Surgical Options for Advanced Heart Failure

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Heart Disease and Heart Failure - The Magnitude of the Problem

- Congestive heart failure affects nearly 5 million in the US and its prevalence is growing around the world.
- About 70,000 new patients each year, with severe heart failure, are expected in the USA by the year 2010
- In 1995 the cost of heart disease in the US was >$174B, with ~70% for hospitalization and nursing home care.

American Heart Association. 1998 Heart and Stroke Statistical Supplement. Dallas, TX: AHA, 1997

Epidemiology of Heart Failure in Israel

- of adults > 65 yrs of age 6-10%
- Total number of patient: 86,000 pts
- New cases: 8,600 per year
- Death per year: 6,000 people

Current Heart Failure Therapy

- Chronic heart failure carries a major social and economical concern
  - The disease is progressive in nature, and many patients become refractory to standard medications
  - As a result they are not functioning and become dependent on society

Treatment Options

- Medical
- Biventricular pacing
- Tissue engineering
- Surgery

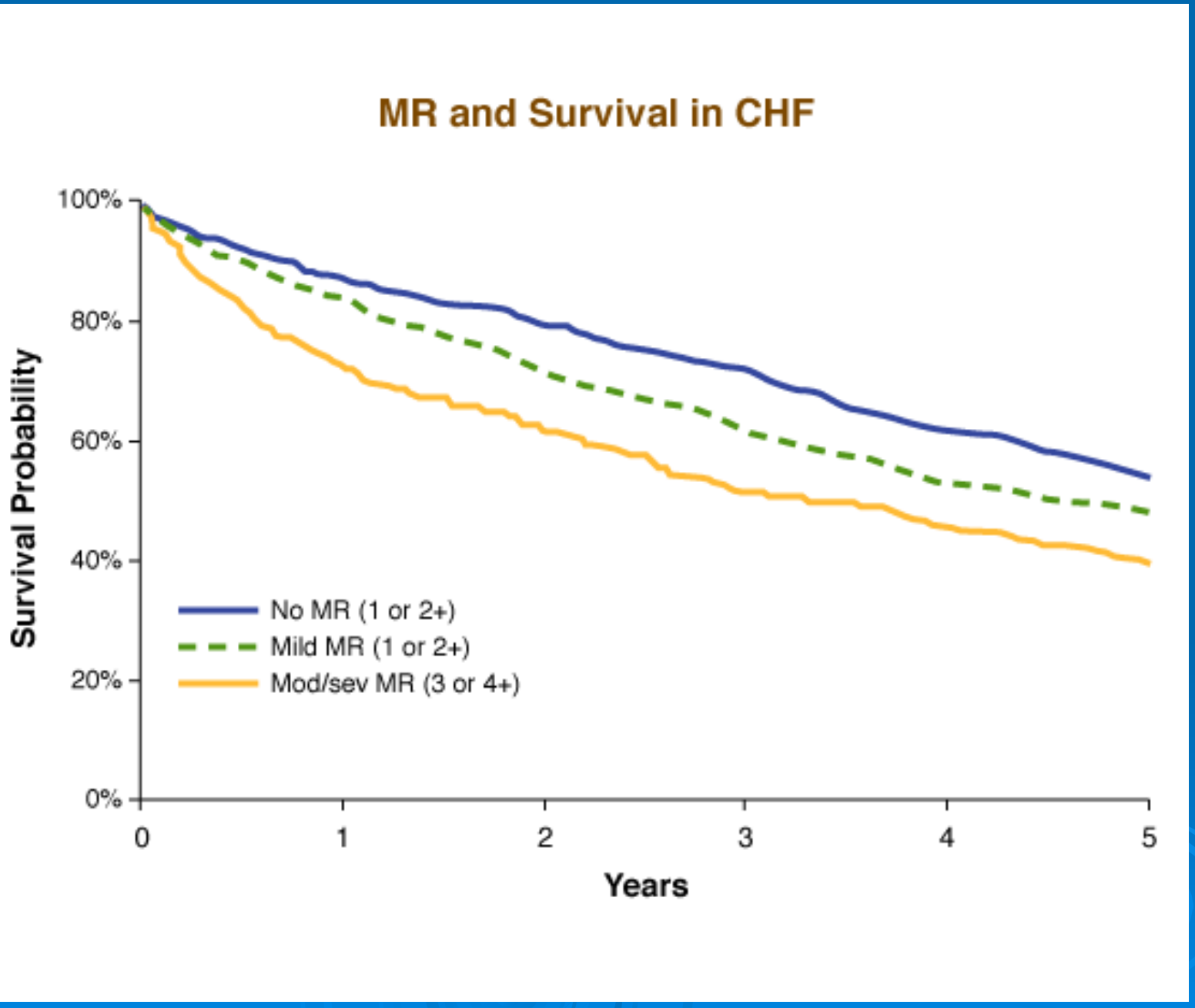
Treatment Options
Surgery

- Revascularization
- Valve repair
- Ventricular reconstruction
- Constraint devices
- Heart (allo)transplantation
- Heart xenotransplantation
- Mechanical devices

Myocardial Revascularization

- Seems to be beneficial when more then 25% viability is present
- Metanalysis *(Allman et al. J Am Coll Cardiol (2002;39:1151-8*
  - patients 3088
  - 32±8% LVEF
  - 25±10 monthsFollow-up
  - Annual mortality

-VIABILITY	VIABILITY+	
7.7%	3.2%	CABG
6.2%	Medical	16%


MR and Survival in CHF
Survival Probability
100%
80%
60%
40%
20%
0%
0
1
2
3
4
5
Years
No MR (1 or 2+)
Mild MR (1 or 2+)
Mod/sev MR (3 or 4+)

Mitral Valve Repair

- Popularized by Bolling
- Downsizing ring
- RV dysfunction and PHT are not doing well
- patients with severe MR and EF<25% 48
  - and 24 months survival: 82% and 71% 12
  - 3.9±0.3 to 2.0±0.6FC:
  - 17±3% to 26±8%LVEF

Bolling et al. J Thorac Cardiovasc Surg 1998;115:381-8.

Mitral Valve Repair

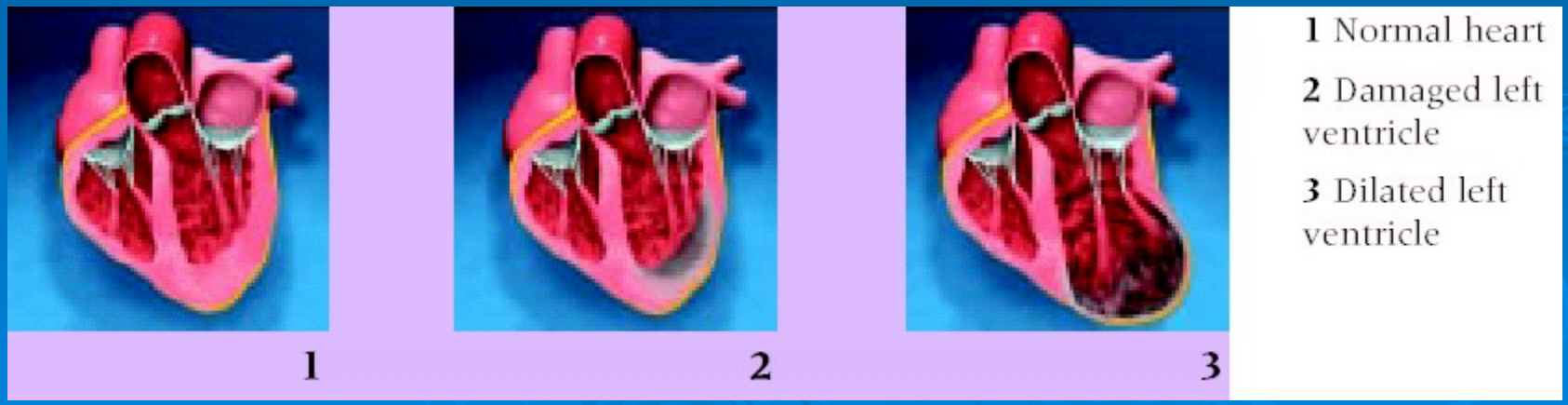
?No Survival Advantage

- patients with severe MR 419
- Death, LV assist device implantation, or transplantation
- Mitral valve annuloplasty (n=126) -> 62 ((49%
- (Treated medically (n=293) -> 120 (41%
- Not significant

Wu AH et al. J Am Coll Cardiol 2005;45:381-7

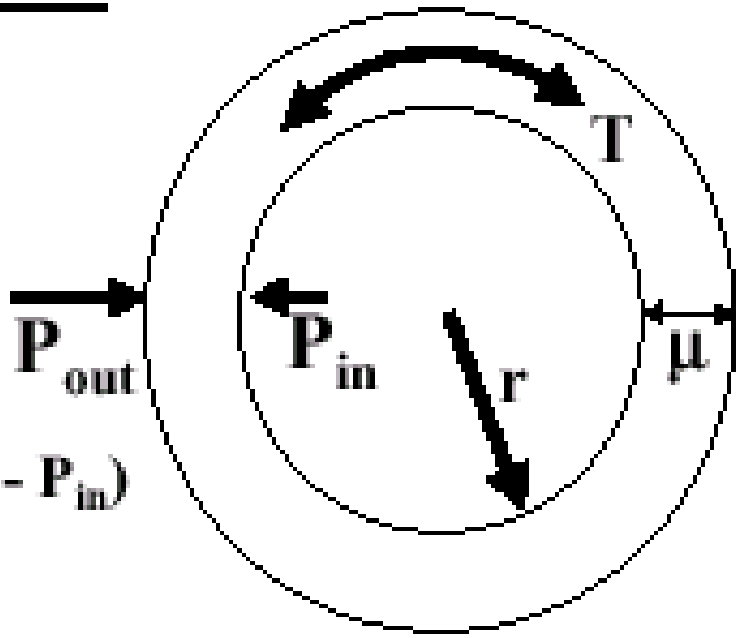
Ventricular Reconstruction

- Popularized by DOR
- Initially used for LV aneurysm only
- Reshaping the globular dilated heart into a conical one became apparent later



