Left Ventricular Assist Device
Good to Great!

Soon J. Park, MD

October 13, 2007

Heart Failure in US

- > 5 million patients
- 250,000 death/year
- Significant progress in medical management
- High morbidity and mortality
- Aging population

Severe Heart Failure

- Very poor quality of life
- Less than 50% alive at 1 year
- Heart transplant
  - >80% survival at 1 year
  - Good quality of life
  - 2000 donor hearts/year in US

Heart Transplant Impact

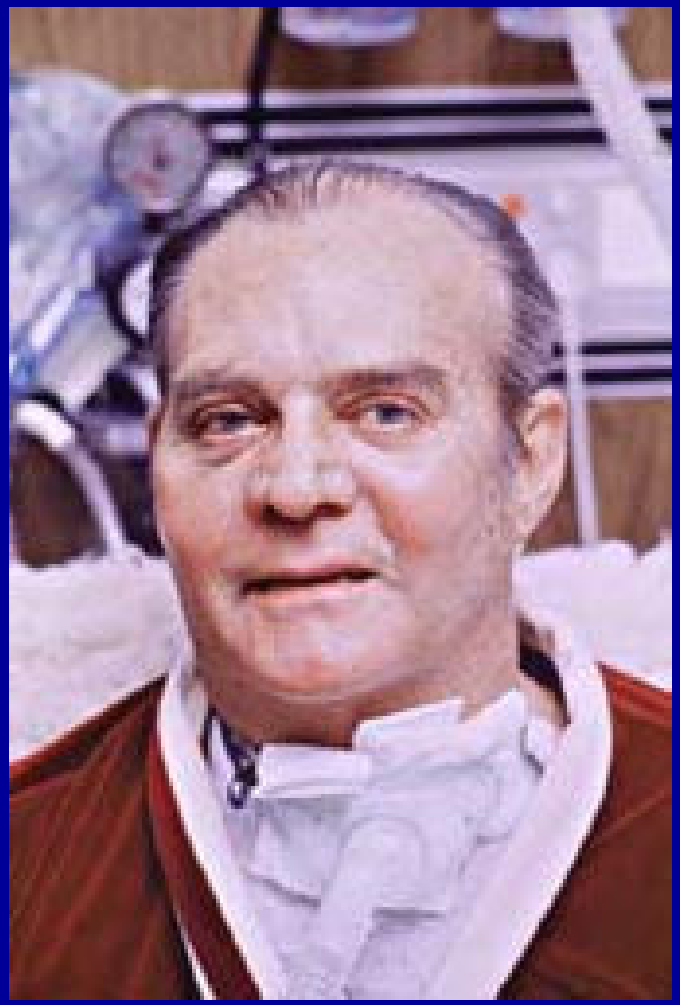
- High for individual patient
- Epidemiologically trivial
- Stimulus to development of alternative myocardial replacement therapies

Heart Replacement Therapy

- NIH funded Total Artificial Heart(TAH) project started in 1960's
- Totally implantable electrical pump for permanent support by 70's → not realized
- Jarvik-7, pneumatic

Jarvik-7 Artificial Heart

Blessing or Curse?



NIH TAH Project

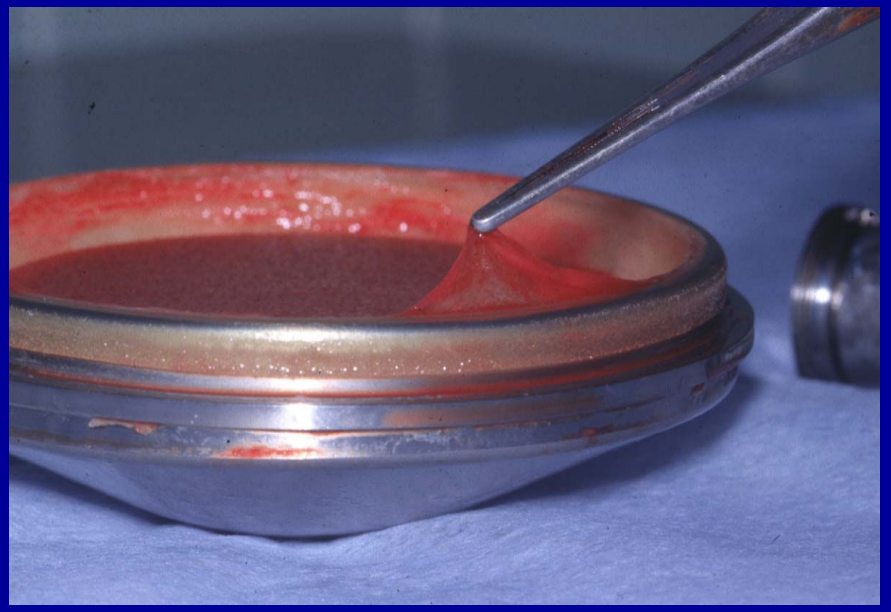
- Jarvik-7
  - Bleeding
  - Thromboembolism
  - Infection
  - Device failure
- TAH → VAD
  - LVAD sufficient in 80% HF patients

