Advancements in Cardiac Surgery
2013 Cardiac Operations
N = 4,405

- Combined Valve (No Aorta): 22%
- Isolated CABG: 13%
- Isolated Valve: 27%
- Other: 16%
- Peds Congenital: 18%
- Aorta: 4%

*107 Adult Congenital Heart Surgeries distributed among the adult operations
Cardiothoracic Surgery National Volume

Cuyahoga County 15%
Cardiothoracic Surgery National Volume

Ohio 9%
Cardiothoracic Surgery National Volume

United States
42%
Patients from 76 Countries Outside the US came for their Cardiovascular Care
Cardiovascular Surgery Mortality

% 

2009 2010 2011 2012 2013 UHC Expected

0 2 4 6 8

Expected
3 Stars in All 3 STS Categories!

### CABG

**Overall**

Rating: ⭐⭐⭐

- Min: 89.3
- 10th: 93.1
- 50th: 96.7
- 90th: 97.9
- Max: 98.9

### AVR

**Overall**

Rating: ⭐⭐⭐

- Min: 85.2
- 10th: 92.2
- 50th: 94.8
- 90th: 96.5
- Max: 98.2

### AVR + CABG

**Overall**

Rating: ⭐⭐⭐

- Min: 78.7
- 10th: 87.8
- 50th: 91.6
- 90th: 94.4
- Max: 97.0
“We are what we repeatedly do. Excellence, then, is not an act, but a habit.”

*Aristotle, 384-322 BC*
Value is driven by provider experience, scale, and learning at the medical condition level.
“21st century care should be innovative.”

“Collaborative care is essential.”
Valves

N = 2,852

- Isolated Aortic: 20%
- Isolated Mitral: 14%
- Isolated Tricuspid: 1%
- Combined: 65%
Evolution of Surgical Technique

- Full median sternotomy
- Upper hemi-sternotomy
- Mini right anterior thoracotomy
- Transapical valve
- Transfemoral valve

Safety must be maintained
Operative Approach – Isolated Valve

N = 960

- Full Conventional Sternotomy: 32%
- Mini Sternotomy: 27%
- Robotic: 12%
- Transcatheter Placement: 19%
- Mini Thoracotomy: 10%
Robotically-assisted Cardiac Surgery

November 3, 2014

Median Sternotomy
>450 procedures

Mini Thoracotomy
>150 procedures

Totally Endoscopic Robotic
>150 procedures
Robotically-assisted Cardiac Surgery

The 4th intercostal space is ideal for Camera Port and Service Port placement.
Isolated Mitral Valve Mortality

<table>
<thead>
<tr>
<th>Procedure</th>
<th>STS Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repair*</td>
<td>0.3%</td>
</tr>
<tr>
<td>Replace</td>
<td>0%</td>
</tr>
</tbody>
</table>

*2013 only
Net Cost of Care

Robot vs. Sternotomy
Aortic Valve Mortality

<table>
<thead>
<tr>
<th>Procedure</th>
<th>STS Expected</th>
<th>UHC Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Isolated</td>
<td>0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1.4%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Primary Combined</td>
<td>0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1.4%</td>
<td>3.7%</td>
</tr>
</tbody>
</table>
Works well in larger patients
Traditional Aortic Valve Choices

- Mechanical
- Stented xenograft
- Stentless xenograft
- Homograft
- Autograft (Ross)
CCF Aortic Valve Replacements
Prosthesis Choice

- Bioprostheses
- Mechanical
- Homograft
Long Term Valve Outcomes

12,569 Perimount (CE) implants

1981-2011

30 yrs of data
Risk of Explant for SVD

Actual Risk within 20 years

%  
40 50 60 70 80 90

Age (years)
New Valves
TAVR

Edwards - S3

Direct Flow - Salus

St Jude’s - Portico

Boston Scientific - Sadra

Medtronic - CoreValve
TAVR over 400

- **TA – TAVR, TAO**
  - N = 135
  - 5 Deaths (3.8%)

- **TF – TAVR**
  - N = 257
  - Conversion 11 (5 TA, 2 Open AVR Rup) (4.2%)
  - 1 Death (0.4%)
  - 2 Strokes (0.8%)
All Stroke (ITT)

HR [95% CI] = 2.79 [1.25, 6.22]
p (log rank) = 0.009

Δ at 1 yr = 5.7%
Δ at 2 yr = 8.3%

Numbers at Risk

<table>
<thead>
<tr>
<th>Group</th>
<th>Months</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>179</td>
<td>128</td>
<td>116</td>
<td>106</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td>Standard Rx</td>
<td>179</td>
<td>118</td>
<td>84</td>
<td>62</td>
<td>42</td>
<td></td>
</tr>
</tbody>
</table>
Transcatheter Mitral Valved Stent

Mitral Valved Stent

Delivery Systems

Trans-Apical Mitral Valve Implant

Echo images of valve implanted in swine
Commence Trial

GLX Valve
Univ of Maryland
St. Vincent’s Hosp – Indiana
Univ of Florida at Shands
Columbia University
Cleveland Clinic
Spectrum Health
Baylor St. Luke’s Houston
Univ of S. California
Emory Univ Hospital
Mt Sinai Medical Center
Univ of Kansas Med Ctr
CCF Valve Exchange Vitality
45 Patients, European CE Label
EDWARDS INTUITY Overview