Laplace's Theorem

$$T = P\ r / \mu$$

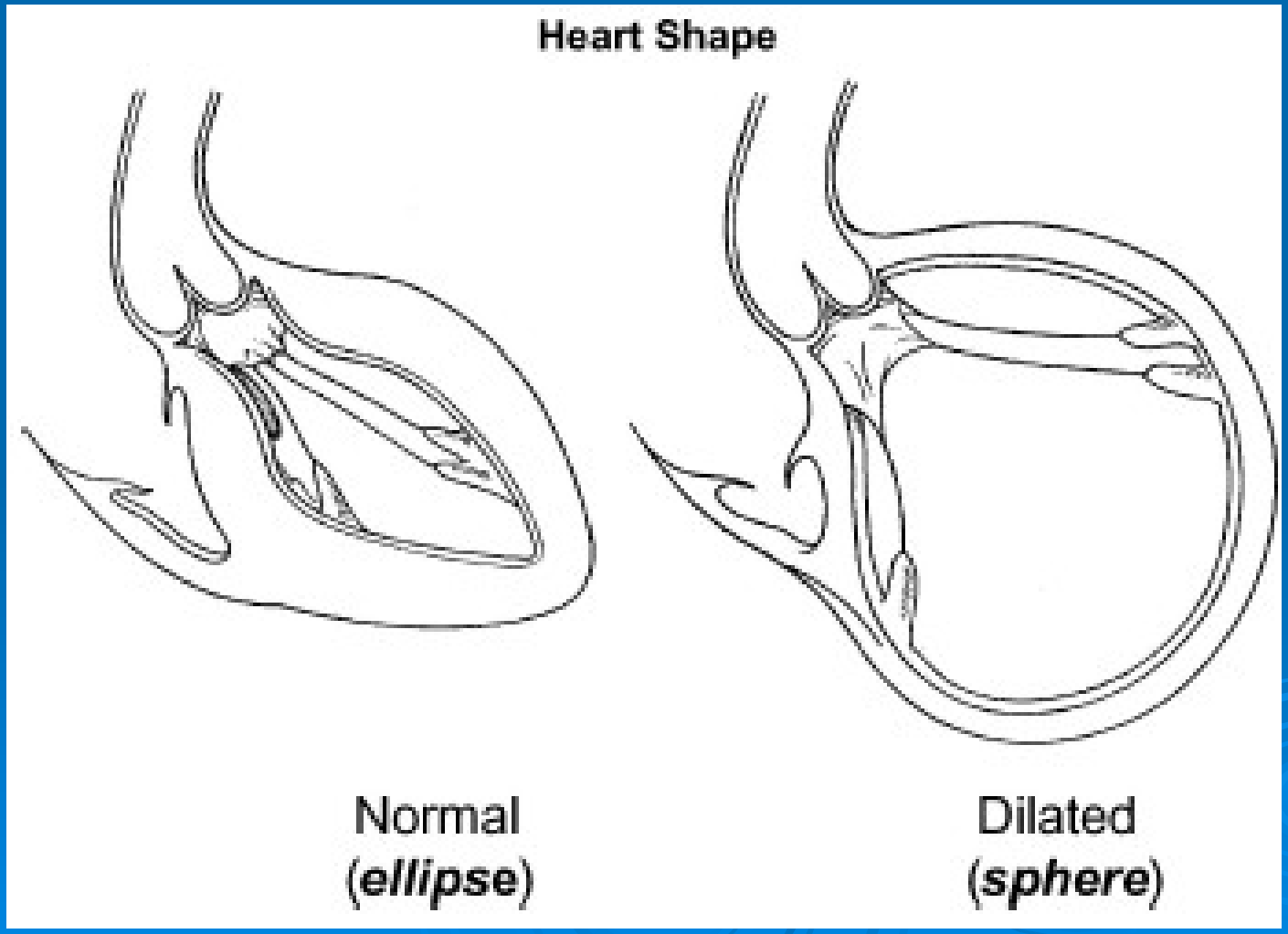


T - tension

P - transmural pressure ($P_{out} - P_{in}$)

r - radius of the vessel

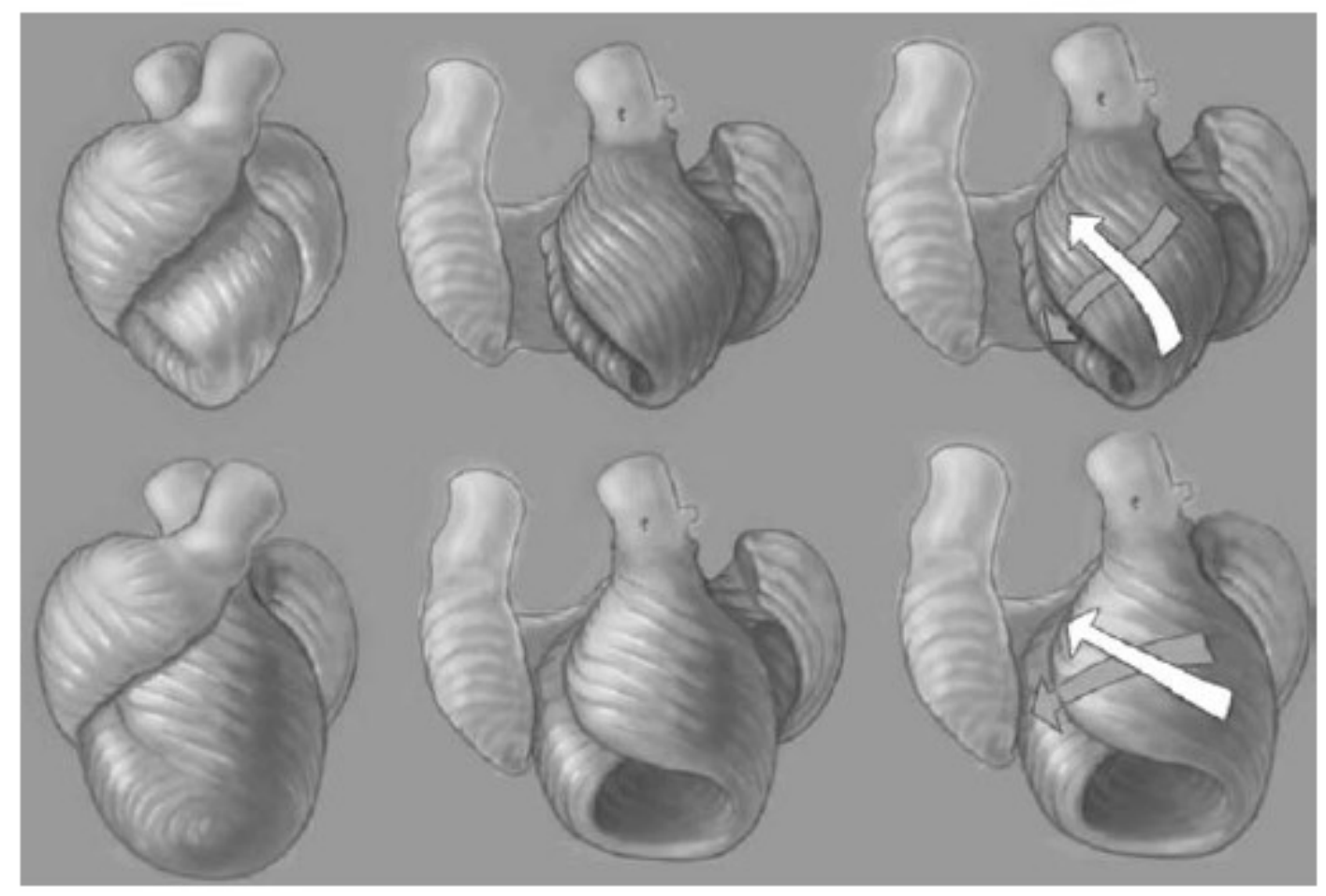
μ - wall thickness


Heart Shape
Normal
(*ellipse*)
Dilated
(*sphere*)

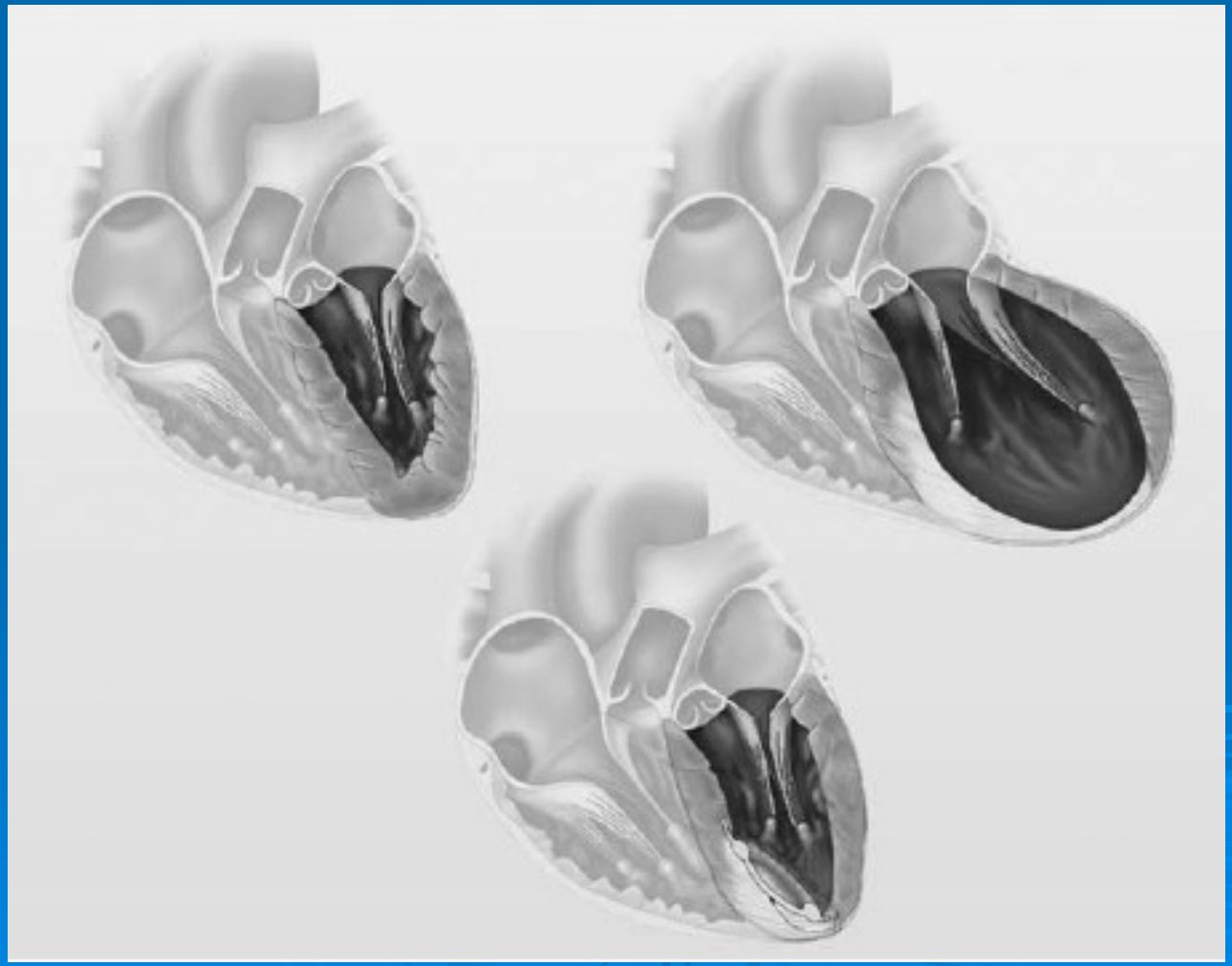
Fiber Orientation

Normal

Remodeled



Objective of Procedure



RESTORE group

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Heart Failure

Surgical Ventricular Restoration in the Treatment of Congestive Heart Failure Due to Post-Infarction Ventricular Dilation

