Overview of MCS in 2017

Bruce B Reid, MD  Surgical Director
Artificial Heart Program/Heart Transplantation
Technology
Technology Adoption Lifecycle

- Innovators
- Early Adopters
- Early Majority
- Late Majority
- Laggards

"The Chasm"

Area under the curve represents number of customers
Internet
Adoption of Technology

CONSUMPTION SPREADS FASTER TODAY

PERCENT OF J.S. HOUSEHOLDS


TELEPHONE  AUTO  RADIO  REFRIGERATOR  CLOTHES WASHER  CLOTHES DRYER  DISHWASHER  AIR-CONDITIONING  COLOR TV  COMPUTER  VCR  CELLPHONE  INTERNET  MICROWAVE
John H. Gibbon, MD
1903 - 1973

Pioneer in the development of extracorporeal circulation
Massive Pulmonary Embolus
May 16, 1953

Thomas Jefferson University

First successful open heart surgery using cardiopulmonary bypass
Heart Lung Machine
Modern Cardiopulmonary Bypass
Mechanical Circulatory Support

**Short Term / Emergency**
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**Destination Therapy (DT)**
- Time frame: Permanent (years)
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The Magnitude of CHF

- 6 million suffer from heart failure: 550,000 new cases per year
- Only form of heart disease increasing in prevalence
- 262,000 deaths per year
- Incidence doubles each decade after 40
- 1 in 5 over age 40 have heart failure
- One year mortality is 28% in men over 75
- Most common cause of hospitalization in patients over 65
Economic Impact of CHF

- Annual cost of $30 billion in U.S.
- Most costly diagnosis in the Medicare population
- More costly than all forms of cancer combined
- 11 million office visits; 3.5 million hospitalizations
- Average total annual cost in Utah of $46 million dollars (79% paid for by the government)*
- $19,843 per hospitalization in Utah*

*Utah Department of Health
Heart Failure:
The Final Cardiovascular Disease

Coronary deaths are down by half

But heart failure has almost tripled

Enhanced survival in other CV diseases leads to expansion of HF Population

Source: National Hospital Discharge Survey data. Centers for Disease Control and Prevention/National Center for Health Statistics and National Heart, Lung, and Blood Institute.
Heart Transplants Reported per Year

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.
Lisa waits for a heart

50,000 Americans need new hearts. Most will never get one. Who lives? Who dies? A special report
Kaplan-Meier Survival by Era
(Transplants: January 1982 - June 2010)

Survival (%)

1982-1992 vs. 1993-2002: p < 0.0001
1982-1992 vs. 2003-6/2010: p < 0.0001
1993-2002 vs. 2003-6/2010: p < 0.0001


ISHLT 2012
1969 - first artificial heart to be implanted into a human (Dr. Denton Cooley).

The patient was sustained by the device for 3 days, but only lived for 36 hours post transplantation.

The patient’s widow accused Cooley of making her husband the “unfortunate victim of human experimentation.”
1982 – Barney Clarke with Mrs. Clarke after his initial recovery.
Jarvik, DeVries and Kolff examine Clarke’s artificial heart after autopsy.
Left Ventricular Assist Device
REMATCH Summary

- NEJM November 2001
- LVAD vs. optimal medical management
- LDS Hospital - largest enrollment in the country
- Landmark trial leading to FDA approval
- 129 patients with NYHA Class IV CHF ineligible for transplant
- 48% risk reduction of death with LVAD
- 52% vs. 25% survival at 1 year
- 24% vs. 8% survival at 2 years
- Improved quality of life (LVAD patients felt better, less depressed, more mobile and active)
HeartMate II

HeartMate XVE and HeartMate II® Comparison
HeartMate II Left Ventricular Device

- Continuous flow pump
- Small and silent
- Requires warfarin (INR: 2.0 – 2.5)
- Available at Intermountain Medical Center as Bridge to Transplant (BTT) or Destination Therapy (DT)
- Durability: 7+ years
- Over 20,000 implanted world-wide
HeartMate II – FDA approved for DT

TRIAL SUMMARY:

• Total of 200 patients
• Median age of 62 years (range 26 to 81)
• Mean LVEF of 17%
• 77% of patients receiving IV inotropes
• 2:1 Randomization HM II vs. HM XVE (stopped at mid-study point due to favorable results)
• All 200 patients were followed for at least 2 years or until death, transplantation or device explantation
• QOL improvement to NYHA Class I - II
## HM II DT – Trial Data

<table>
<thead>
<tr>
<th></th>
<th>HM II</th>
<th>HM XVE</th>
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<tbody>
<tr>
<td>Survival @ 2 years</td>
<td>58%</td>
<td>24%</td>
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<tr>
<td>Median duration of support</td>
<td>1.7 years</td>
<td>0.6 years</td>
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<tr>
<td>Relative Risk (95% CI)</td>
<td></td>
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<tr>
<td>Device repair or replacement</td>
<td>0.06</td>
<td>0.51</td>
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<tr>
<td>Stroke</td>
<td>0.13</td>
<td>0.22</td>
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<td>LVAD-related infection</td>
<td>0.48</td>
<td>0.90</td>
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<tr>
<td>Bleeding requiring surgery</td>
<td>0.23</td>
<td>0.29</td>
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<tr>
<td>Rehospitalization</td>
<td>2.64</td>
<td>4.25</td>
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</table>
HeartWare HVAD™