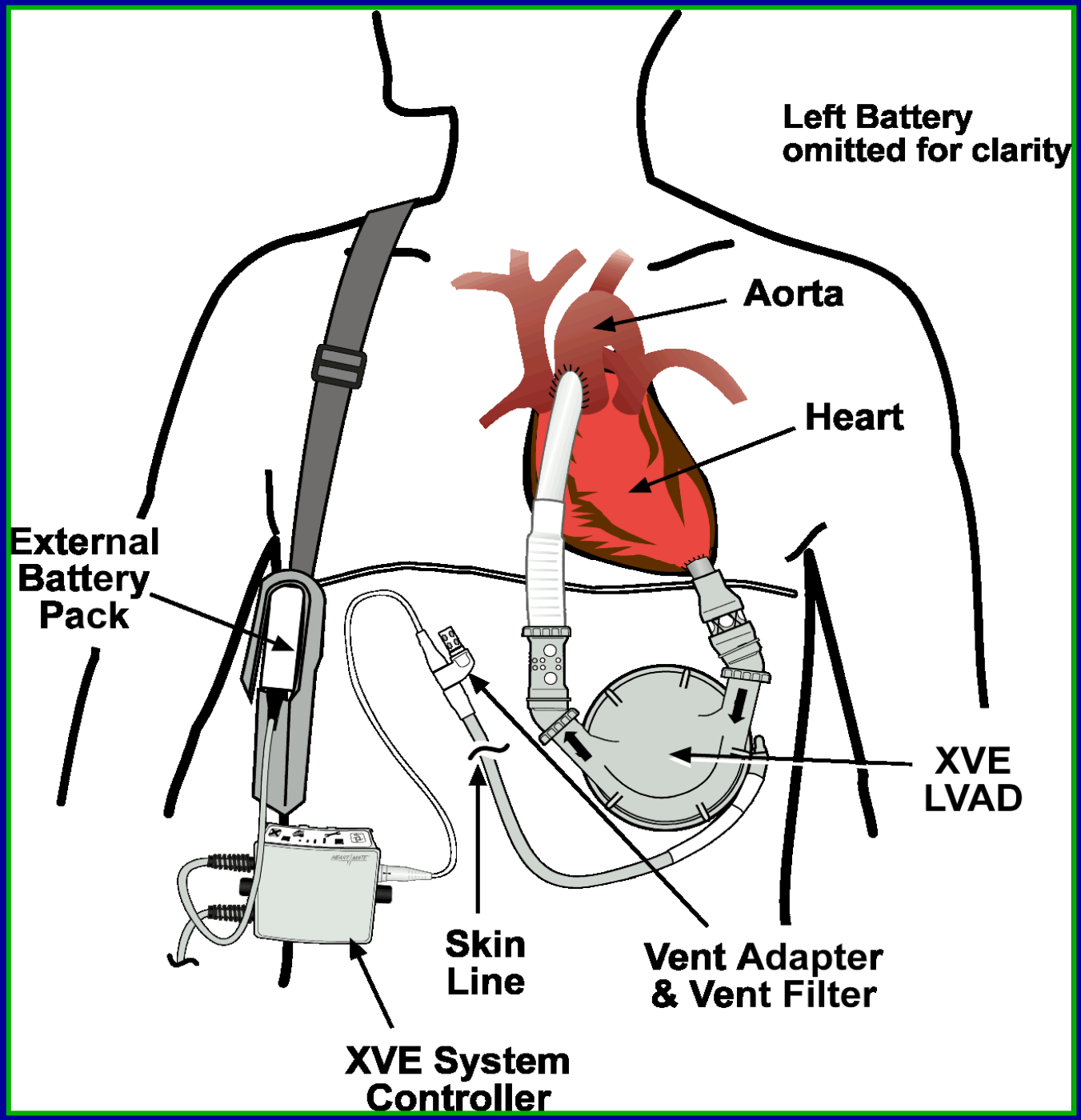

Heartmate® XVE LVAS

Ventricular Assist Device

- Externally vented devices
- Shorter term support
- Bioprosthetic valves
- Textured membrane

Textured Membrane and Neointima Formation




Left Battery
omitted for clarity
Aorta
Heart
External
Battery
Pack
XVE
LVAD
Skin
Line
Vent Adapter
& Vent Filter
XVE System
Controller

The Heartmate-IP/VE

- Bridge therapy to heart transplant
  - Performance reliable
  - Survival benefit
  - QoL acceptable in outpatient setting
- ? Destination therapy?

REMATCH

Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure

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*

Rose, E A et al.; NEJM 2001; 345:20

Eligibility for REMATCH

- NYHA Class IV symptoms for ≥90 days on ACEI, digoxin, diuretics
- LVEF ≤ 25%
- CI ≤ 2.2 l/min
- PCWP ≥ 18 mm hg
- Peak VO_2 ≤ 14 ml/kg/min or IV inotrope dependent
- Ineligible for cardiac transplantation

