

Intermountain Heart Institute

Intermountain Medical Center

Overview of Advanced Mechanical Circulatory Support and Heart Transplantation

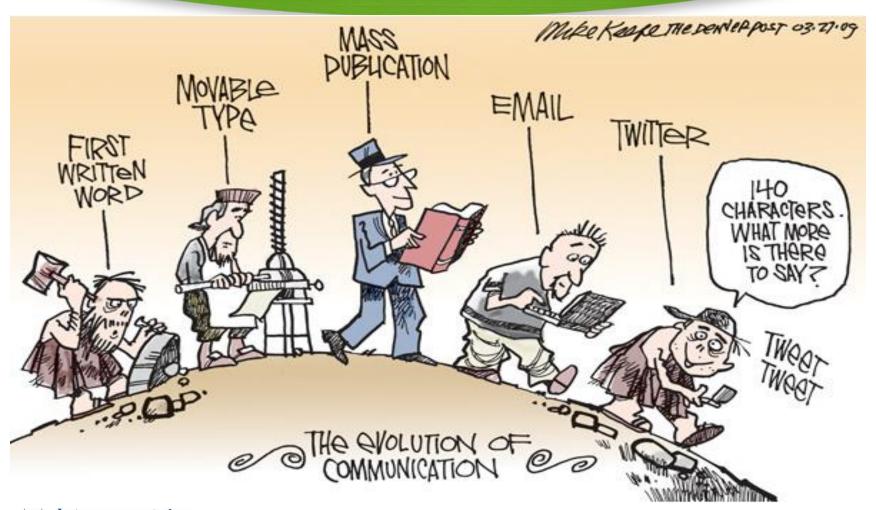
Bruce B Reid, MD Surgical Director Artificial Heart Program/Heart Transplantation

Technology





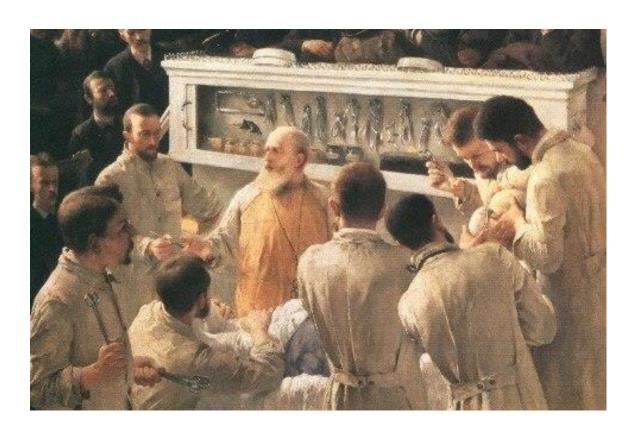
Embracing Progress





Early Milestones in Cardiac Surgery

1800s



"A surgeon who tries to suture heart wounds deserves to lose the esteem of his colleagues."

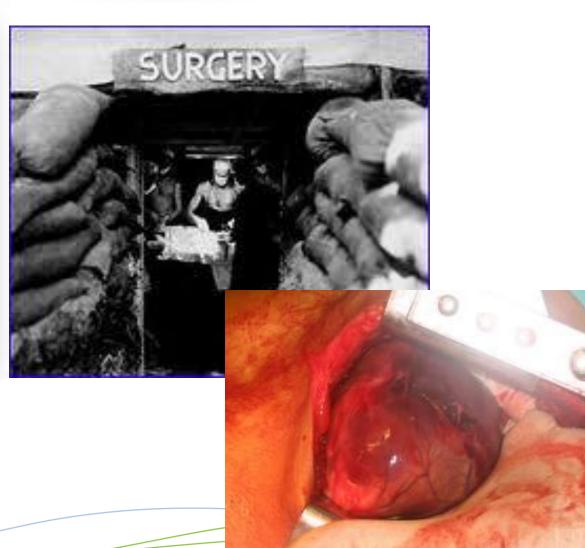
Theodor Billroth (1829 – 1894)

Penetrating Cardiac Trauma



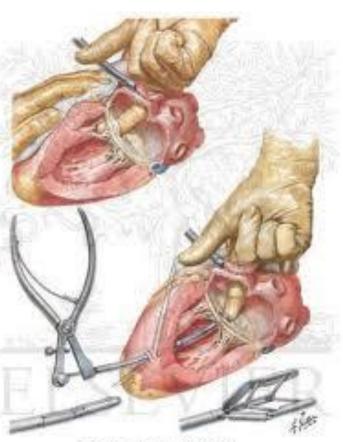
Dwight Harken, MD 1910-1993





Closed Mitral Commissurotomy

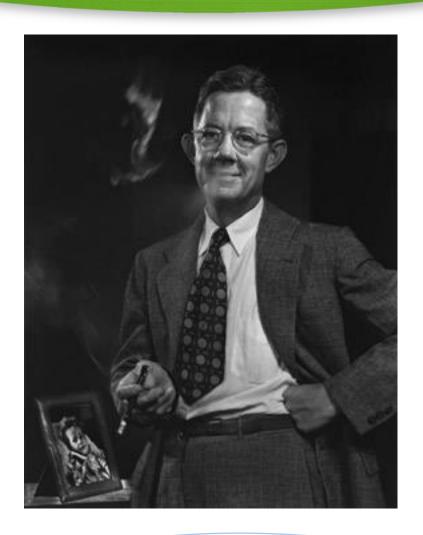




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Alfred T. Blalock, MD 1899-1964





Johns Hopkins





Helen B. Taussig, MD







Helen B. Taussig, MD 1898 - 1986





Johns Hopkins University

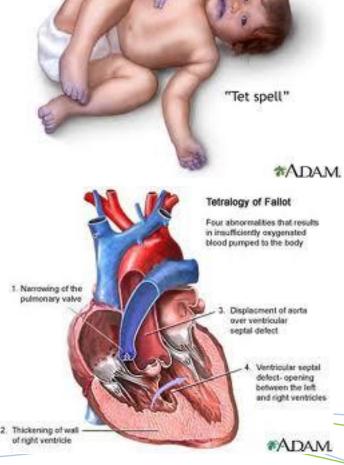


Helen B. Taussig, MD 1898 - 1986





Children with Tetralogy of Fallot exhibit bluish skin during episodes of crying or feeding.

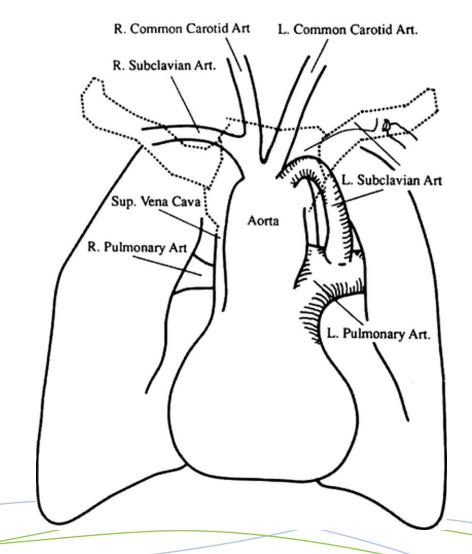


BT Shunt

Blalock A, Taussig HB:

The surgical treatment of malformations of the heart in which there is pulmonary stenosis or pulmonary atresia.