EDWARDS INTUITY Valve

Flexible shaft delivery system

Note: EDWARDS INTUITY Valve System is not available for commercial distribution in the United States or Canada.
Procedure Overview

Note: EDWARDS INTUITY Valve System is not available for commercial distribution in the United States or Canada.
Perceval - Sutureless Valve
Prediction: In 10 Years:

- Percutaneous Valves, ASDs, Aortas, PCI
  - Outpatients
  - Echo
  - Local Anesthetic
Aortic Surgery

- Open Asc Arch Repair
- Open Des Thor Repair
- Endo Des Thor Repair/TAA
- Open Abd Repair/TAAA
- Endo Abd Repair


- 2009: 2,000
- 2010: 1,900
- 2011: 1,500
- 2012: 1,178
- 2013: 1,178
Mortality
Aorta Surgery

O/E Ratio = 0.8

University HealthSystem Consortium (UHC) Comparative Database, January through November 2013 discharges

Observed: 2.8%
Expected: 3.6%
The New Thoracic Paradigm

Endovascular options for treating the thoracic aorta have already had a significant impact.
Descending Thoracic Endovascular Repairs: Proven Technology
Current Device Choices

Gore

Cook

Medtronic
Survival after Thoracic Aneurysm Repair

Survival data showing the probability of survival over time for open surgical control and endograft repair. The graph indicates that the probability of survival is similar for both methods, with a p-value of 0.48. The data is from Bavaria. *JTCVS*, 2007.
The New Frontier: Thoracoabdominal Aortic Aneurysms

Acute Mortality: 7.4 – 17%

- Older Age
- Co-morbid conditions
  - COPD
  - CRI
  - CAD
  - Frail
The Visceral Segment

The more proximal the clamp, the greater the mortality risk.

The greater the mortality risk, the more benefit may be realized from a minimally invasive procedure.
Thoracoabdominal Aneurysms
Standard Repair
Circa 1999
TAA - EVAR

Mortality for CCF TAAA 2008-2011

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2008-2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular</td>
<td>2.8%</td>
<td></td>
</tr>
<tr>
<td>Open</td>
<td>3.1%</td>
<td></td>
</tr>
</tbody>
</table>

Elective TAAA

Emergency
Disasters occur when Hazards meet Vulnerability

Cardiogenic shock
Progress

1980

Now

Survival improving with prompt therapy and newer devices

Left to die
Emergency Circulatory Support

ECMO

Tandem Heart

Impella
Emergency Circulatory Support

ECMO

Tandem Heart

Impella
ECMO
ECMO
Cleveland Clinic Experience

- **Blood pump**
  - Rotaflow centrifugal pump
  - Low cost, small size
  - 0-10 L/min

- **Oxygenator**
  - Quadrox D
  - Minimal plasma leak
  - Long-lasting
ECMO
Modes of Support

Veno-venous

Veno-arterial
Tandem Heart

- Extracorporeal axial flow pump: 0 - 5L/min
- Inflow: left atrium via trans-septal puncture
- Outflow: femoral artery
- LAP and PCWP
- Myocardial oxygen demand
- MAP and CO
Tandem Heart
Tandem Heart Versatility
Conversion to ECMO
Tandem Heart Versatility
Conversion to ECMO
**Impella 5.0**

- 21F micro-axial flow pump
- 9F peripheral insertion
- Flow: 0 - 5L/min
- Duration of support: 7 days
- Fully unloads left ventricle
Impella 2.5 and 5.0
Impella Positioning
Chronic Heart Failure in the US

~240 Million Population ≥ age 20 years old

HF=2.6 % Population* or 6.24 Million Total

~50 % Preserved Systolic Function 3.12 M

~50 % Systolic HF 3.12 Million

80-85% Stage A-B

15-20% Stage C (3-4% advanced Stage C)

0.5-5 % Stage D

Advanced Stage C / NYHA class IIIB 93,600-124,800

Stage D / NYHA functional class IV 15,600-156,000

Advanced Stage C and Stage D ≥ age 20 years old 109,200 – 280,800
Chronic Heart Failure

Mortality Rate Similar to Aggressive Malignancies

1 year mortality

% 100

Leukemia Lung CA Pancreatic CA NYHA IV HF

5 Data on file. Pleasanton, Calif: Thoratec Corp.
Risk factor reduction, patient and family education

Treat HTN, DM, CAD, dyslipidemia. ACEI or ARB

ACEI, ARB’s if intolerant of ACEI, BB if MI or low LVEF

ACEI, BB in all. Is patient candidate for surgery?