Study Design

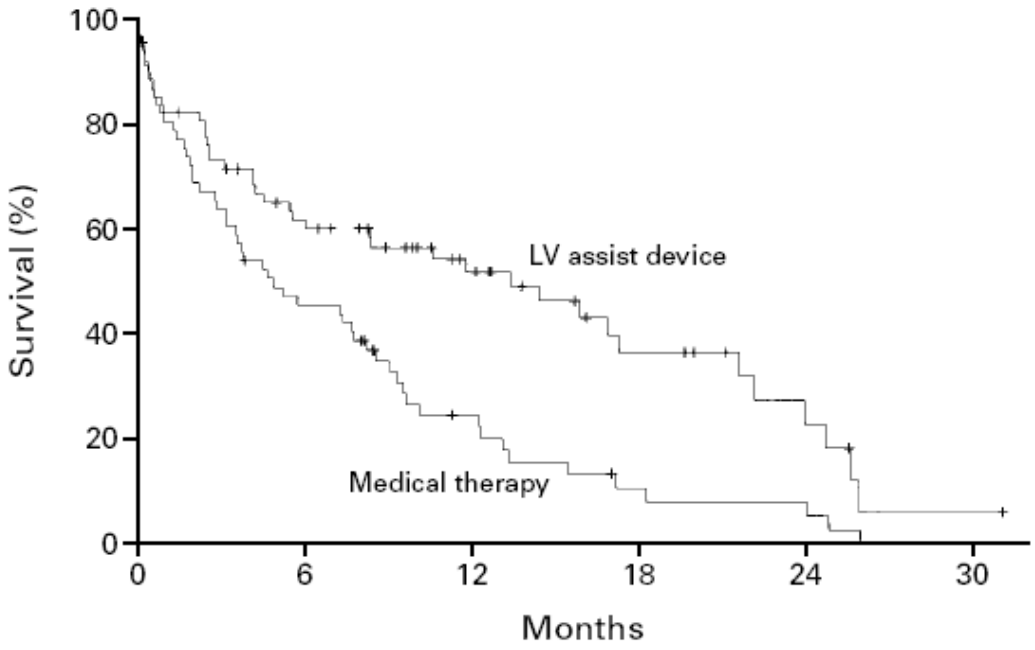
- Prospective randomized trial between LVAD v. OMM
- Primary end-point: survival benefit
- Secondary end-points: adverse events, hospitalization, cost, cost-effectiveness
- N=140 patients for 90% power to document hypothesized benefit

Control: Optimal Medical Management

- Guided and monitored by medical management committee
- Digoxin, diuretics, ACEI unless contraindicated
- Beta-blockers, spironolactone at investigator discretion
- Routinized intravenous inotropic drug weaning efforts

Baseline Characteristics

Baseline Characteristic	OMM (N=61)	LVAD (N=68)	P
Age (years)	68±8.2	66±9.1	0.16
LVEF {%}	17±4.5	17±5.2	0.92
Cardiac Index {l/min/sq.m}	2±0.61	1.9±0.99	0.36
Serum Creatinine {µmol/liter}	1.8±0.66	1.7±0.65	0.35
IV Inotropes (%)	72	65	0.45
MLHF (Total score)	75±17	75±18	0.63



No. at Risk						
LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

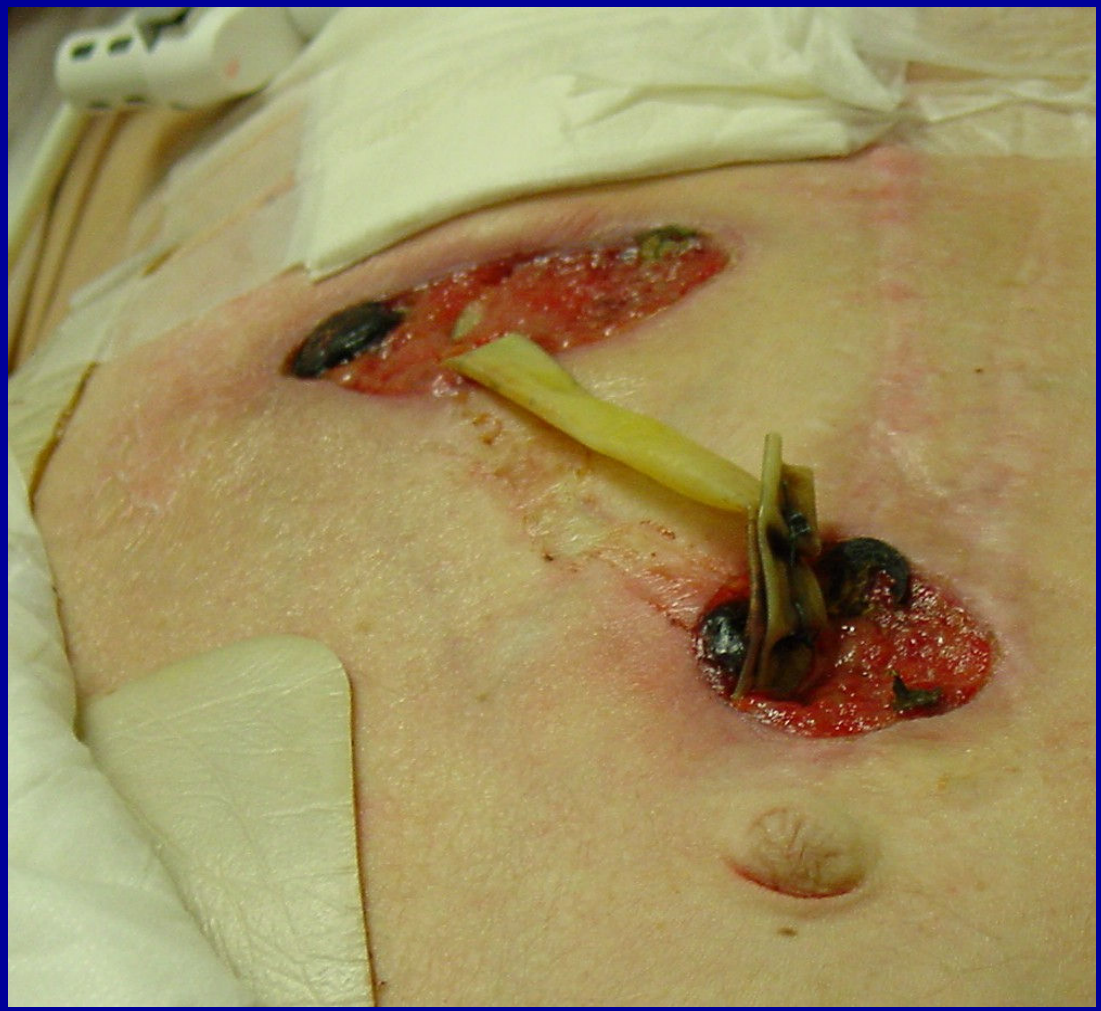
Figure 2. Kaplan–Meier Analysis of Survival in the Group That Received Left Ventricular (LV) Assist Devices and the Group That Received Optimal Medical Therapy.