JAMA 1945; 128:189





Vivien Thomas





First Blalock-Taussig Shunt 1944





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OPERATION: Nov. 29, 1964 Dr. Alfred Blalock Ether - Oxygen - Dr. Harnel

a little of the Delay for Consulty ANASTOMOSIS OF LEFT PULMONARY ARTERY TO LEFT SUBCLAVIAN ARTERY

This patient was an undernourished child who had cyanosis on frequent occasions. The diagnosis was pulmonary stenosis.

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Under other and oxygen, administered by the open method, an incision was made in the left chest extending from the edge of the sternum to the axillary line in the third interspace. The second and third costal cartilages were divided. The plaural cavity was entered. The left lung looked normal. No thrill was felt in palpating the heart and pulmonary artery. The left pulmonary artery was identified and was dissected free of the neighboring tissues. The left pulmonary artery seemed to be of normal size. The superior pulmonary vein, on the other hand, seemed considerably smaller than normal to me. I had hoped that the artery to the left upper lobe might be sufficiently long to allow an anastomosis, but this did not appear to be the case. The left subclavian artery was then identified and was dissected free of the neighboring tissues. The vertebral artery and the branches of the thyrocervical axis were doubly ligated and divided. The subclavian was so short that there would not have been sufficient length for our purposes, had this not been done. The subclavian artery was then ligated distal to the thyrocervical trunk. A bulldog clip was placed on the subclavian artery at a point just distal to its origin from the aorta. The subclavian artery was then divided just proximal to the ligature. Two buildog clips were them placed on the left pulmonary artery, the first clip being placed at the origin of the left pulmonary artery, and the second clip being placed just proximal to the point where the artery entered thelung. There was ample space between these two clips for our purpose. A small transverse incipion was then made in the wall of the pulmonary artery. By the use of china beaded silk on fine needles, an anastomosis was then performed between the end of the left subclavian actory and the side of the left pulmonary artery. A posterior row of sutures was placed first. There was practically no bleeding following the removal of the bulldog clips.

The anastomosis seemed to be a satisfactory one, and the main point of worry comes from the small size of the left subclavian artery. I was disturbed because I could not feel a thrill in the oulmonary artery after the clips were removed. I do not believe that this was due to any clot in the subclavian artery, because it seemed to julsate vigorously. It is possible that it we due to a low pressure in the systemic circulation. I do not actually know what the systemic pressure was. Another possibility was that it might have been due to spass of the subclavian artery. My only regret was that the subclavian artery was not bigger. It is possible that the increased red cell count in this patient may have predisposed to thrombosis.

Intermountai **Heart Institute** Intermountain Me

(over)

Surgical Pioneers



Dr. Alfred Blalock

Vivien Thomas

PHOTOS BY BY THE ALAN MASON CHESNEY MEDICAL ARCHIVES OF THE JOHNS HOPKINS MEDICAL INSTITUTIONS



Blue Babies

NEW YORK HERALD TRIBUNE, FRIDAY, FEBRUARY 15, 1946

'Blue Babies' Who Were Restored to Health and Doctors Who Did It





Herald Tribune—Rice

Alan Beck, three and a half, of
1700 Sterling Place, Brooklyn



Herald Tribune-Acme

Marilyn Firsenbaum, nine and a Horry Goldzweig, seven, of 935

How 2 Doctors **Give New Lives** To Blue Babies

Blalock-Taussig Operation, First Tested on Dogs, Reroutes Flow of Blood

By Lester Grant

BALTIMORE, Feb. 14 .- This is the story of the work of two doctors-a man from Georgia and a woman from Massachusetts—who met in Baltimore and combined their talents to save the lives of "blue babies."

The doctors are Alfred Blalock, forty-six, surgeon in chief at Johns Hopkins Hospital here and pro-fessor of surgery at the Hopkins Medical School, and Helen B. Taussig, forty-seven, physician in charge of the cardiac clinic of the Harriet Lane Home for Invalid Children. The Harriet Lane Home constitutes the pediatries division of Johns Hopkins Hospital.

The surgery, known as the Blalock-Taussig operation, first was used on an infant on Nov. 29, 1944. Its development since then is one of the most exciting stories in

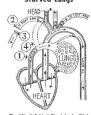


half, 80 Chester Street, Brooklyn

Dr. Alfred Blalock and Dr. Helen B. Taussig at Johns Hopkins Hospital in Baltimore



Switching Arteries Sidetracks Blood and Oxygen to Otherwise Starved Lungs



By Robert D. Potter

By Robert D. Potter
Selece Editor
WOMAN physician's courseous research and Imaginapeous research and Imaginathe worth's great surgeous have comindeed to bring hope that many "blue"
to early death—may be saved.
Three balles are hise because
oxygen in their blood streams, in a
continion known as cyanosis. The
continion known as cyanosis. The
continion known as cyanosis. The
is as constricted that their blood never
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research by Dr. Helon B. Thussig. Daughter of the late Frot, F. W. Taussig, weelf-famous Barvard combustions of the late frot, F. W. Taussig, weelf-famous Barvard combustions of the late of Johns Hopkins Ho

Saving our Doomed Blue' Babies the blood would pick up its life-giv-ing oxygen. Then it would go back to the heart again to move outward through the body. But could it be done? It is one thing to have a plumber rearrange a pluing system and something quite different to lay bare the human heart,