Constantine L. Athanasuleas, MD,* Gerald D. Buckberg, MD,† Alfred W. H. Stanley, MD,* William Siler, PHD,* Vincent Dor, MD,‡ Marisa Di Donato, MD,§ Lorenzo Menicanti, MD,‖ Sergio Almeida de Oliveira, MD,¶ Friedhelm Beyersdorf, MD,# Irving L. Kron, MD,** Hisayoshi Suma, MD,†† Nicholas T. Kouchoukos, MD,‡‡ Wistar Moore, MD,§§ Patrick M. McCarthy, MD,‖‖ Mehmet C. Oz, MD,¶¶ Francis Fontan, MD,## Meredith L. Scott, MD,§§ Kevin A. Accola, MD,§§ and the RESTORE Group

Birmingham, Alabama; Los Angeles, California; Monte Carlo, Monaco; Florence and Milan, Italy; Sao Paulo, Brazil; Freiburg, Germany; Charlottesville, Virginia; Kanagawa, Japan; St. Louis, Missouri; Orlando, Florida; Cleveland, Ohio; New York, New York; and Bordeaux, France

RESTORE Study

- patients with postinfarction dilated 1,198 cardiomyopathy had CABG and LV restoration between 1998 - 2003
- Non contracting segments excluded
- Improved EF and NYHA
- Perioperative mortality – 5.3%
- Overall 5 years survival – 69%
- Freedom from readmissions for CHF – 78%

Athanasuleas et al. JACC 2004; 44: 1439-45

Surgical therapy for ischemic heart failure: Single-center experience with surgical anterior ventricular restoration

Lorenzo Menicanti, MD,[a] Serenella Castelvecchio, MD,[a] Marco Ranucci, MD,[a] Alessandro Frigiola, MD,[a] Carlo Santambrogio, MD,[a] Carlo de Vincentiis, MD,[a] Jelena Brankovic, MD,[a] and Marisa Di Donato, MD[b]

J Thorac Cardiovasc Surg 2007;134:433-41

- patients between 1989 – 2005 1,300
- patients between 1998-2005 with 488 complete ECHO follow-up
- Improved EF and NYHA
- Perioperative mortality – 4.7%
- Overall 10 years survival – 63%
- Freedom from readmissions for CHF – 82%

LV RECONSTRUCTION

Indications

- Post MI
- EF<40%
- NYHA Class II - IV
- LVEDVI>100 ml/m^2
- LVESVI>60 ml/m^2

Contraindications

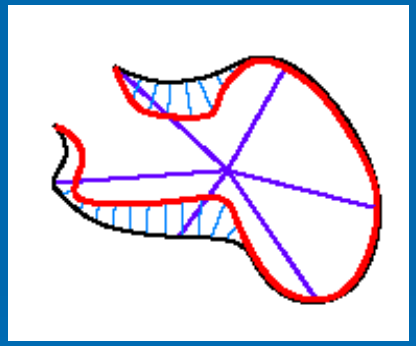
- Severe RV dysfunction
- Severe PHT
- Restrictive diastolic pattern (E/A>2) with high FC and MR

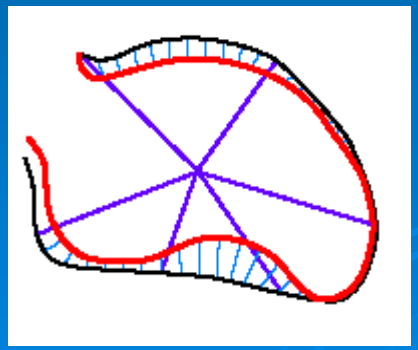
High risk

- Age>75
- EF<30%
- LVESVI>80 ml/m^2
- NYHA Class IV
- Diastolic dysfunction ((E/A>2

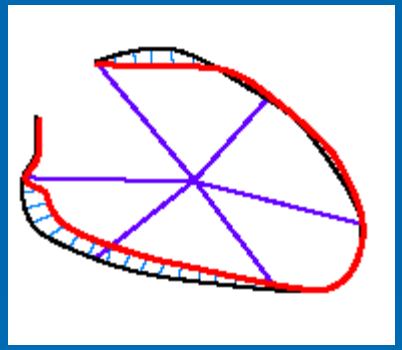
LV RECONSTRUCTION

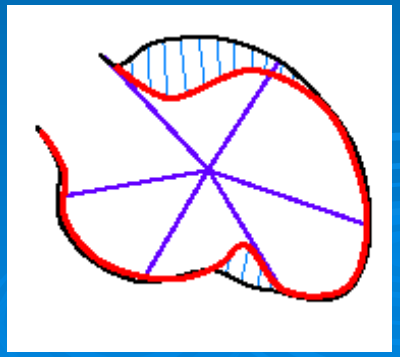
Benefit





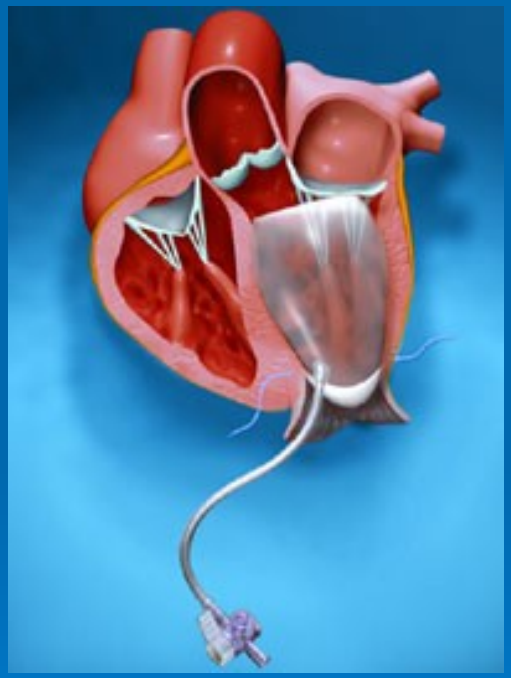
Do Not Benefit



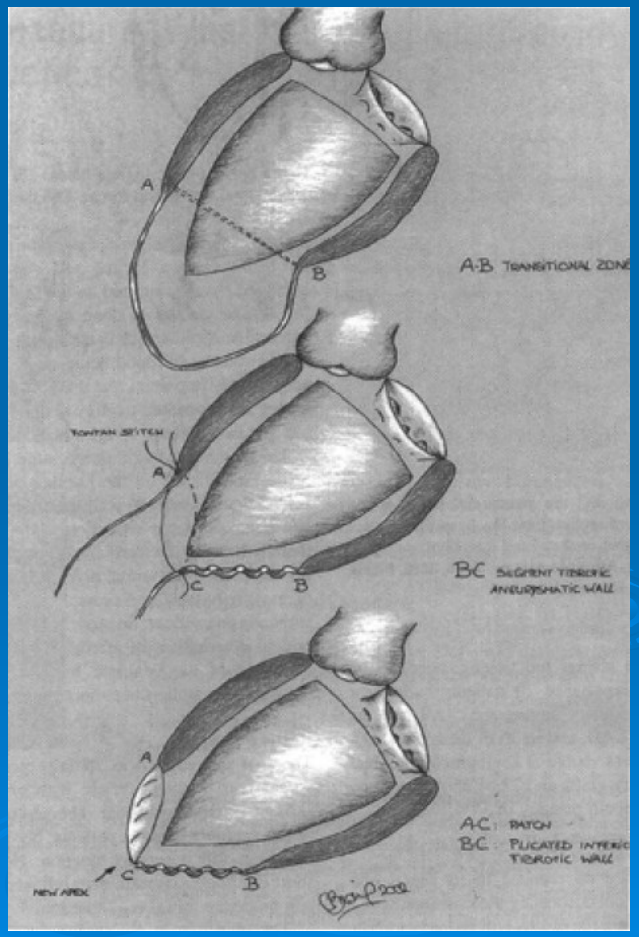


SVR assistance

Blue Egg
BioVentrix



TRISVR
CHASE Medical



STICH

Surgical Treatment for Ischemic Heart Failure

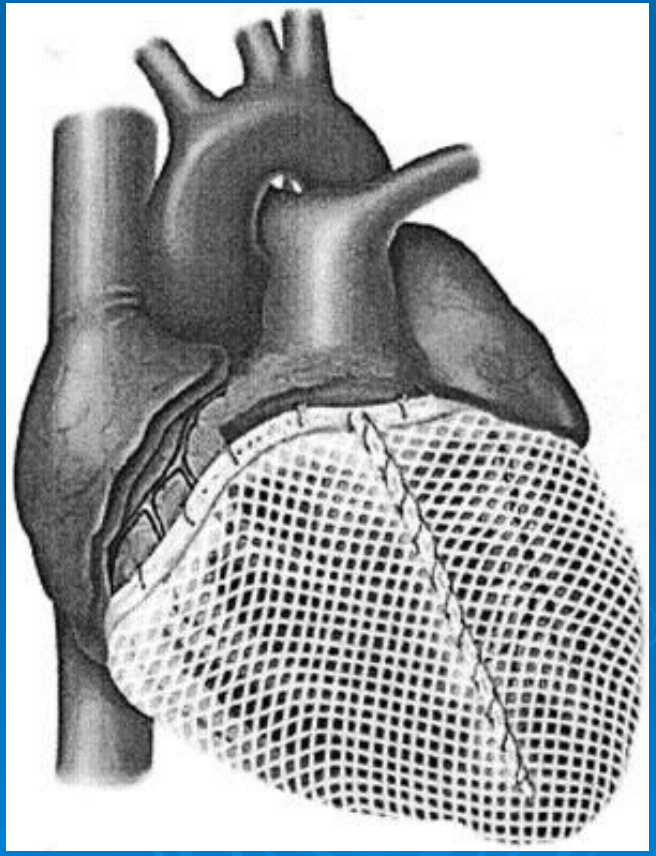
- Multi center trial
- About 3,000 patients will be enrolled
- MED vs. CABG + MED vs. CABG and LV reconstruction + MED
- LVEF<=35%