Crosses depict censored patients. Enrollment in the trial was terminated after 92 patients had died; 95 deaths had occurred by the time of the final analysis.

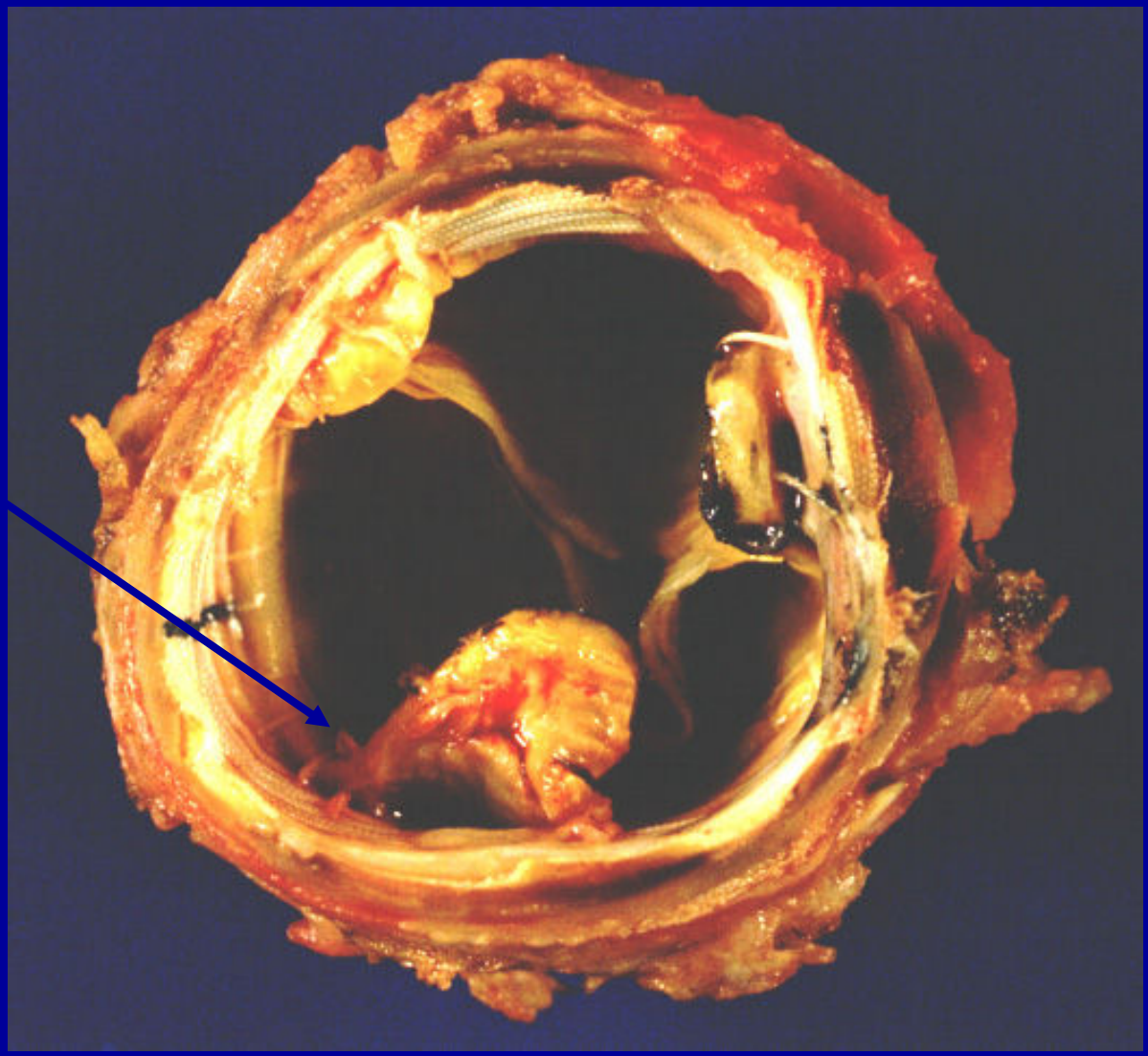
Causes of Death

Cause of Death	OMM	LVAD	Total
LV Dysfunction	50	1	51
Sepsis	1	17	18
LVAD Failure	0	7	7
Other Non-Cardiac Cause	0	5	5
Cerebrovascular Disease	0	4	4
Other Cardiovascular	1	2	3
Pulmonary Embolism	0	2	2
Acute Myocardial Infarction	1	0	1
Cardiac Procedure	1	0	1
Perioperative Bleeding	0	1	1
Unknown	0	2	2
TOTAL	54	41	95

Infection

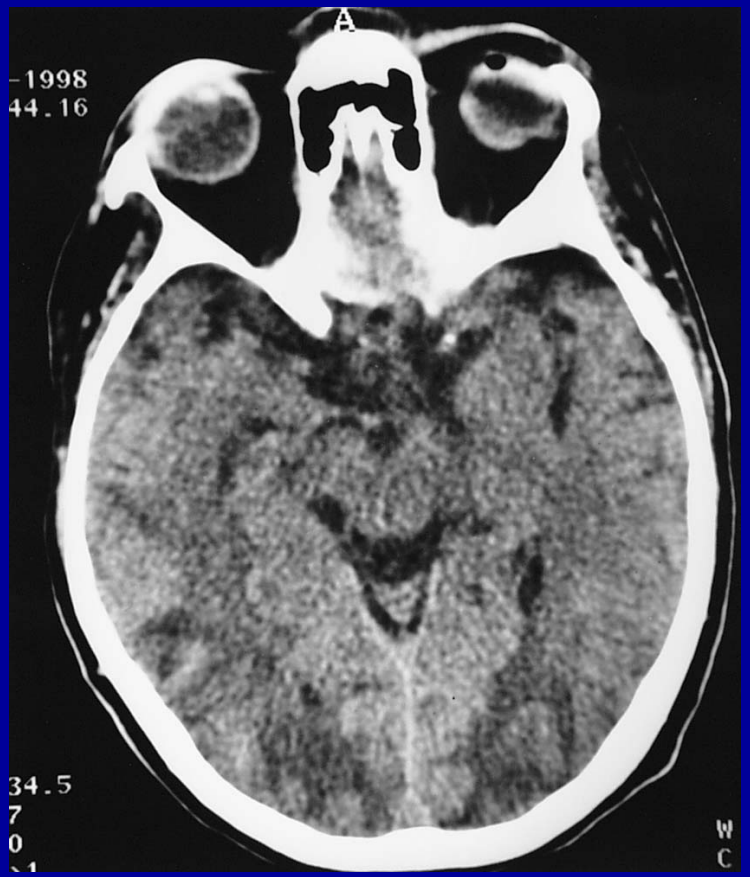


Separation of a commissure resulting in inflow valve leak



Posterior Leukoencephalopathy

- Seen in patients with acute uncontrolled severe hypertension
- Diffuse white matter swelling
- Brian death



Lessons from REMATCH

- Medical therapy is ineffective resulting in exceedingly high mortality
- The HeartMate XVE improves survival and quality of life compared to medical therapy
- Significant improvement needed for DT therapy acceptance