that Milke ended grow up. But then Milke a the M



Blalock and Taussig in London



Legacy to Children



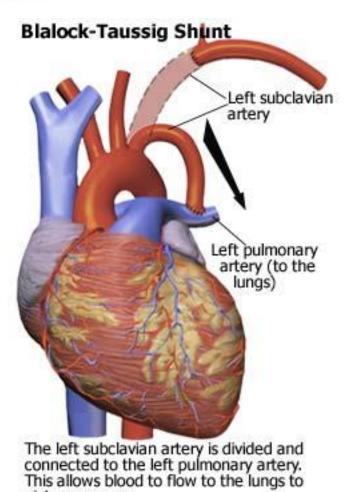


Blalock-Taussig Shunt





Intermountain Medical Center



pick up oxygen. © 2004 - Duplication not permitted

Johns Hopkins University







C. Walton Lillehei, MD 1918 - 1999

Donor
Cross Circulation



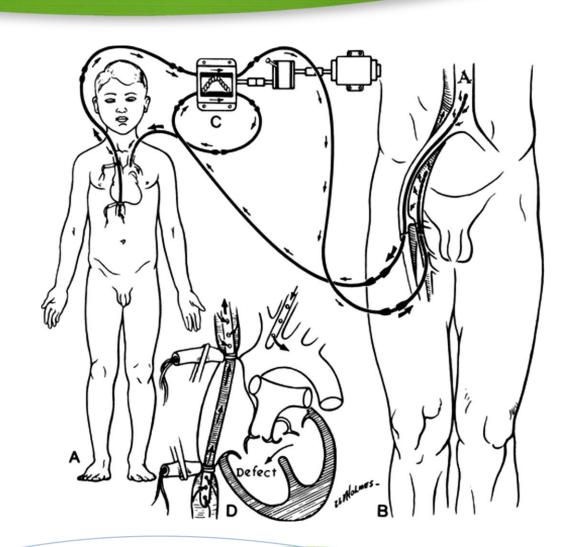
Donor Cross Circulation

Lillehei CW, Cohen M, Warden HE, et al

The results of direct vision closure of ventricular septal defects in eight patients by means of controlled cross circulation.

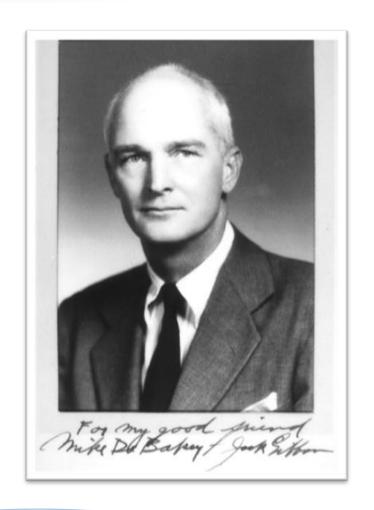
Surg Gynecol Obstet 1955; 101:446





John H. Gibbon, MD 1903 - 1973

Pioneer in the development of extracorporeal circulation

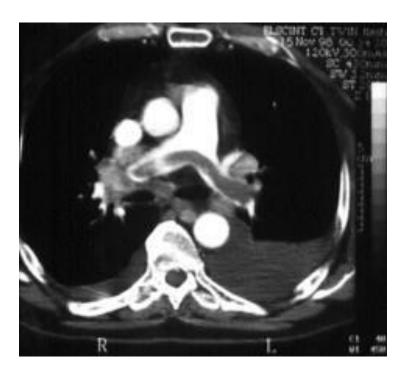


Mass General



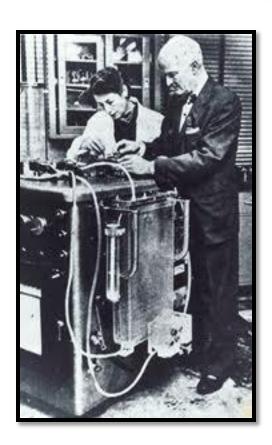


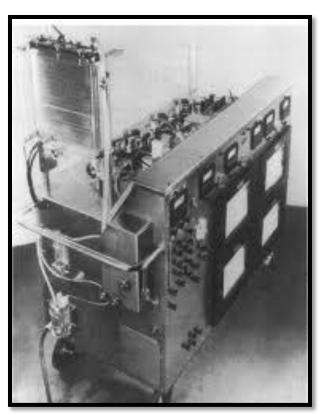
Massive Pulmonary Embolus

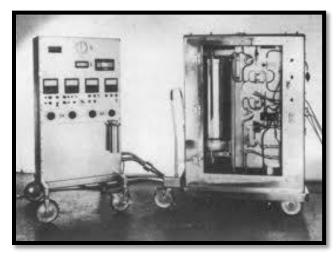




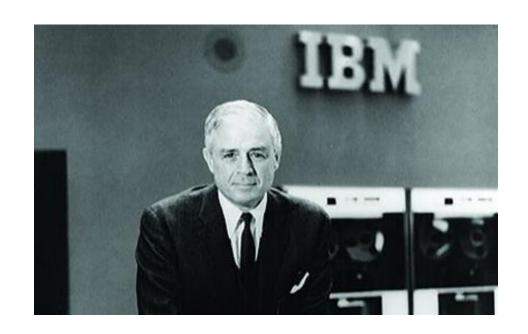
Early Heart Lung Machine

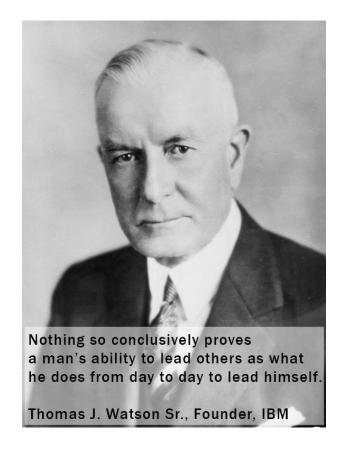






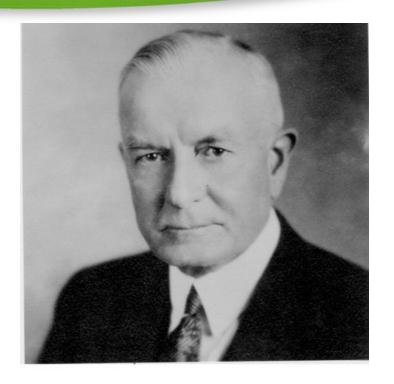
Thomas J. Watson





Thomas J. Watson





"Our work is one of service."

--Thomas J. Watson, Sr

May 16, 1953

Thomas Jefferson University

First successful open heart surgery using cardiopulmonary bypass





Success

war after an armistice.

list her go," he said.

by the F tor, gare

said he h

Science Unveils Machine That Acts As Both Heart and Lungs of Humans

Philadelphia (P) - A machine large opening between the surfthat functioned as both heart and cles causing the trouble. Dr. Giblungs of a human being for the bon said the opening "about the first time in medical history was size of a half dollar" meant that unveiled yesterday by surgeons at a large portion of her blood was Jefferson Medical College Hospi- continuously being recirculated tal.

Invented by Dr. John H. Gibbon Jr., director of surgical research at the college, the machine was shown to newsmen yesterday with the announcement that it had performed the combined functions of both organs while surgeons closed an abnormal opening in the wall of a patient's heart.

The operation was performed Wednesday on Miss Cecelia Bavolek, of Swoyersville, Pa., 18-yearold student at Wilkes College in Wilkes-Barre, Pa.

through her lungs. Only a small part of it was pumped through German the remainder of her body, causing a condition known as circular no part of spetal defect which deprives the muscles and bones of the body of their normal nourishment.