Sodium restriction, diuretics

Aldosterone antagonists

Digoxin

Inotrope, nesiritide

Hospice

VAD, TX

CRT, ICD if applicable

Sodium restriction, diuretics

Stage A
High risk with no symptoms

Stage B
Structural heart disease, no symptoms

Stage C
Structural disease, prior or current symptoms

Stage D
Refractory symptoms requiring special intervention

Stages & steps: treatment of systolic HF

Brief inotrope or nesiritide
Biologic or Mechanical Replacement
“Proposing heart transplantation to cure heart failure is analogous to proposing the lottery to cure poverty.” LW Stevenson, MD

“Cardiac transplantation is ‘epidemiologically trivial’ solution.” Eric Rose, MD

5/4/2014 – 3,972 awaiting heart transplantation
## 2013 Transplant Activity

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplants</td>
<td>44</td>
</tr>
<tr>
<td>Listed</td>
<td>73</td>
</tr>
<tr>
<td>Referrals</td>
<td>242</td>
</tr>
<tr>
<td>Full evaluations</td>
<td>182</td>
</tr>
</tbody>
</table>
Centers within a 500 mile radius
For a sample of transplant programs

Depending on the geographic location of the center, the 500 mile radius for each program includes from 4 to 67 other transplant programs.
Number of Candidates Ever Actively Waiting (2010-2012)

Each symbol represents one transplant center, with the size of the symbol proportional to the number of centers within 500 miles.
**CC Heart Transplant Trends**

**Median Wait Months**

<table>
<thead>
<tr>
<th>Year</th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>5.4</td>
</tr>
<tr>
<td>2008</td>
<td>1.8</td>
</tr>
<tr>
<td>2011</td>
<td>7.5</td>
</tr>
<tr>
<td>2012</td>
<td>8.6</td>
</tr>
<tr>
<td>2013</td>
<td>9.7</td>
</tr>
</tbody>
</table>
“We’re seeing a transition in care for heart failure,” says Randall Starling
CC Heart Transplant Trends

Bridge to Transplant

<table>
<thead>
<tr>
<th>Year</th>
<th>Devices %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>13.8</td>
</tr>
<tr>
<td>2008</td>
<td>22.8</td>
</tr>
<tr>
<td>2011</td>
<td>44.6</td>
</tr>
<tr>
<td>2012</td>
<td>44.2</td>
</tr>
<tr>
<td>2013</td>
<td>57.9</td>
</tr>
</tbody>
</table>
VAD Implants

- Bridge to Decision
- Destination Therapy
- Bridge to Transplantation

#

- 2001
- 2003
- 2005
- 2007
- 2009
- 2011
- 2013
LVAD In Hospital Mortality

University HealthSystem Consortium (UHC) Comparative Database, January through November 2013 discharges
VAD Complications

- Any Re-op
- Re-op for Bleeding
- Renal Failure
- Stroke
- Deep Wound Infection

% for the years 2011, 2012, and 2013.
CC Primary LVAD by Era

P (log-rank) = 0.0746

SEvent: Death (censored at transplant or recovery)
LVAD Technology

HeartMate II
CE Mark, FDA Approved
BTT
DT

HeartWare HVAD
CE Mark, FDA approved
BTT
DT clinical trial
CircuLite Synergy Subcutaneous LVAD
Partial Support 2.5 to 3.5 L/min
CCF Total Artificial Heart
• Most patients who get a transplant will be Status 1
• Majority will be on an LVAD
• Status 2 patients are unlikely to receive a transplant but are unlikely to die waiting
• LVAD survival very close to transplant survival
THE BIONIC BRIDE

Thanks to a powerful new heart pump, Ally Smith has a second lease on life—and big plans for her wedding day.

Ally Smith was herself in her taffeta gown, staring back in the mirror—and makeup. "I felt beautiful," she says. "This was never going to happen." Just last year, Ally, 31, was planning her funeral. A rare heart failure led to a broader infection that left the Richmond, Texas, student in advanced heart failure. In an eight-hour surgery, doctors implanted a revolutionary new version of a left ventricular assist device (LVAD), a device that pumps blood for the body when the heart can't do it. "Without this," says Ally's physician, Dr. Roberto Rea, "she would be dead. Now she has a great life." While the former competitive swimmer can't go back in the pool (the tubing linking to the battery pack can't be submerged), Ally can do just about everything else—she can swim, dance, and even walk down the aisle down 30 in her gown and feathers in her hair. "Now," says her fiancé, Mike Richardson, 32, "we replace her."
EU late 2013
US 2014
Trial design:
all comers
## HVAD and MVAD Side-by-Side Comparison

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HVAD</th>
<th>MVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pump Type</strong></td>
<td>Centrifugal</td>
<td>Axial</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>160 g</td>
<td>58 g</td>
</tr>
<tr>
<td><strong>Pericardial Volume</strong></td>
<td>50 cc</td>
<td>15 cc</td>
</tr>
<tr>
<td><strong>Priming Volume</strong></td>
<td>15 cc</td>
<td>5 cc</td>
</tr>
<tr>
<td><strong>Inflow OD</strong></td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>

HeartMate III*

Hematologically Friendly, Proven Full Magnetically Levitated VAD

“Artificial pulse”
Transplant Advancements: Transmedics Organ Care System

• Broaden retrieval distances/locations
• Increase marginal donor supply
Convergence: Hybrid Operating Room
Value

Best Quality
+
Highest capabilities
+
Competitive costs
Cleveland Clinic
Every life deserves world class care.