Constraint Devices

- Passive restrain
  - (Acorn (CorCap
  - ParaCor
- Alteration of ventricular shape
  - Myosplint
  - Coapsys
  - CardioClasp
- (Dynamic (True assist
  - MyoVAD

Acorn - CorCap

- Polyester mesh
- Decreases diastolic wall .stress
- Shows beneficial effect in chronic dilated heart failure as well as post .acute MI in canine model



Acorn – CorCap

Clinical

- Safety and lack of constriction was proved .in 60 patients
- Randomized clinical trial – 300 patients
  - (with mitral (half and half 200
  - (medical (half and half 100
- Improved 18 months quality of life

AHA meeting, 2004

שאלה 1

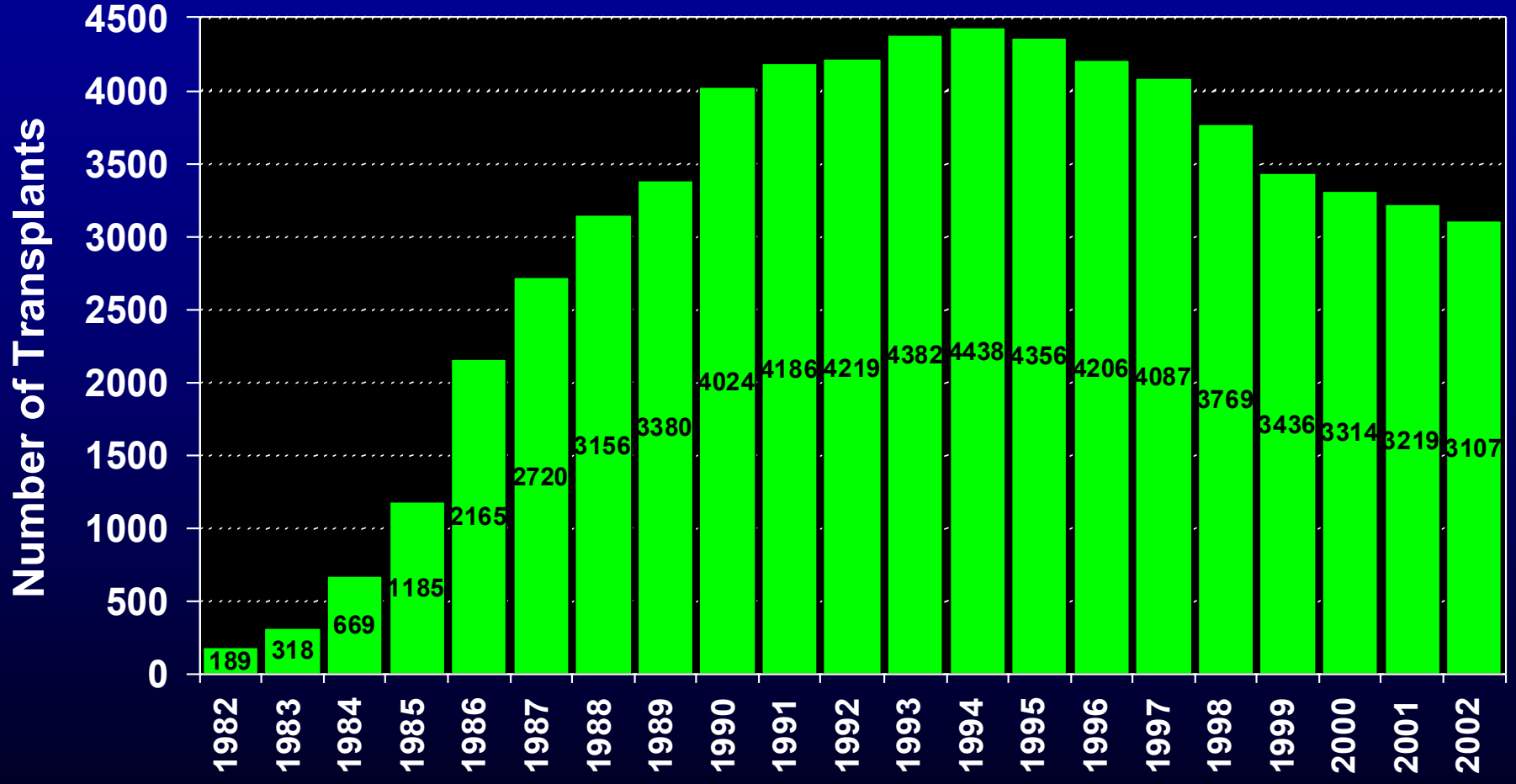
- בניתוחים הבאים כשהאינדיקציה הינה אי ספיקת לב ותפקוד לבבי ירוד קיימת <u>הארכת</u> תוחלת חיי החולה.

1. הקטנת טבעת מסתם מיטרלי בנוכחות אי ספיקה קשה של המסתם.
2. ניתוח מעקפים כשהבעייה איסכמית בנוכחות ויאביליות של 30%.
3. שימוש ב- constrain device בנוכחות הפרעה דיאסטולית קשה.
4. הקטנת חדר שמאל (SVR) כאשר LVEDVI>100ml/m2.

Heart (allo)transplantation

Pros	Cons
Current gold standard	**Limited supply** Requires immunosuppressive medications • Rejection is common • Infection is common