Dr. Gibbon described the operation in this way:

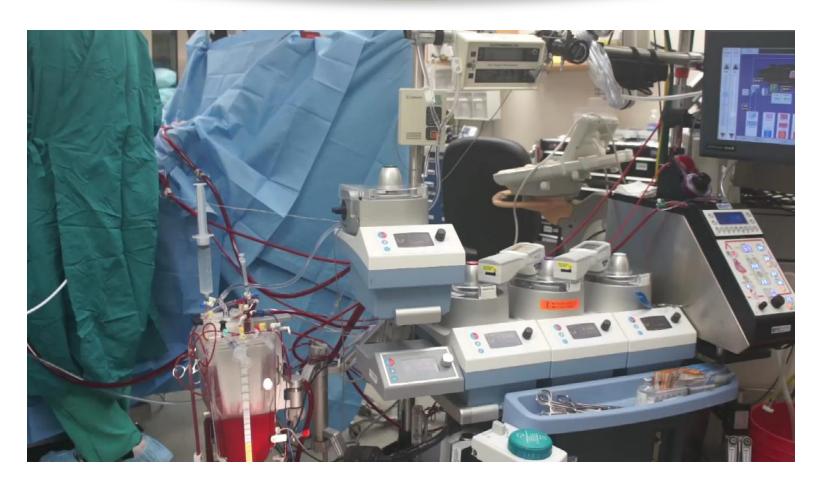
The patient's heart was opened and the abnormal opening closed. The surgeons placed tubes in the the girl. two blg veins leading to the heart lantie Ci and another in the artery in the of his pic chest. The tubes in the veins were of Collies connected to pumps which drew five furt warm the girl had suffered the blood out and circulated it the Unite

Heart Lung Machine





Modern Cardiopulmonary Bypass





Heart Transplantation

- "Thus saith the Lord God, 'A new heart also will I give you, and a new spirit will I put within you; and I will take away the stony heart out of your flesh, and I will give you an heart of flesh." '
- Ezekial, chapter 36, verse 26

First Heart Transplant 1967

Moments in History

In December, 1967, a young woman, Denise Darvall, was walking across a street in Woodstock to buy a cake when a car struck her. She died in Groote Schuur Hospital and in doing so achieved immortality by becoming the world's first heart donor when Christiaan Neethling Barnard transferred her heart into the chest of Lõuis Washkansky.

Cape Town has been witness to many historic moments since the day Van Riebeeck anchored in Table Bay. Few, if any, brought more limelight to the city than the heart transplant. For the surgeon, Dr Barnard, soon to be a household name throughout the world, "the heart is merely a pump". But for those who equated the heart with love and death, the transplant seemed close to a miracle.

"Mr Louis Washkansky, the 55-year-old Cape Town man whose life is being sustained today by the heart of a dead 25-year-old woman after the world's first successful heart transplant yesterday, is conscious in Groote Schuur Hospital and in a satisfactory condition." Monday, 4th December 1967



Professor Chris Bureard, leader of the beart-transplant team, in a characteristic once during one of his many



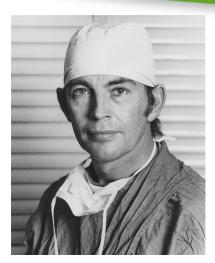
First close-up photograph to be taken of Mr Leuis Wachkansky, who unforward the world's first heart-transplant operation, was taken by a surgest using an Army photographer's manner at Goots Echner Hospital. Mr Wachkansky, whose condition was given as good, is being assisted to hearthe by a reminister. A 12 1007.

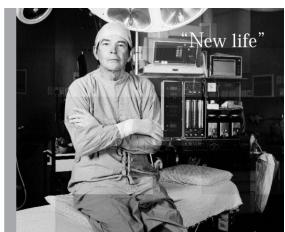






Christiaan N. Barnard, MD



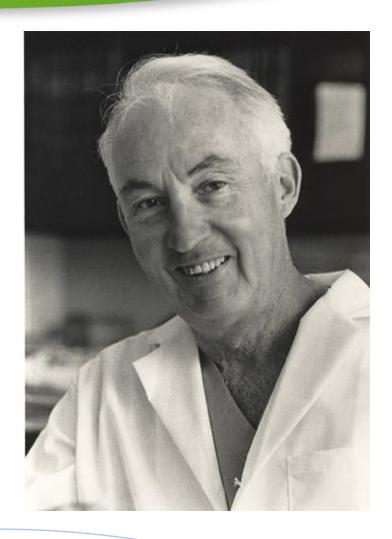






Norman E. Shumway, MD





First Transplant in US 1968







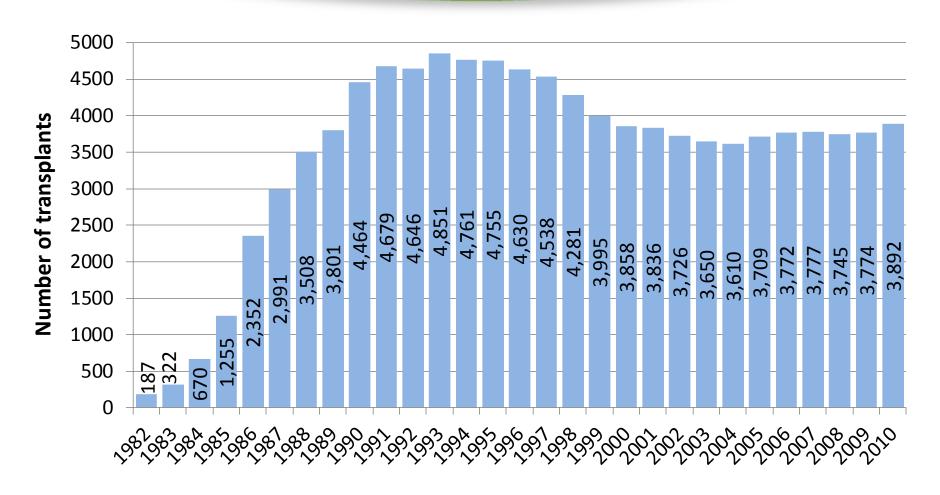


"OK, the old one's in my right hand, the donor's in my left. Right?"