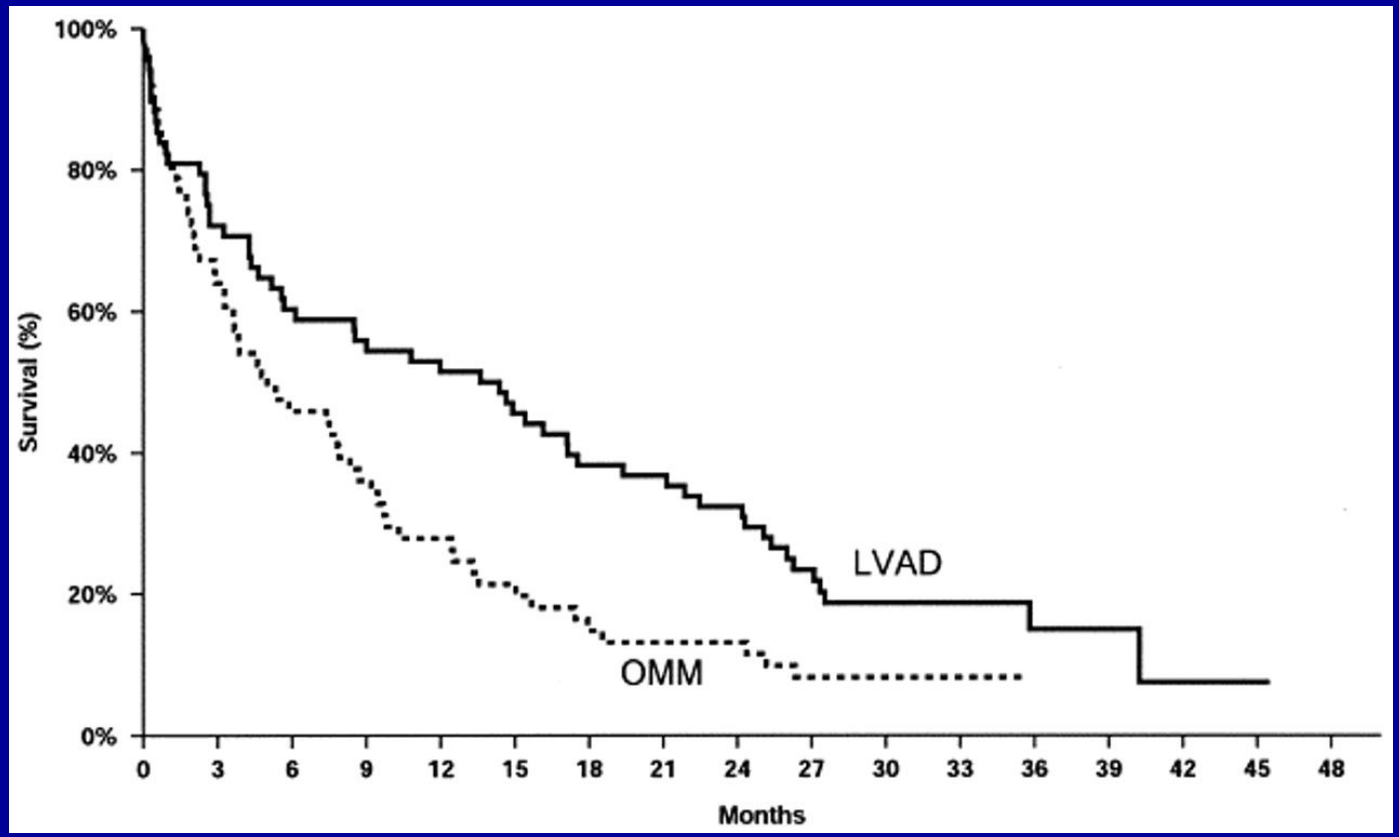
REMATCH*

- 7 LVAD patients
- 2 deaths
- 5 alive, NYHA 1
  - 1 cross over from OMM
- 1 VAD exchange
- >72% actual survival

- 6 OMM patients
- 5 deaths