NUMBER OF HEART TRANSPLANTS REPORTED BY YEAR

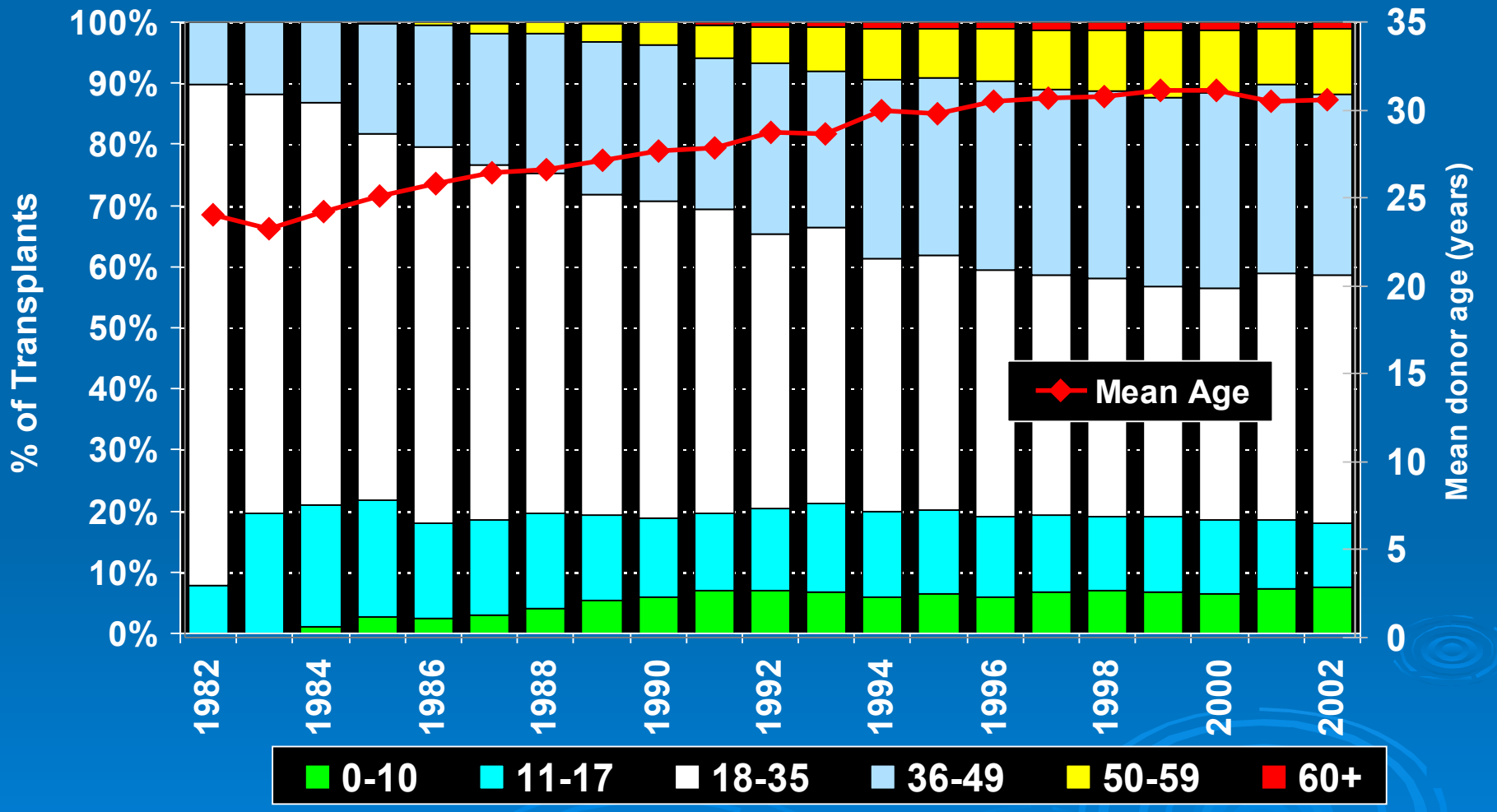


ISHLT

2004

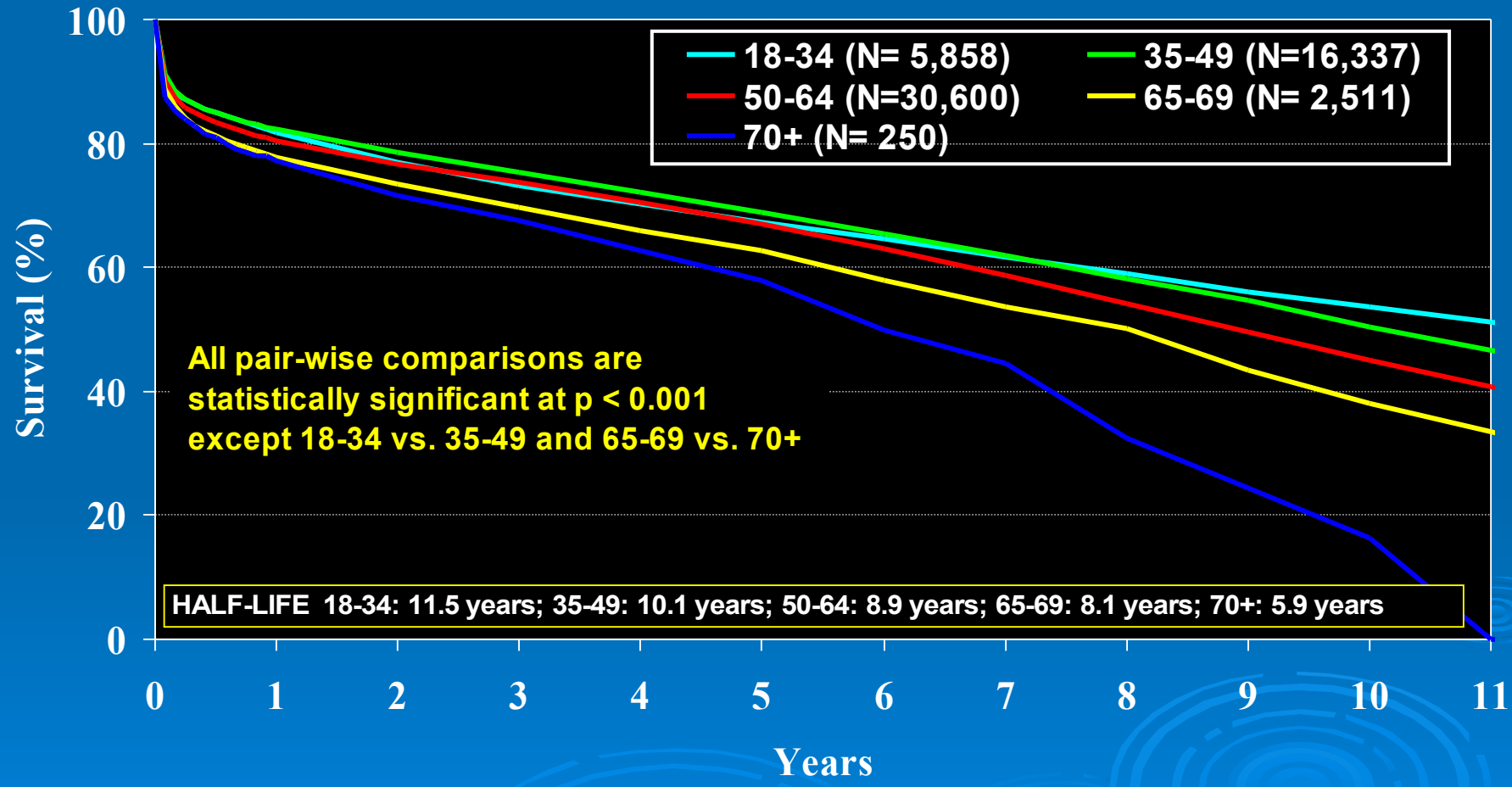
J Heart Lung Transplant 2004; 23: 796-803

HEART TRANSPLANTS:
Donor Age by Year of Transplant



ADULT HEART TRANSPLANTATION

Kaplan-Meier Survival by Age Group ((Transplants: 1/1982-6/2002



Heart xenotransplantation

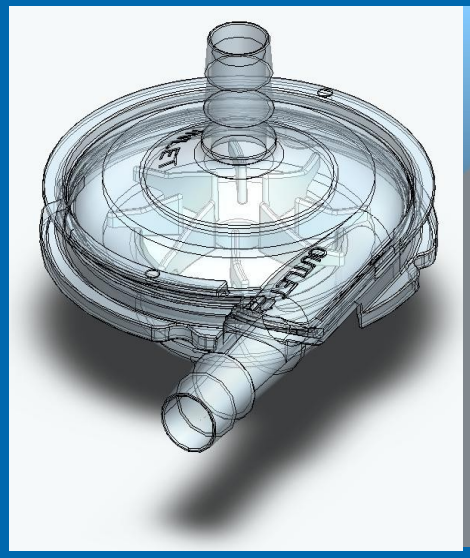
Pros	Cons
Unlimited supply	Moral and ethical concerns
	Viral infection
	Immunosuppressive issues
	Not available yet

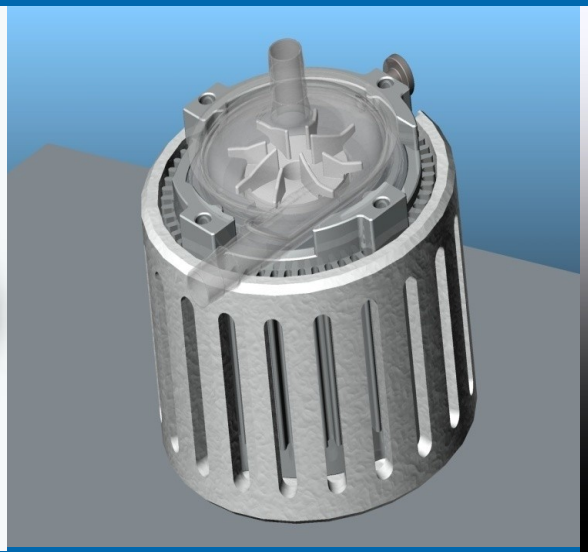
"Xenotransplantation is the future of cardiac transplantation and always will be"
N. Shumway, 1990

Mechanical Assistance availabe

- Short term (Centrifugal pumps) LVAD, RVAD, BiVAD, ECMO
  - Biomedicus
  - Jostra
  - Levitronix
- Long term
  - Thoratec (pulsatile) LVAD, RVAD, BiVAD
  - HeartMate II (Axial flow) LVAD

Levitronix

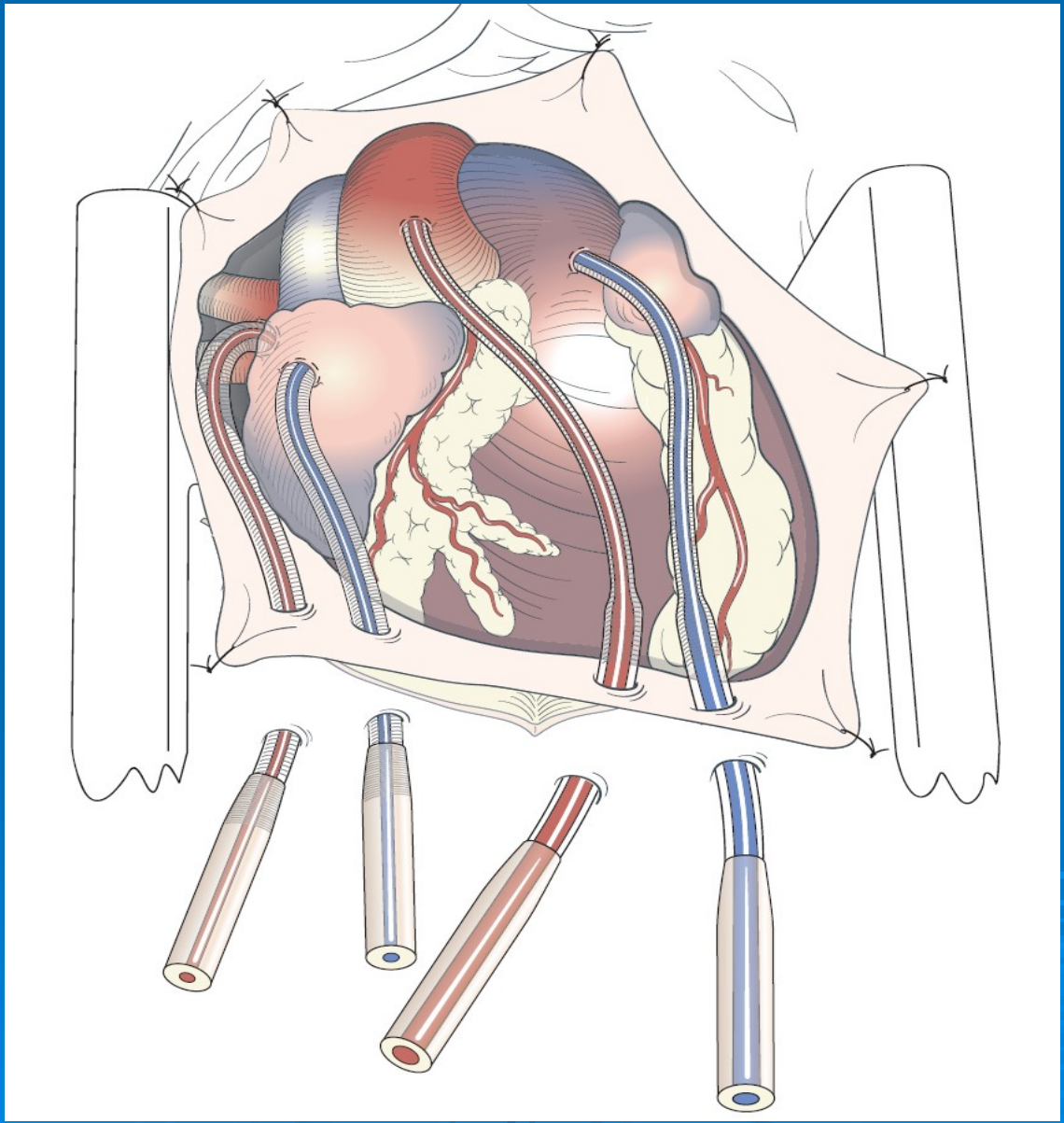




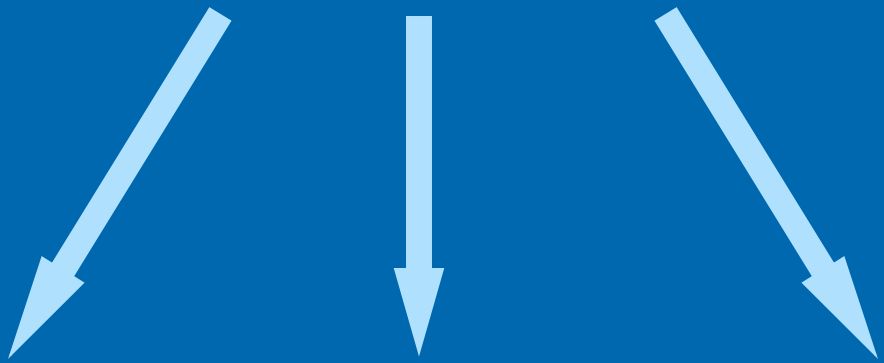
The Levitronix® CentriMag VAS is designed to provide temporary support for patients suffering potentially .reversible cardiogenic shock