Heart Transplantation

- First performed in 1967—clinically useful in the early 80s
- Inherent limitations—lack of donors
- ~2000 transplants per year; 3200 listed (many patients die on the waiting list)
- 15-20 transplants at IMC per year
- The majority of transplant recipients in the modern era are "bridged" to the procedure with an LVAD

Heart Transplants Reported per Year

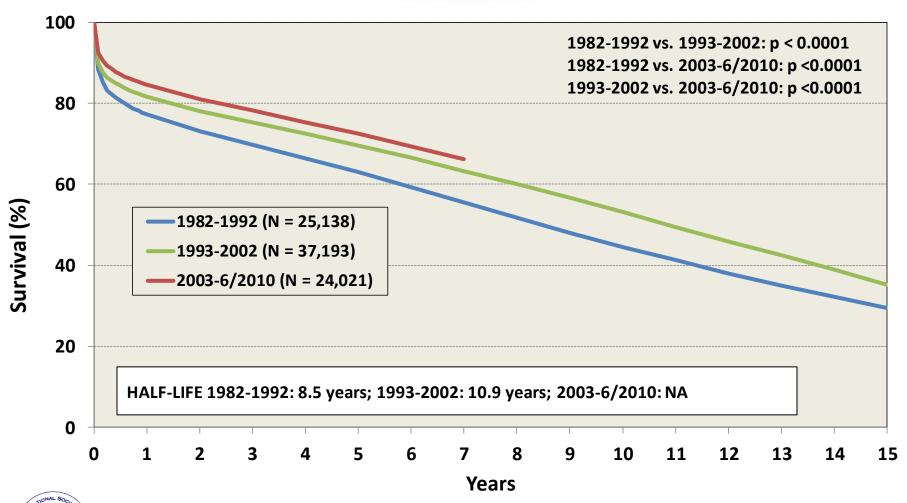




NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide

Kaplan-Meier Survival by Era

(Transplants: January 1982 - June 2010)



Post-Heart Transplant Morbidity for Adults

Cumulative Prevalence in <u>Survivors</u> at 1, 5 and 10 Years Post-Transplant (Follow-ups: April 1994 - June 2009)

<u>Outcome</u>	Within 1 <u>Year</u>	Total N with known response	Within 5 <u>Years</u>	Total N with known response	Within 10 <u>Years</u>	Total N with <u>known</u> response
Hypertension	73.2%	(N = 24,229)	93.1%	(N = 10,485)	97.4%	(N = 2,238)
Renal Dysfunction	26.8%	(N = 25,254)	31.1%	(N = 12,146)	36.8%	(N = 3,681)
Abnormal Creatinine < 2.5 mg/dl	18.1%		21.0%		24.3%	
Creatinine > 2.5 mg/dl	7.0%		7.3%		6.2%	
Chronic Dialysis	1.5%		2.3%		4.8%	
Renal Transplant	0.3%		0.5%		1.5%	
Hyperlipidemia	58.1%	(N = 25,572)	87.8%	(N = 11,800)	93.3%	(N = 2,659)
Diabetes	27.4%	(N = 25,292)	36.6%	(N = 11,154)	38.5%	(N = 2,401)
Cardiac Allograft Vasculopathy	7.8%	(N = 22,853)	31.0%	(N = 8,197)	51.8%	(N = 1,830)

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"Your insurance won't pay to transplant a human heart or even a baboon heart, so we'll be using an artichoke heart."



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



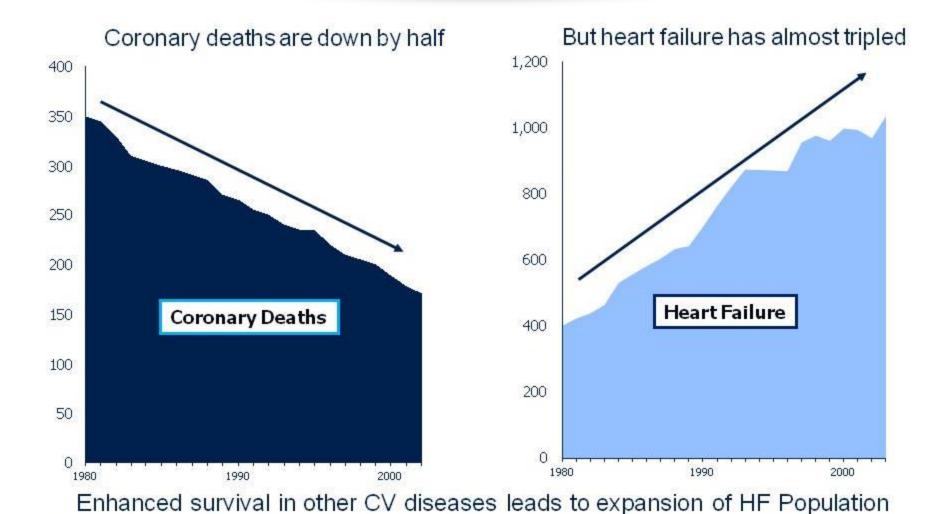
Economic Impact of CHF



- 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*

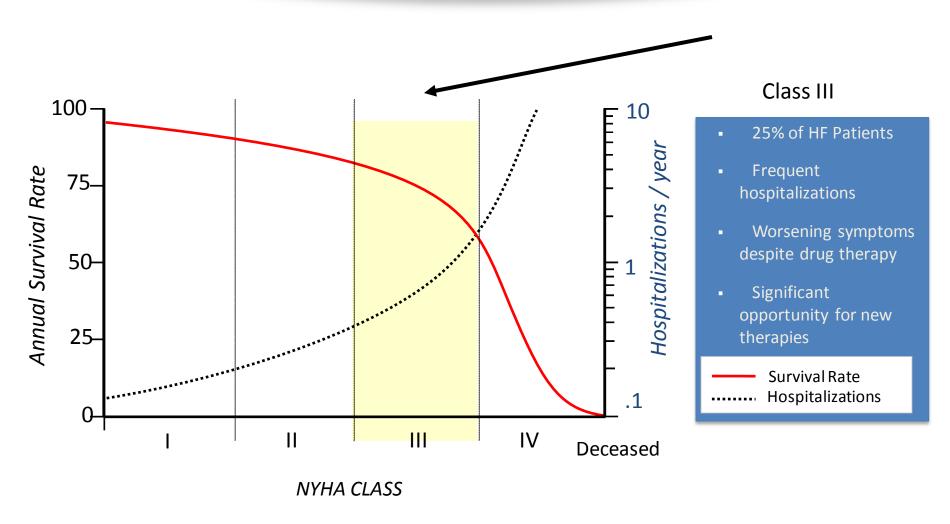
*Utah Department of Health

Heart Failure: The Final Cardiovascular Disease



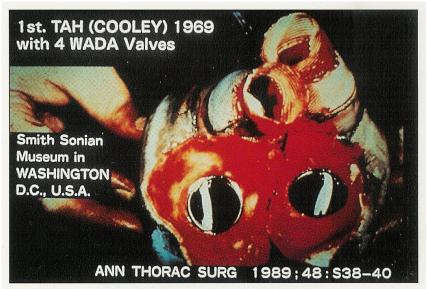
Source: National Hospital Discharge Survey data. Centers for Disease Control and Prevention/National Center for Health Statistics and National Heart, Lung, and Blood Institute.

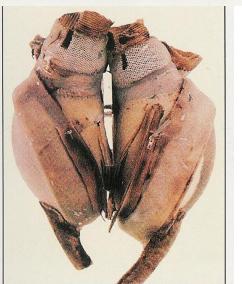
Natural History of Heart Failure



Adapted from Bristow, MR Management of Heart Failure, <u>Heart Disease: A Textbook of Cardiovascular Medicine</u>, 6th edition, ed. Braunwald et al.