- 1 alive, NYHA 3-4
  - cross over to VAD
- <17% actual survival

*Experience at Dr. Park's center

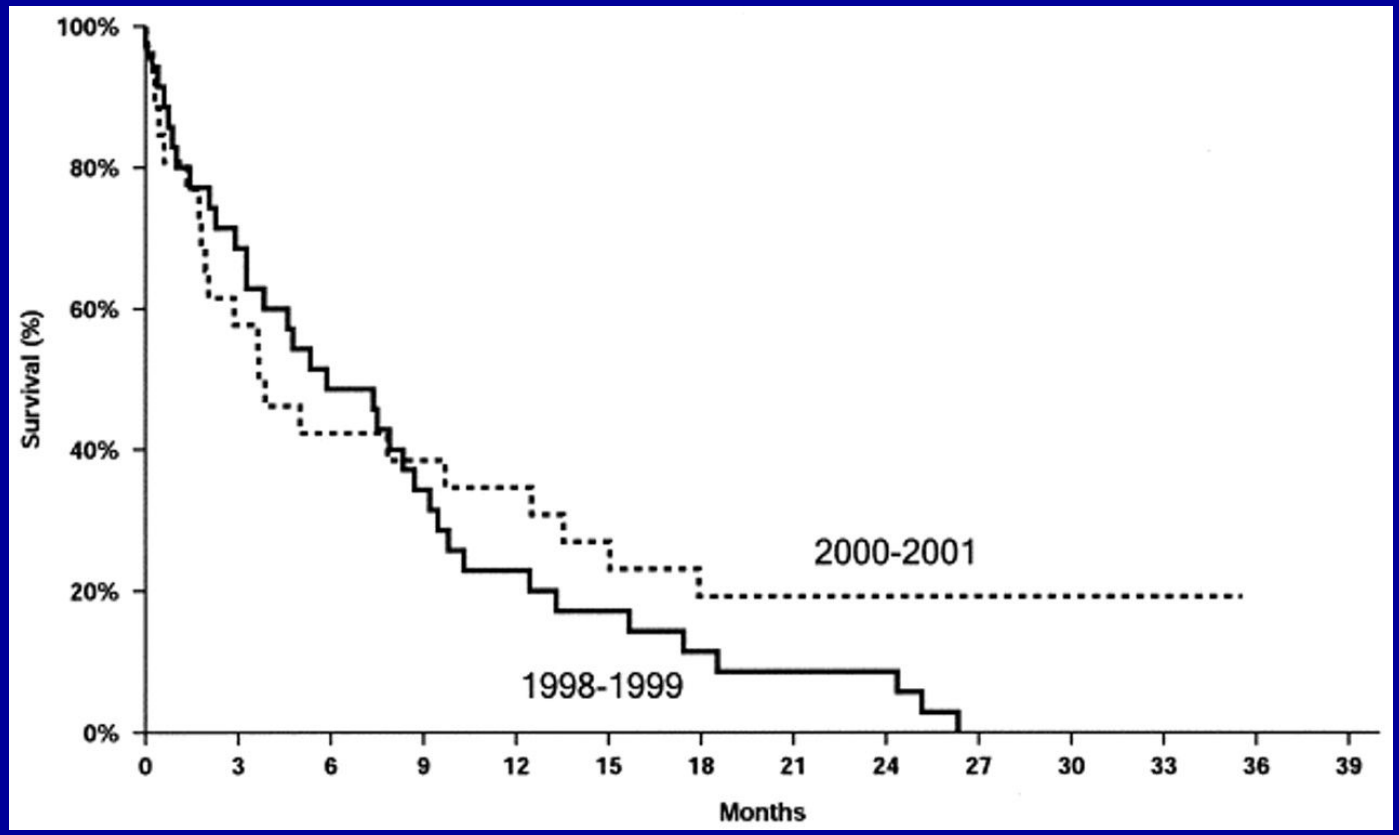
Kaplan-Meier survival curve (P = .0077)