.FDA approved for up to 30 days of use

Cannulation



Mechanical Assistance



Bridge to transplant

Bridge to recovery

Destination therapy

Devices

Complications

- Infection
- Malfunction
- Thromboembolism

Limitations

- Size
- Durability
- Portability
- Energy source

Bridge to Transplantation

- Main use of devices today
- Most require LVAD only
- About 10% will require additional RVAD
- About 70% will survive to transplantation
- Survival after transplantation similar to those without a device

Bridge to Recovery

- Currently unpredictable results
- It is yet to be discovered who are the patients that will recover and will not fail shortly after removal of device

Left Ventricular Assist Device and Drug Therapy for the Reversal of Heart Failure

Emma J. Birks, M.R.C.P., Ph.D., Patrick D. Tansley, F.R.C.S., James Hardy, M.B., B.S., B.Sc., Robert S. George, M.R.C.S., B.Sc., Christopher T. Bowles, Ph.D., Margaret Burke, F.R.C.Path., Nicholas R. Banner, F.R.C.P., Asghar Khaghani, F.R.C.S., and Magdi H. Yacoub, F.R.S.

N ENG L J MED 355;18 WWW.NEJM.ORG NOVEMBER 2, 2006

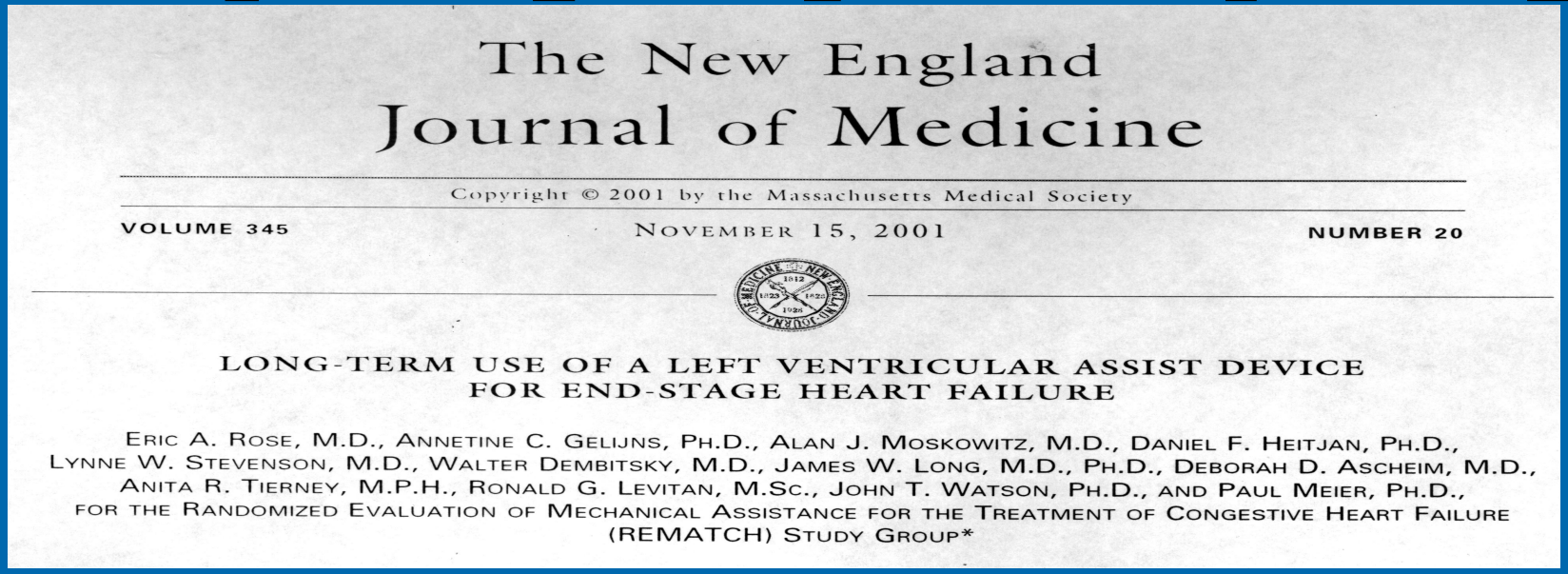
- patients, NICM receiving inotropes 15
- Extensive HF therapy post LVAD implantation
- patients were explanted after 320±186 11 days
- (died (1 arrhythmia, 1 carcinoma 2
- Freedom from HF at 1 and 4 years was 100% and 89%

Destination Therapy

- Lack of donors and successful long term support as bridge, opened a new era

REMATCH study

R**andomized **E**valuation of **M**echanical **A**ssistance for the **T**reatment of **CHF



The New England Journal of Medicine

VOLUME 345 NOVEMBER 15, 2001 NUMBER 20

LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE

ERIC A. ROSE, M.D., ANNETINE C. GELIJNS, PH.D., ALAN J. MOSKOWITZ, M.D., DANIEL F. HEITJAN, PH.D., LYNNE W. STEVENSON, M.D., WALTER DEMBITSKY, M.D., JAMES W. LONG, M.D., PH.D., DEBORAH D. ASCHEIM, M.D., ANITA R. TIERNEY, M.P.H., RONALD G. LEVITAN, M.SC., JOHN T. WATSON, PH.D., AND PAUL MEIER, PH.D., FOR THE RANDOMIZED EVALUATION OF MECHANICAL ASSISTANCE FOR THE TREATMENT OF CONGESTIVE HEART FAILURE (REMATCH) STUDY GROUP*

- (patients (68 – LVAS, 61 – optimal medical 129
- Mean age: 66 ± 9 years
- reduction in risk of death 48%
- year survival: 52% vs. 25% 1
- year survival: 23% vs. 8% 2
- Improved quality of life at 1 year

Destination Therapy

- Heartmate XVE - an enhanced version of the VE version used in the REMATCH study was approved for destination therapy in non transplanted .candidates in 2002 by the FDA

Post-REMATCH study

Outcomes of Left Ventricular Assist Device Implantation as Destination Therapy in the Post-REMATCH Era

Implications for Patient Selection

Katherine Lietz, MD, PhD; James W. Long, MD, PhD; Abdallah G. Kfoury, MD; Mark S. Slaughter, MD; Marc A. Silver, MD; Carmelo A. Milano, MD; Joseph G. Rogers, MD; Yoshifumi Naka, MD, PhD; Donna Mancini, MD; Leslie W. Miller, MD

Circulation. 2007;116:497-505.

- .patients (HeartMate XVE) , Nov 2001 – Dec 2005 280
- Mean age: 66 ± 9 years
- year survival: 56% 1
- year survival according to risk score: 81%, 62%, 28%, 1 11%

.for low, medium, high, and very high scores

Post-REMATCH study

Scoring System

TABLE 4. Multivariable Analysis of Risk Factors for 90-Day In-Hospital Mortality After LVAD as DT (n=222)

Patient Characteristics	Odds Ratio (CI)	*P*	Weighted Risk Score
Platelet count $\leq 148\times10^3/\mu L$	7.7 (3.0 to 19.4)	<0.001	7
Serum albumin ≤3.3 g/dL	5.7 (1.7 to 13.1)	<0.001	5
International normalization ratio >1.1	5.4 (1.4 to 21.8)	0.01	4
Vasodilator therapy	5.2 (1.9 to 14.0)	0.008	4
Mean pulmonary artery pressures ≤25 mm Hg	4.1 (1.5 to 11.2)	0.009	3
Aspartate aminotransferase >45 U/mL	2.6 (1.0 to 6.9)	0.002	2
Hematocrit ≤34 %	3.0 (1.1 to 7.6)	0.02	2
Blood urea nitrogen >51 U/dL	2.9 (1.1 to 8.0)	0.03	2
No intravenous inotropes	2.9 (1.1 to 7.7)	0.03	2