Total Artificial Heart





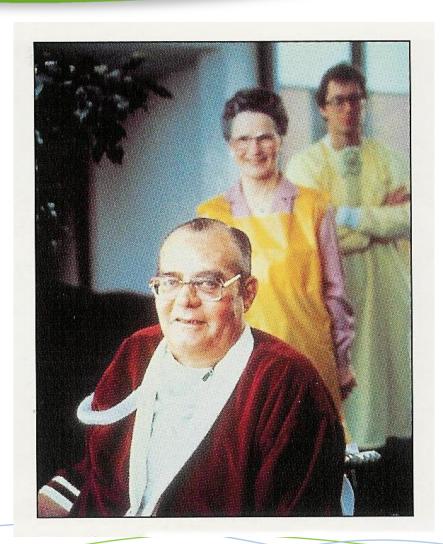
1969 - first artificial heart to be implanted into a human (Dr. Denton Cooley).

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

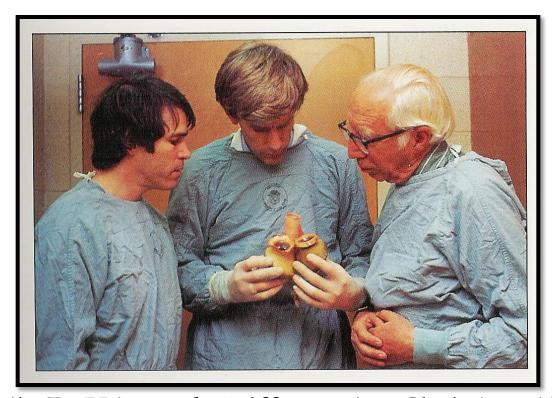
The patient's widow accused Cooley of making her husband the "unfortunate victim of human experimentation."

Barney Clarke

1982 – Barney Clarke with Mrs. Clarke after his initial recovery.



Barney Clarke



Jarvik, DeVries and Kolff examine Clarke's artificial heart after autopsy.



Total Artificial Heart





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 – FDA approved for DT



NEJM, Nov. 2009 FDA approved Jan. 20, 2010



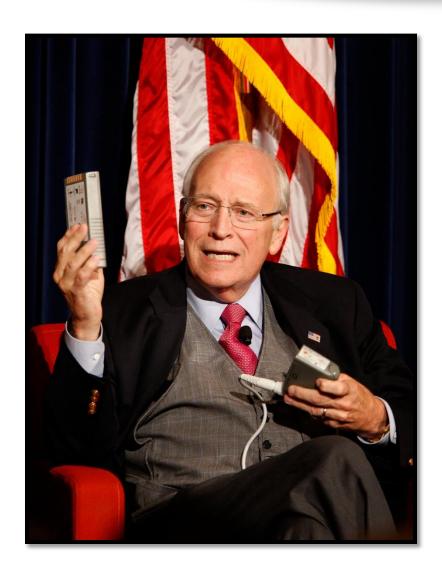
TRIAL SUMMARY:

- 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

	HM II	HM XVE	
Survival @ 2 years	58%	24%	
Median duration of support	1.7 years	0.6 years	
Relative Risk (95% CI)			
Device repair or replacement	0.06	0.51	
Stroke	0.13	0.22	
LVAD-related infection	0.48	0.90	
Bleeding requiring surgery	0.23	0.29	
Rehospitalization	2.64	4.25	

Former Vice President Dick Cheney

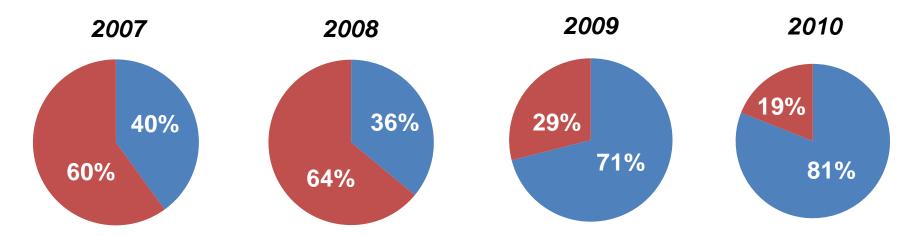


- HeartMate II implant August 10, 2010 as BTT
- 1.5 years of support
- Successful bridge to transplant
- Age 70

'It's brought me back from end-stage heart failure," says Cheney, who has suffered five heart attacks, the first at age 37. 'I was in bad shape 14 months ago. Now I'm back to leading a relatively normal life. I fish, hunt a little bit, write books, (am) able to travel."

Bridge to Transplantation (BTT)

An increasing percentage of patients listed for cardiac transplantation require VAD support as a bridge.

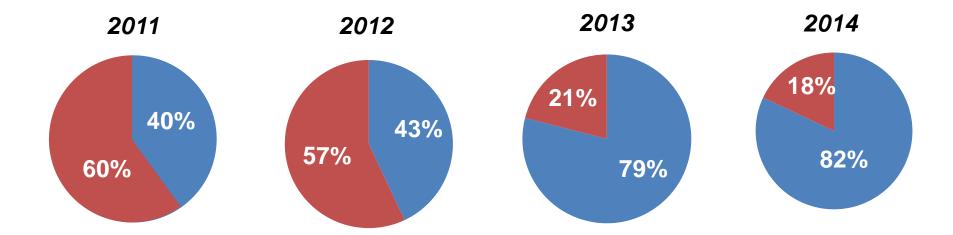


- Bridge requiring VAD/Artificial Heart
- Traditional Transplantation

OUTCOMES AT OUR CENTER: HM II Survival to Transplant: 100%



Bridge to Transplantation (BTT)



■ Bridge requiring VAD/Artificial Heart

Traditional Transplantation

Recent transition to HeartWare HVAD with excellent outcomes as bridge

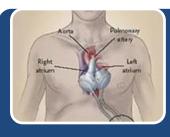


Mechanical Circulatory Support



Short Term / Emergency

- •Time frame: hours to days
- Rapid MCS for cardiogenic shock, post cardiotomy failure, or during high-risk Cath Lab procedures



Bridge to Transplant (BTT)

- •Time frame: months to years
- Temporary implanted MCS for patients waiting for a donor heart to become available

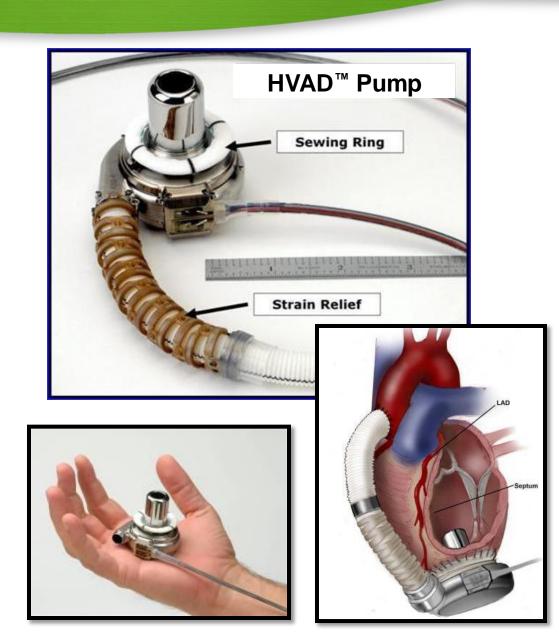


Destination Therapy (DT)