Park, S. J. et al.; J Thorac Cardiovasc Surg 2005;129:9-17

The Journal of
THORACIC AND
CARDIOVASCULAR SURGERY

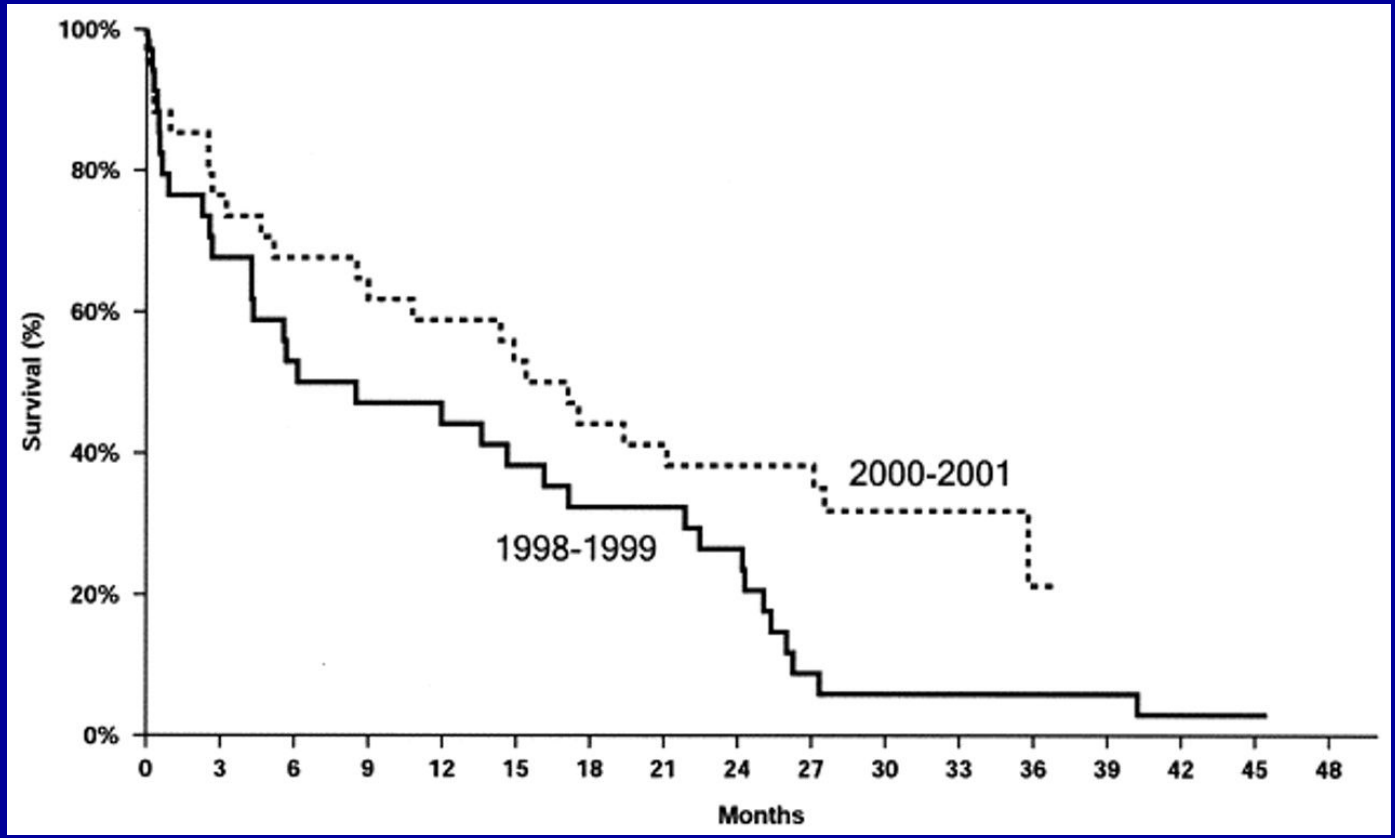
Kaplan-Meier curves of OMM survival in patients enrolled in 1998-1999 and those enrolled in 2000-2001 (P = .2551)



Park, S. J. et al.; J Thorac Cardiovasc Surg 2005;129:9-17

The Journal of
THORACIC AND
CARDIOVASCULAR SURGERY

Kaplan-Meier survival curves for patients receiving LVADs enrolled in 1998-1999 and those enrolled in 2000-2001 (P = .00293)