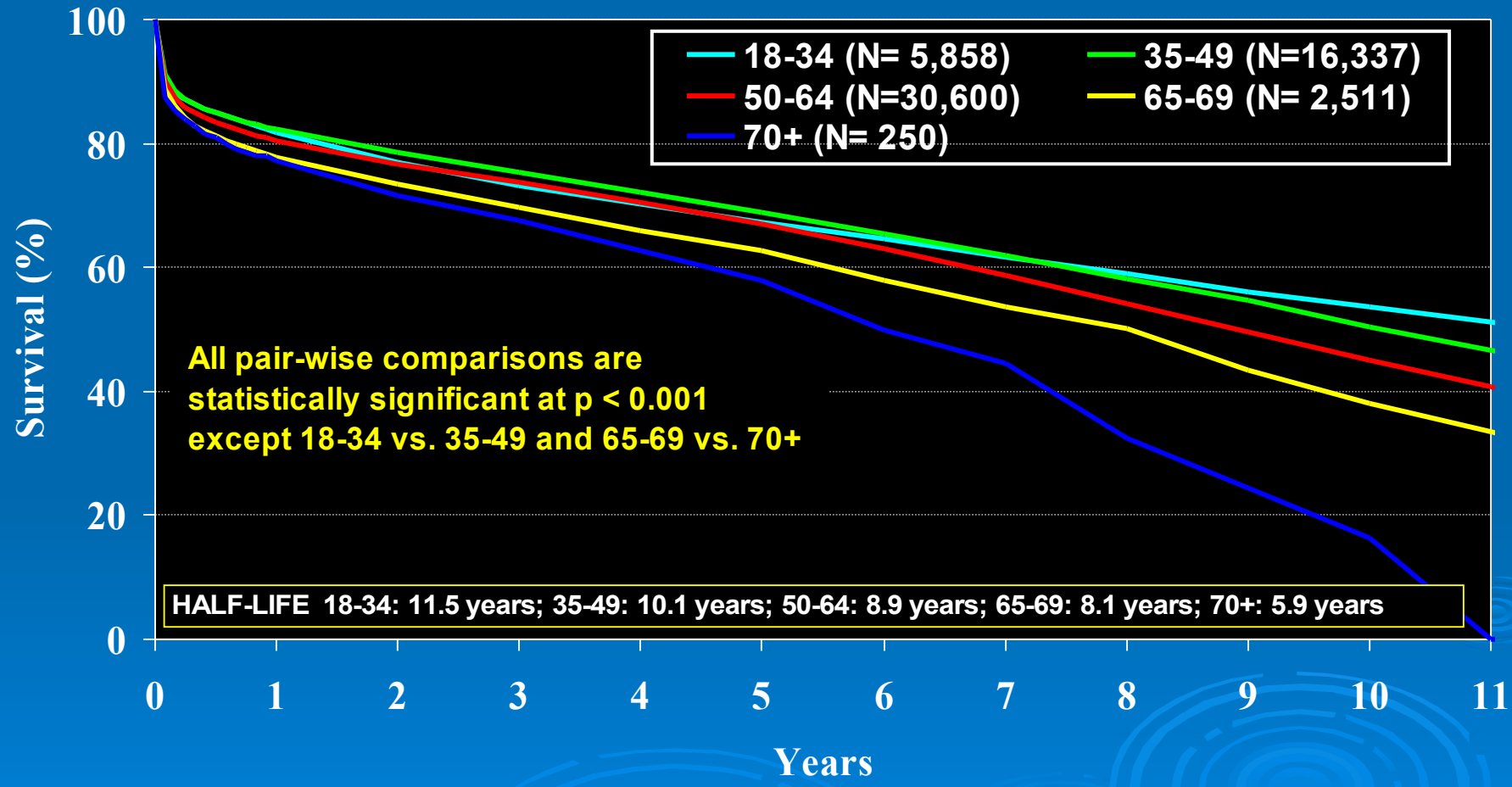
TABLE 6. Operative Risk Categories With Corresponding Cumulative Risk Score for 90-Day In-Hospital Mortality After LVAD Implantation as DT and Survival to Hospital Discharge and 1-Year Survival Depicted by the Operative Risk Categories*

			In-Hospital Mortality Within 90 Days			Survival, %		
Operative Risk Categories	Risk Score	No.	Observed, n	Predicted, n	% Probability (CI)	To Discharge, %	90 d	1 y
Low	0 to 8	65	2	1.6	2 (1.1 to 5.4)	87.5	93.7	81.2
Medium	9 to 16	111	12	13.7	12 (8.0 to 18.5)	70.5	86.5	62.4
High	17 to 19	28	10	7.9	44 (32.8 to 55.9)	26	38.9	27.8
Very High	>19	18	22	22.8	81 (66.0 to 90.9)	13.7	17.9	10.7

* Analysis limited to 208 patients with available measures of pulmonary artery pressure and serum albumin level.

ADULT HEART TRANSPLANTATION

Kaplan-Meier Survival by Age Group ((Transplants: 1/1982-6/2002

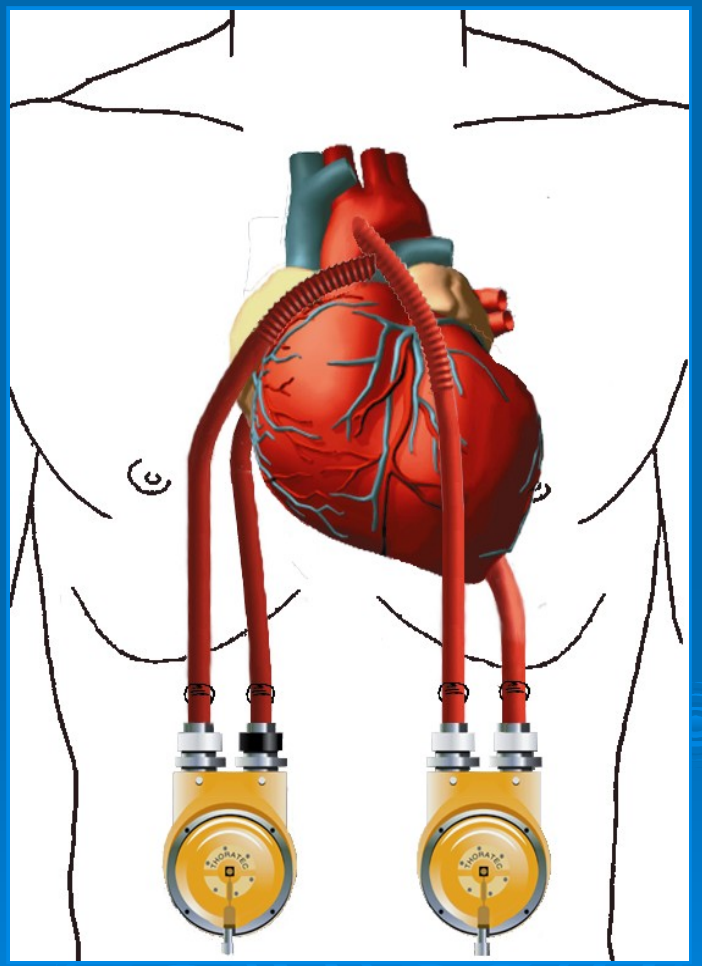


The HeartMate® Left Ventricular (Assist System (LVAS

- Bridge to transplant
- Bridge to recovery
- Destination therapy for non-transplant candidates

Thoratec®:
Paracorporeal VAD

- Pulsatile
- Pneumatic
- Univentricular or Biventricular Support
- Numerous Cannulation Options
- Small and Large Patients
  ((17 Kg - 144 Kg
- Short to Long-Term Support



Univentricular vs. Biventricular Assist Device Support

- Indications for Biventricular Support
  - Signs of Right Heart Failure
  - Intractable Arrhythmias
  - RV/Septal Infarction
  - Elevated PVR
  - Secondary Organ Involvement
  - Prolonged Cardiogenic Shock “Sicker “Patients

Total artificial heart

Pros	Cons
Unlimited supply	Complex
Replaces left and right hearts	No native heart backup

Total Artificial Heart

AbioCor

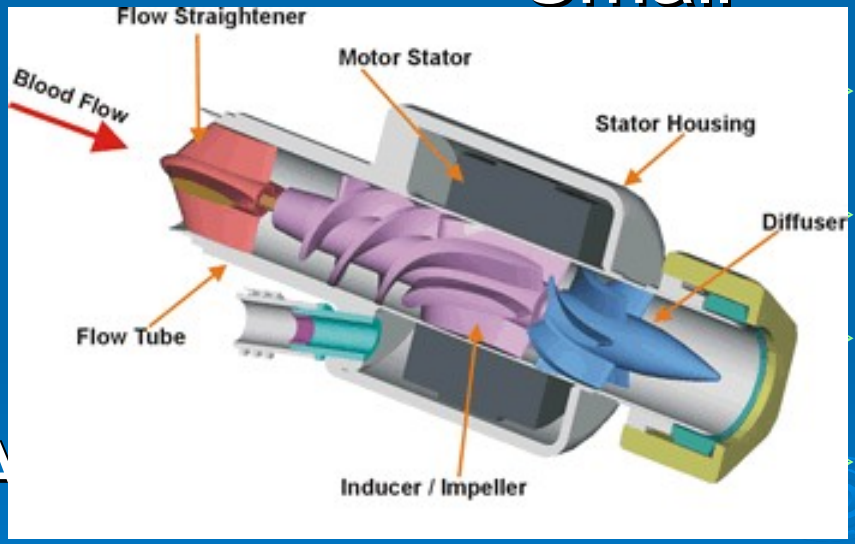
- Totally implantable, pulatile and electrical
- Use TETS - Transcutaneous Energy Transfer System

CardioWest

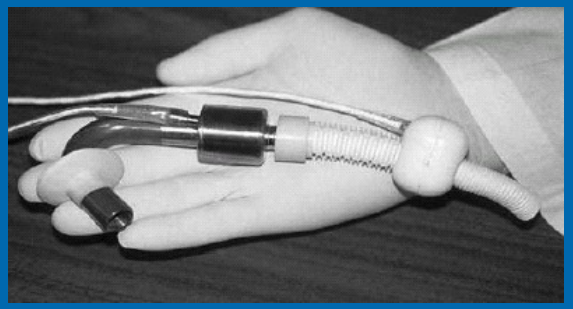
- Pulsatile, pneumatic driven
- Big Console (smaller console is about to be (available

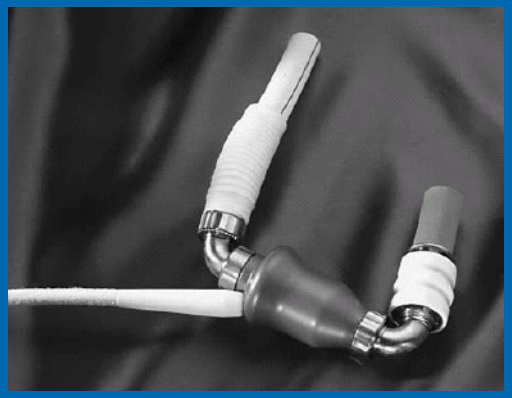
Axial Flow Pumps

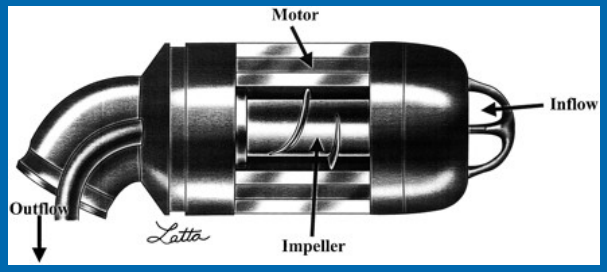
- magnetically suspended
- Small
- A
- In reality can deliver 3-5 lit/min