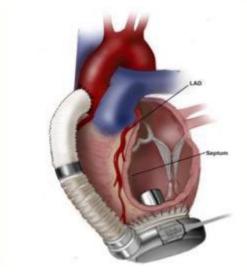
- •Time frame: Permanent (years)
- Long-term implanted MCS for patients who are not eligible for a heart transplant

HeartWare HVADTM

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



HeartWare HVAD





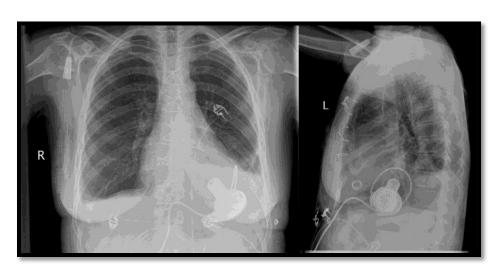


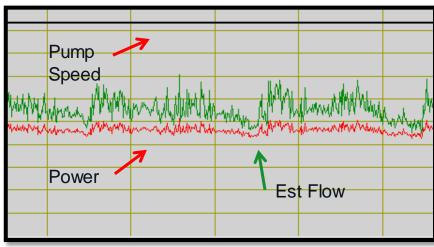
- Inflow cannula integrated with device
- Small pump housing: 2 inch outside diameter, displaced volume of 50 cc
- Magnetically suspended impeller, only moving part (increased durability potential)
- Intrapericardial no pump pocket
- Requires warfarin (INR: 2.0 2.5)
- Approved for use in Europe
- Destination Therapy clinical trial in U.S. (ENDURANCE)
- UAHP: 43 implants to date

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

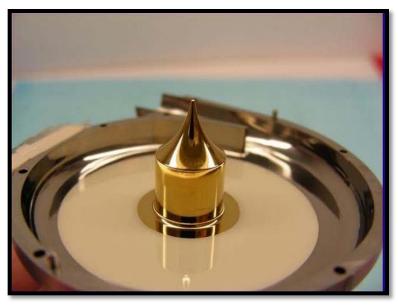




Interior of pump shown after 427 days of support in human patient



IMPELLER



PUMP HOUSING

- Impeller only moving part
- Completely suspended by a combination of passive magnets and hydrodynamic thrust bearings
- Never touches pump housing

HeartWare HVAD

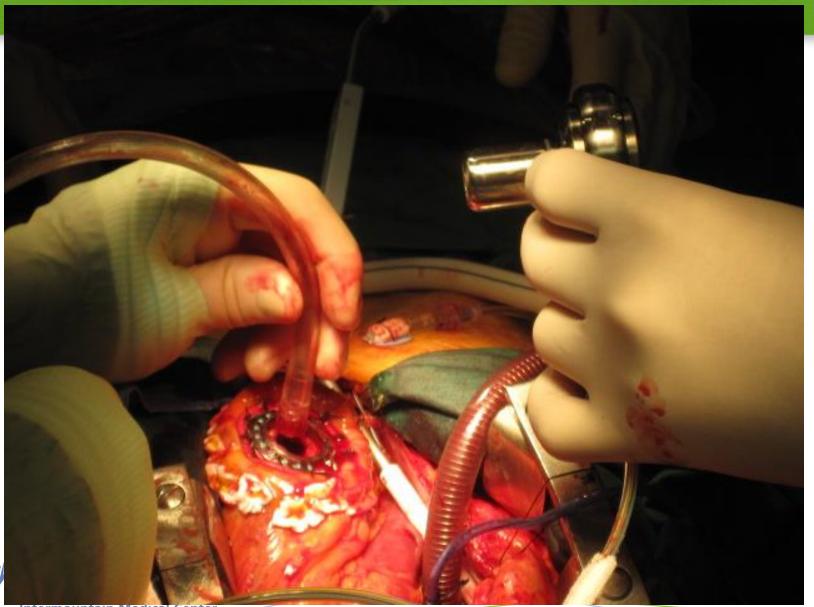


MCS Case Review

- 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



09/21/2010 12:27:36PM TIS0.1 MI 0.5 X7-2t/Adult FR 52Hz 18cm Μ4 2**D** 76% C 50 P Off Gen 20 180 **POST** RPM 2500 **JPEG** *** bpm PAT T: 37.0C TEE T: 39.3C



