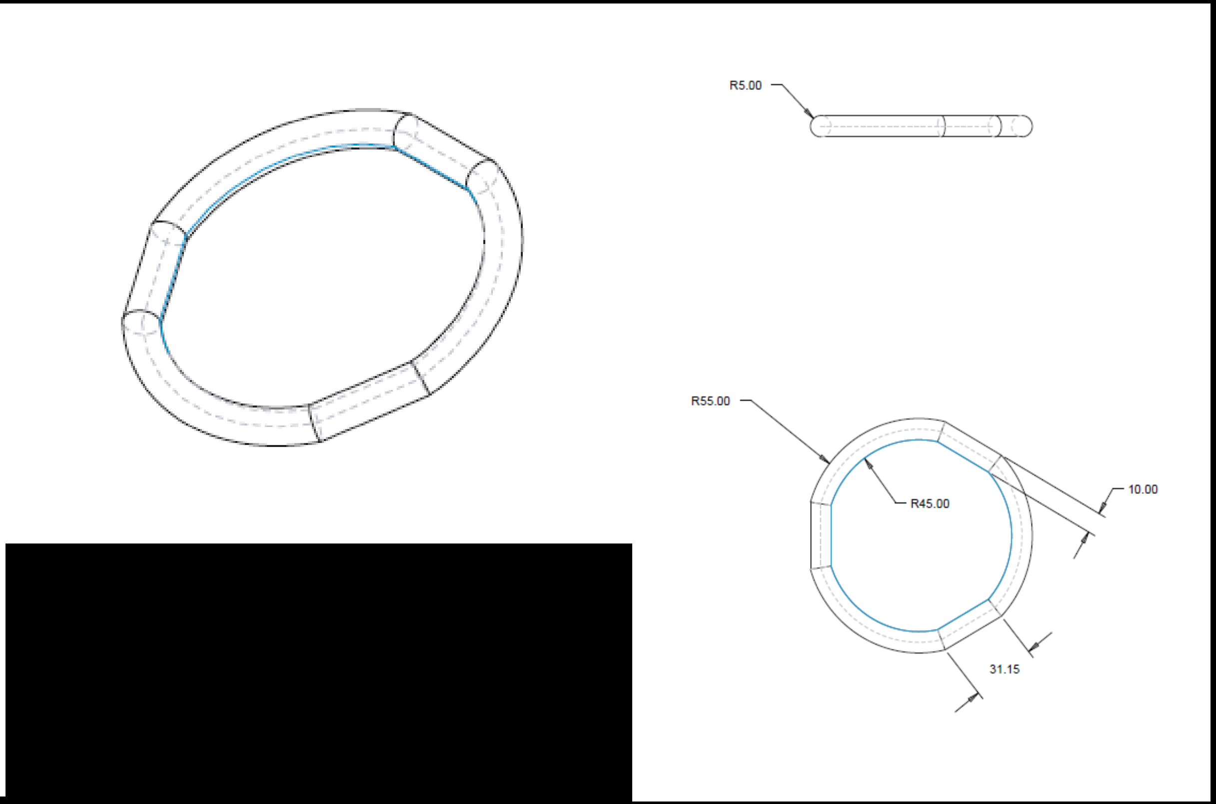
Analysis of Implant

- Reliability
  - Average life
  - Number of cycles to failure
  - Re-operative frequency
- Safety
  - Deaths per operation
  - Post-operative life expectancy
- Cost Analysis
  - Approximately $5,000 for current artificial heart valves
  - Cost-effective compared to other medical care management options according to Annals of Cardiothoracic Surgery
- Testing
  - Finite Element Analysis
  - Cavitation testing
  - Accelerated valve wear tester
- Effectiveness
  - Low regurgitation
  - Large number of cycles to failure
  - Promotes naturalistic hemodynamic flow
- Surgical procedure similar to that of current mechanical heart valves



Individual Components





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