Axial Flow Pumps in Trial







Micromed Debaky	HeartMate IIb	Jarvic 2000
100		implants 262
84 days		Mean 90 days
5 years		Max 518 days
Thrombus formation around pump		Thromboembolism

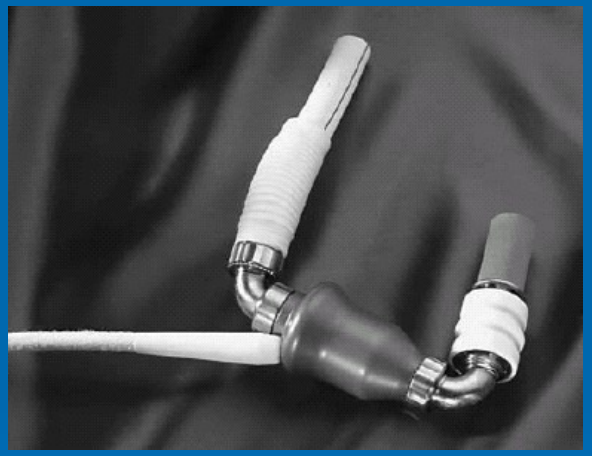
Use of a Continuous-Flow Device in Patients Awaiting Heart Transplantation

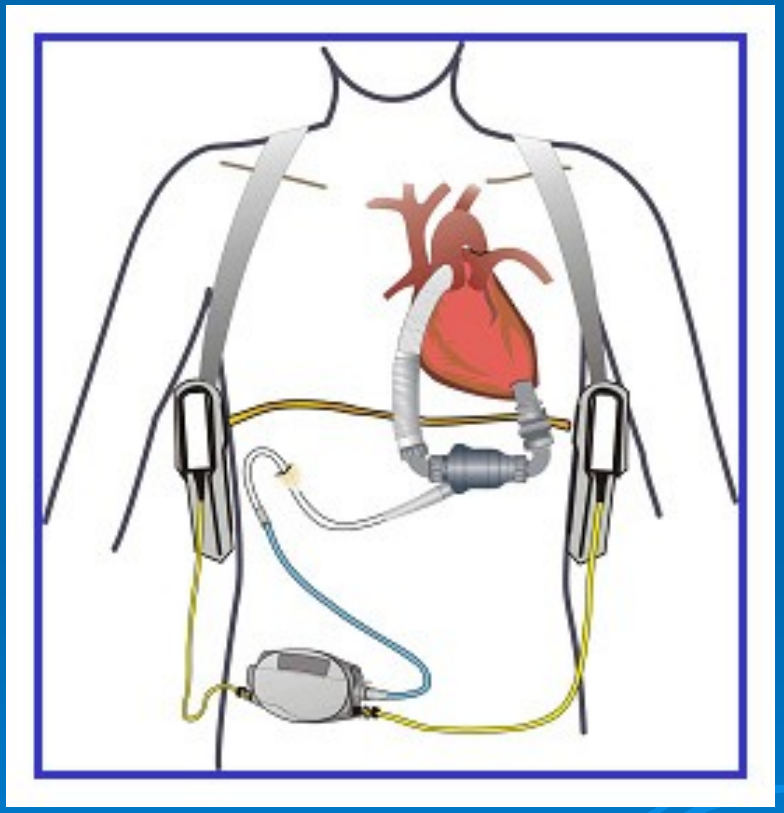
Leslie W. Miller, M.D., Francis D. Pagani, M.D., Ph.D., Stuart D. Russell, M.D., Ranjit John, M.D., Andrew J. Boyle, M.D., Keith D. Aaronson, M.D., John V. Conte, M.D., Yoshifumi Naka, M.D., Donna Mancini, M.D., Reynolds M. Delgado, M.D., Thomas E. MacGillivray, M.D., David J. Farrar, Ph.D., and O.H. Frazier, M.D., for the HeartMate II Clinical Investigators*

N Engl J Med 2007;357:885-96.

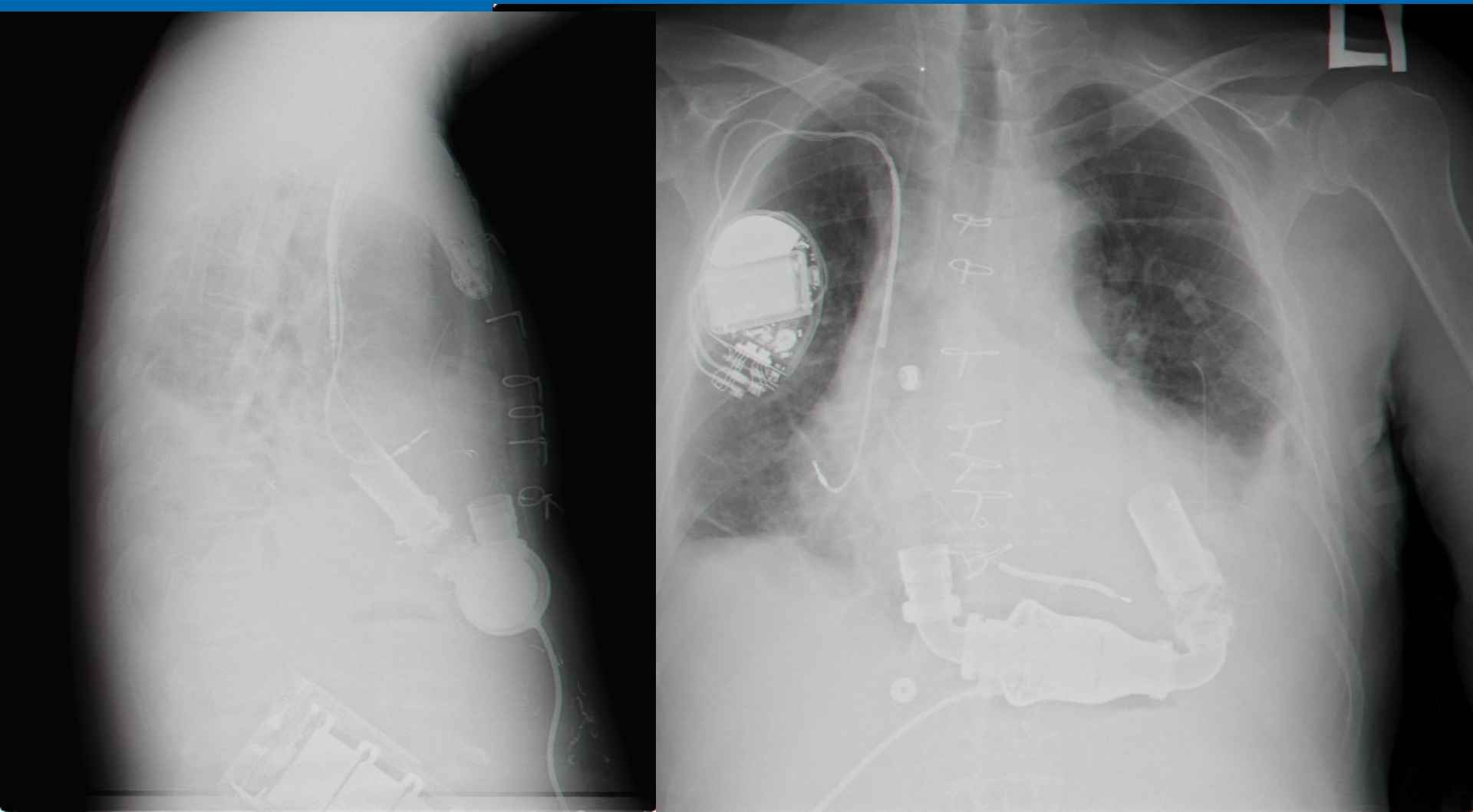
- Prospective, multicenter, 133 Tx candidates
- HeartMate II
- year survival with LVAD – 68% 1
- Significant functional improvement

HeartMate II





70 y/o male, ICM, s/p CABG, LV+RV dysfunction



Worldwide Experience July of 2008

- Clinical VAD Implants
- Over 1200 Patients
- 3.6 yearsLongest Support Duration: ((ongoing
- Age 14 – 82 years
- BSA 1.3 – 2.8 m^2
- Transplanted, recovered, or supported to 180 days: 80%

Indication for VAD

- Heart failure must be .present
- ? Heart Transplant candidate
- Signs of failure, despite best medical :management, such as
  - PCWP > 20 mm Hg
  - CI < 2.0 L/min/m^2
  - Systolic BP < 80 mm Hg
  - Metabolic acidosis
  - Rising creatinine
  - Life threatening arrhythmias

Contraindication for VAD

- Sepsis
- Coma
- Anuria
- Multiorgan failure

שאלה 2

1. בנוגע לטיפול ב- VAD's בחולים עם אי ספיקת לב קשה.
    1. בחולים עם קרדיומיופטיה לא איסכמית, יש בדר"כ צורך בהשתלת BiVAD.
    2. המכשירים המודרניים הינם בעלי זרימה פולסטילית שהוכחה כעדיפה.
    3. יכול להוות תחליף להשתלת לב, במועמדים ראויים להשתלה, המעדיפים פתרון זה.
    4. במשאבות אקסיאליות, הסיכוי לכשלון לב ימני גבוה מאשר במשאבות פולסטיליות.

Consult

- I've known this guy with heart failure EF 10% for years. He's been doing great. But he acutely decompensated two weeks ago and arrested at home. Went to his local ED and arrested again. They put a balloon pump and shipped him to us.
- He arrested twice on the way. The last one was a long one, and he got intubated. His kidneys took a hit and we put him on CVVH for a few days. He looked great, and we got him extubated.
- We got him down to only milrinone and he was sitting in a chair, we placed it PICC line in him and we thought we could get him home.
- But…

Consult

- He arrested again the day before yesterday, got reintubated, and got a balloon pump again. He's back on CVVH (hasn't made urine in two days, but his baseline creatinine is 'only' 2.3). He's on three high dose inotropes with a cardiac index of 1.2. It took us all day yesterday to get it above 1.
- I think he's got some shock liver too. His transaminases are going up. His INR is 4.5 but that could be because he has not been eating well and may be vit K deficient.
- I think a pneumonia or line sepsis, could have triggered all this recent decompensation. But its hard to tell, his lungs are whited out, and it may just be from fluid.

"In general, erring on the side of early implantation is advisable because after a certain level of decompensation the patient may not be able to recover in time"

P.M. McCarthy, in The Stanford Manual of Cardiopulmonary Transplantation