WY

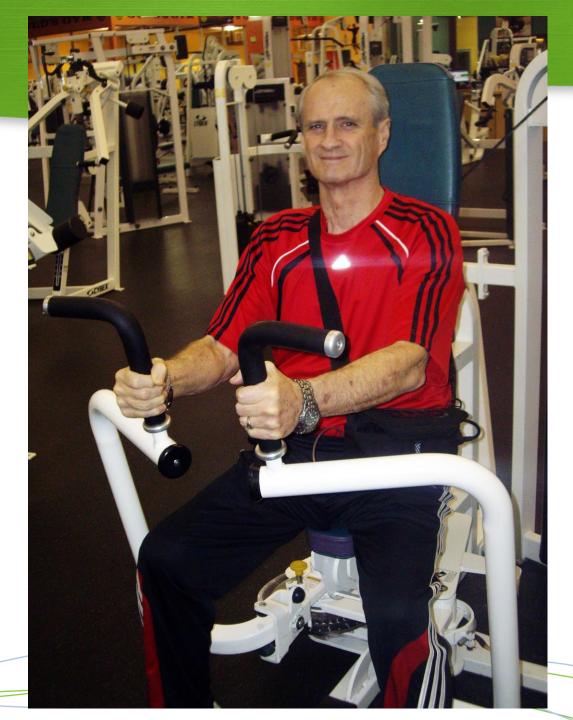




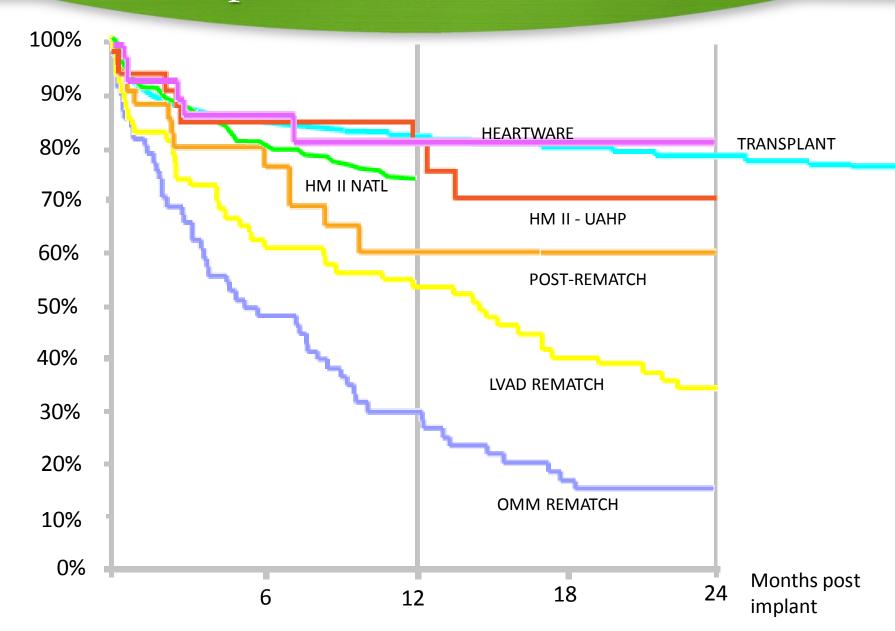


Postoperative Day #1

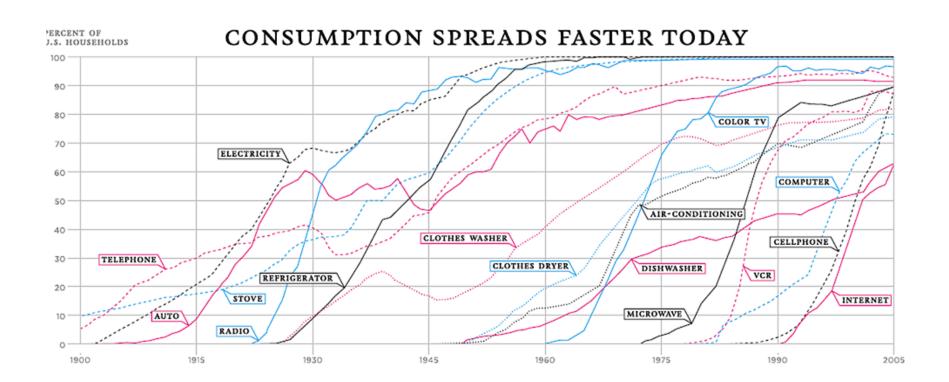
3 months later...



Improvements in Survival

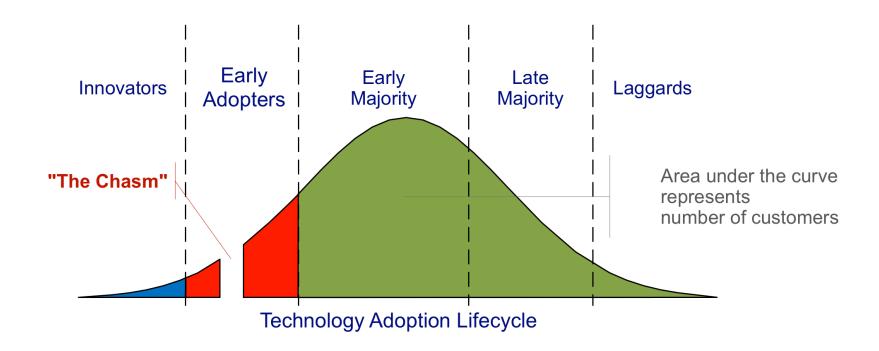


Adoption of Technology





Technology Adoption













- Ford Model T
- 1908 1927
- First affordable automobile
- Mass production
- Moving assembly line: every three minutes
- 20 horsepower 1.7 L 4 cylinder engine
- Top speed \sim 40 mph



- Most influential car of the 20th Century
- Widespread adoption worldwide
- 50% of all cars in 1920
- 1909: 10,666 produced and sold for \$825 (\$21,650 in 2015)
- 1925: 1.9 million sold for \$260 (\$3,500 today)









Aviation





Aviation





Aviation



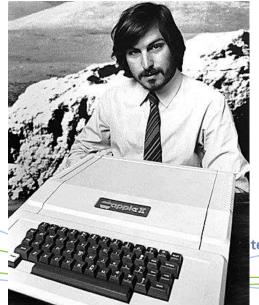




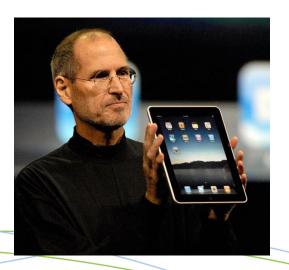












Internet















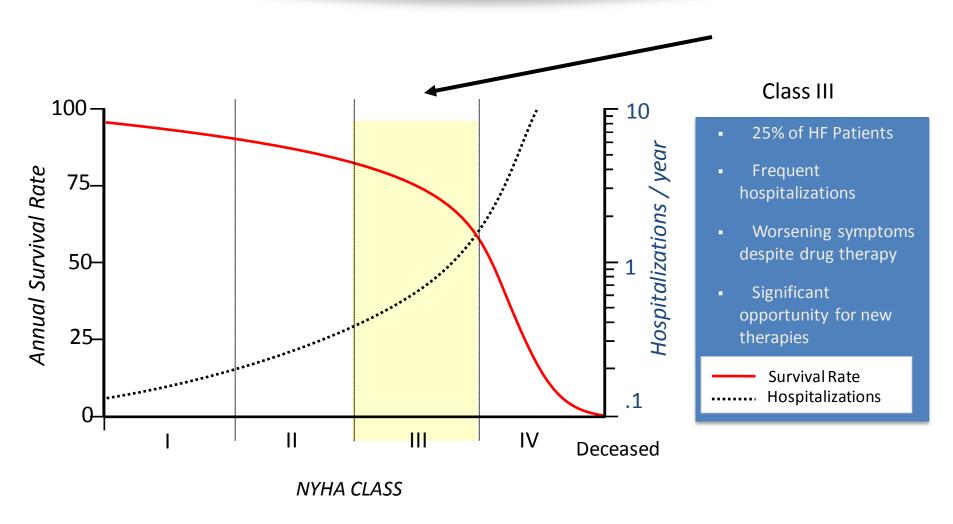
Life Expectancy – Pancreatic Cancer

- Best case scenario
 - Node negative
 - Clear margins at surgical resection (Whipple)
- 20% survival at 5 years for Stage I
- 10% survival at 1 year for all stages





Who and When?



Adapted from Bristow, MR Management of Heart Failure, <u>Heart Disease: A Textbook of Cardiovascular Medicine</u>, 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

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

Contact Information

Bruce B Reid, MD

Office: 801-507-3600

Cell: 801-719-8253

24 Hour Hotline: 801-507-LVAD

Bruce.Reid@imail.org