- Centrifugal pump
- One moving part
- Short integrated inflow cannula
- 10mm outflow graft
- Dual motor stators
- Thin, flexible driveline
- Sewing ring
Unique Features

- No abdominal surgery or pump pocket
- Fits in the pericardial space
- Anatomically fits smaller patients
- Less surgery; potentially minimizes blood transfusions
- Novel impeller design enables excellent hemodynamics
- Accurate flow estimation
- Log files enable flow and power waveform analysis
Interior of pump shown after 427 days of support in human patient

- Impeller only moving part
- Completely suspended by a combination of passive magnets and hydrodynamics
- Never touches pump housing
MCS Case Review

- 68 year male with 12 year history of IDC
- Sudden death in August 2009
- Discharged with BiV ICD
- Progressive deterioration to class III/IV
- Multiple hospitalizations over the following year
- Outpatient dobutamine
- Multidisciplinary review to assess candidacy for DT LVAD
- Enrolled in ENDURANCE trial—randomized to receive the HeartWare HVAD
- 3rd HVAD implant in the United States for DT
Postoperative Day #1
3 months later…
HeartWare HVAD
HeartWare HVAD Survival

Consistent Survival with HVAD® System vs. Projected Survival

Observed Survival (%)

Years

HVAD ADVANCE (N=140)
SHFM Medical Therapy#
HVAD – CAP (N=242)
HVAD BTT – Europe (N=50)

# SHFM performed against the ADVANCE population

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the “Instructions For Use” for complete indications for use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.

Intermountain Medical Center
• HeartWare HVAD versus HeartMate II
• 2:1 randomization--noninferiority study
• 2-year survival free from disabling stroke
• No difference between pumps (57.4 v 55.0%)
• Higher rate of stroke in HVAD
• More device malfunction requiring removal with the HeartMate II
HeartMate III
HeartMate III

- Intrapericardial
- Fully magnetically levitated
- Reduced shear stress on blood elements
- Frictionless without bearings
- Wide blood-flow passages
- Software programmed to create an intrinsic artificial pulse
• HeartMate II versus HeartMate III
• Designed to demonstrate noninferiority
• Composite of 6 m survival free of disabling stroke
• No pump thrombosis (versus 10.1% in H II)
• Outcome: 72.5 and 83.5% survival at 6 months free of disabling CVA
• Conclusion: Incremental improvement in outcome due to a lower rate of pump malfunction
Mechanical Circulatory Support

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[Intermountain Heart Institute
Intermountain Medical Center]
Case Presentation

• 40 year-old female who delivered a term infant a week earlier by Cesarean delivery
• 3rd trimester troubled by gestational diabetes
• Presented to ED one week postpartum with abrupt onset of severe chest pain and dyspnea
• Initial evaluation suggestive of STEMI
• Taken to the cath lab for emergency coronary angiography
Coronary Angiography
Coronary Angiography
Coronary Angiography
Coronary Angiography
Coronary Angiography
VA ECMO

- Profound cardiogenic shock despite salvage percutaneous intervention and IABP
- VA ECMO initiated via femoral vessels using the CardioHelp device
- Transported to Intermountain Medical Center for supportive care
- Neurologically intact
Echo at 1 week
Echo at 1 week
HVAD as BTT

• 1 week of support on VA ECMO
• End organs intact
• No cardiac recovery
• HVAD implant as bridge to transplant
• 4 months of support to full recovery
• Successful explant/transplant
• Normal graft function
Life Depends on Technology
Who and When?

NYHA CLASS

Adapted from Bristow, MR Management of Heart Failure, Heart Disease: A Textbook of Cardiovascular Medicine, 6th edition, ed. Braunwald et al.
Evaluation Criteria

Consider an evaluation when **three** of the following indications are present:

- Class III – IV heart failure symptoms
- Inability to walk < 1 block without dyspnea
- Sodium < 136 mEq/L
- BUN > 40 mg or Cr > 1.8 mg/dL
- ACE/ ARB/ BB intolerance
- Diuretic dose > 1.5 mg/kg/d
- 1 HF admit in the past 6 months
- No clinical improvement with CRT
Ready for Prime Time?

"The Chasm"

Innovators
Early Adopters
Early Majority
Late Majority
Laggards

Technology Adoption Lifecycle

Area under the curve represents number of customers
Steps to Clear the Adoption Chasm

- Viable tool for management of CHF
- Improve patient selection and perioperative management
- Fewer complications and shorter length of stay
- Smaller, less expensive, more durable devices
- ~100% success as a bridge to transplantation
- 5 - 10 year DT survival equal to transplantation
- Enhance patient length and quality of life
Increasing the LENGTH and QUALITY of life for patients with heart failure…