The History of Heart Valves an Industry Perspective: From Initial Designs to Today

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From an Idea

Discovery

Advanced Materials

Strategy & Marketing

To Saving Lives

Quality

Engineering

Biological Research Center

Clinical & Regulatory

Research

Analytical Models

Animal Models
Why does this matter?

- Heart disease is the #1 cause of death for men and women in the US, claiming approximately 1 million lives annually.

- Every 33 seconds someone in the United States dies from cardiovascular disease.

- More die of heart disease than of AIDS and all cancers combined.
The Different Valves

Goal of a heart valve: Unidirectional blood flow

Left Sided Valvular Diseases

Prevalence of moderate or severe valve disease

- Any Left Sided Valve Disease
- Mitral
- Aortic

Age (years)

Complexity in Structure

Aortic Valve

Mitral Valve

Leaflets

Annulus

Leaflets

Papillary muscles

Tendinous cords
Current Options and Trends

Surgical Replacement

Transcatheter Replacement
Which Valve is Best?

- If the patient is young....
Computation Fluid Dynamics to Improve Designs

Platelet Activation = Shear Stress and/or Residence Time
Moving towards

Blood Thinners  Aspirin  No Medications

?
Which Valve is Best?

- If the patient is young....

  Durability → Materials, Design, Process

- If the patient cannot tolerate anti-coagulants

  Hemodynamics → Fluid Mechanics
Accelerated Wear Testing
## Accelerated Wear Testing

<table>
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<tr>
<th>Time Zero</th>
<th>25 Simulated Years</th>
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<tr>
<td>(0 Cycles)</td>
<td>(1 Billion Cycles, ~2.5 years)</td>
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Which Valve is Best?

- If the patient is young....
- If the patient cannot tolerate anti-coagulants
- If the patient is a high risk surgical candidate
Minimally Invasive Procedures

Traditional Surgical Valves VS EDWARDS INTUITY Elite Valve

12-15 Sutures

3 Sutures

Streamlined Delivery

Utilizes a balloon expanded frame and 3 guiding sutures to provide greater ease of implantation and excellent visualization.
Transcatheter Technologies

Apical Access

Femoral Access

Aortic Access
Transcatheter Landscape is Growing

- CoreValve
- Edwards SAPIEN
- Edwards SAPIEN XT
- JenaValve
- Medtronic CoreValve
- Direct Flow Medical
- Symetis
- St. Jude Portico

2007 → 2008 → 2009 → 2010 → 2011 → 2012 → 2013
Extending the Life of Tissue Valves

Place a Valve in a Valve
Which Valve is Best?

• If the patient is young....

Durability \rightarrow \text{Materials, Design, Process}

• If the patient can not tolerate anti-coagulants

Hemodynamics \rightarrow \text{Fluid Mechanics}

• If the patient a high risk surgical candidate

Implantation \rightarrow \text{Anatomy}
New Challenges
Left Sided Valvular Diseases

Prevalence of moderate or severe valve disease

Graph adapted from Burden of Valvular Heart Disease: A Population Based Study (2006)

Transcatheter Mitral Valve Replacement

Pre-clinical Animal Models

Leaflet Attachment

Atrial Flange

“Transcatheter Mitral Valve Implantation is Complex”
Transcatheter Mitral Valve Replacement

Nitinol frame
Inflow (“atrial portion”)
Large inflow sealing area
Short left ventricular projection
Support arms
Outflow (“ventricular portion”)

Engager - Medtronic

Tiara - Neovasc

Flat aspect of the “D” shaped Tiara
Atrial “skirt”

CardiAQ
The Future....

**Planning** for the best valve for the patient specific anatomy

**Expanding** to help more patients

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3D Echocardiography

3D Computed Tomography

Computation Fluid Dynamics
Helping Patients is Our Life’s Work, and