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The Journal of
THORACIC AND
CARDIOVASCULAR SURGERY

New Data since REMATCH

280 patients implanted with HeartMate XVE since FDA approval

NYHA IV for ≥60 days despite best medical therapy

EF≤25%: $VO_{2\ MAX}$ <12 ml/kg/min

Ineligible for transplantation

Early mortality with VAD therapy

Leading Causes of Early Death

Some end-stage heart failure patients are served poorly by LVAD implantation

Sepsis

Multiorgan Failure

Better patient selection may improve early outcomes

Right Heart Failure

Risk Factors – Post REMATCH

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 ≤148×10^3/μL	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

Lietz et al. Circulation 2007;116;497-505

Mortality Risk Factors

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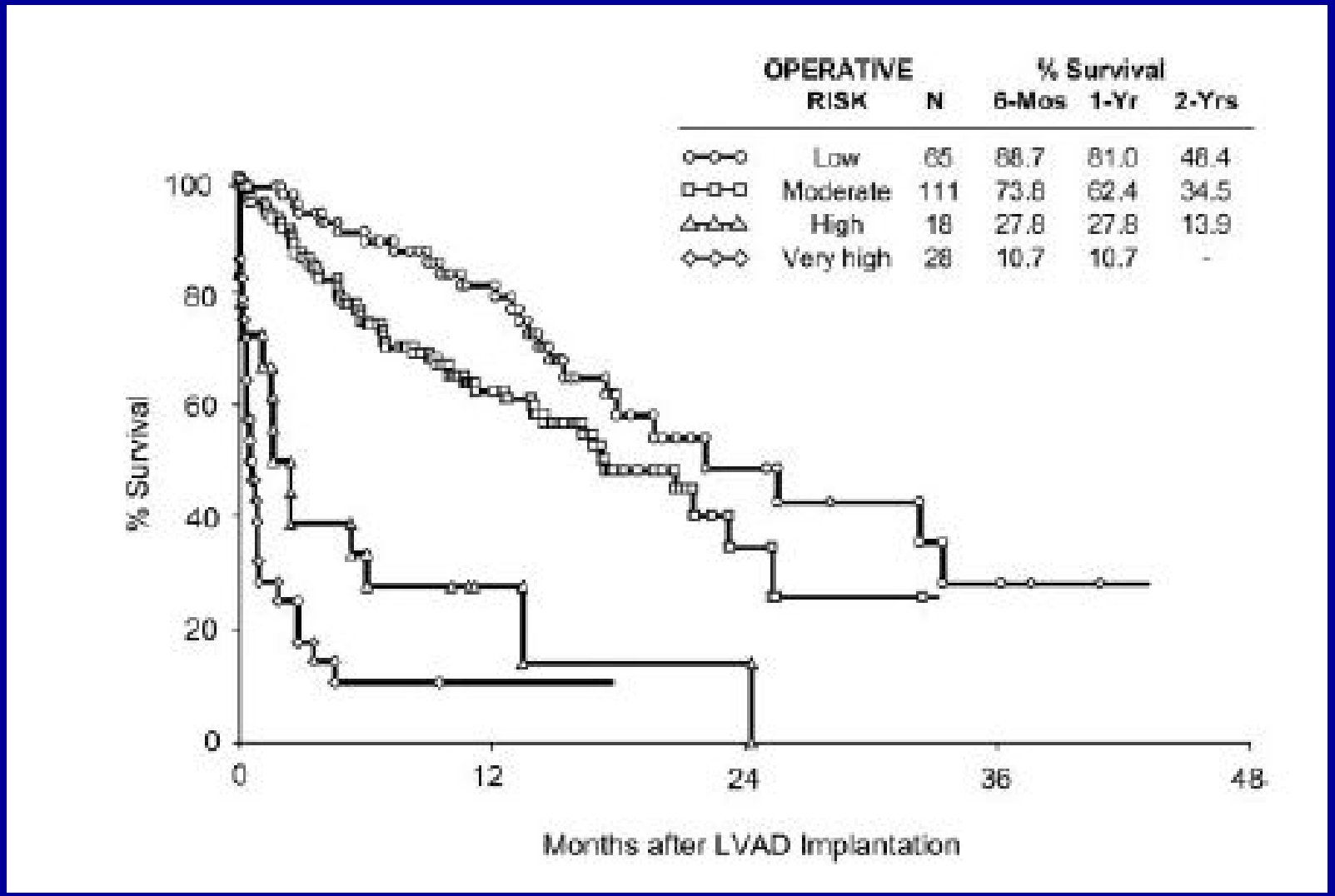
6. Operative Risk Categories With Corresponding Cumulative Risk Score for 90-Day In-Hospital Mortality After LVAD
ıtation as DT and Survival to Hospital Discharge and 1-Year Survival Depicted by the Operative Risk Categories*

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

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

Patient Selection and Survival



Lietz et al. Circulation 2007;116;497-505

Selecting patients for destination VAD therapy

REMATCH and Post-REMATCH

Patients who will derive *greatest benefit* from VAD may a less sick population

Patients selected were inpatients

NYHA IV, most of whom on inotropic support

Outpatients in the community

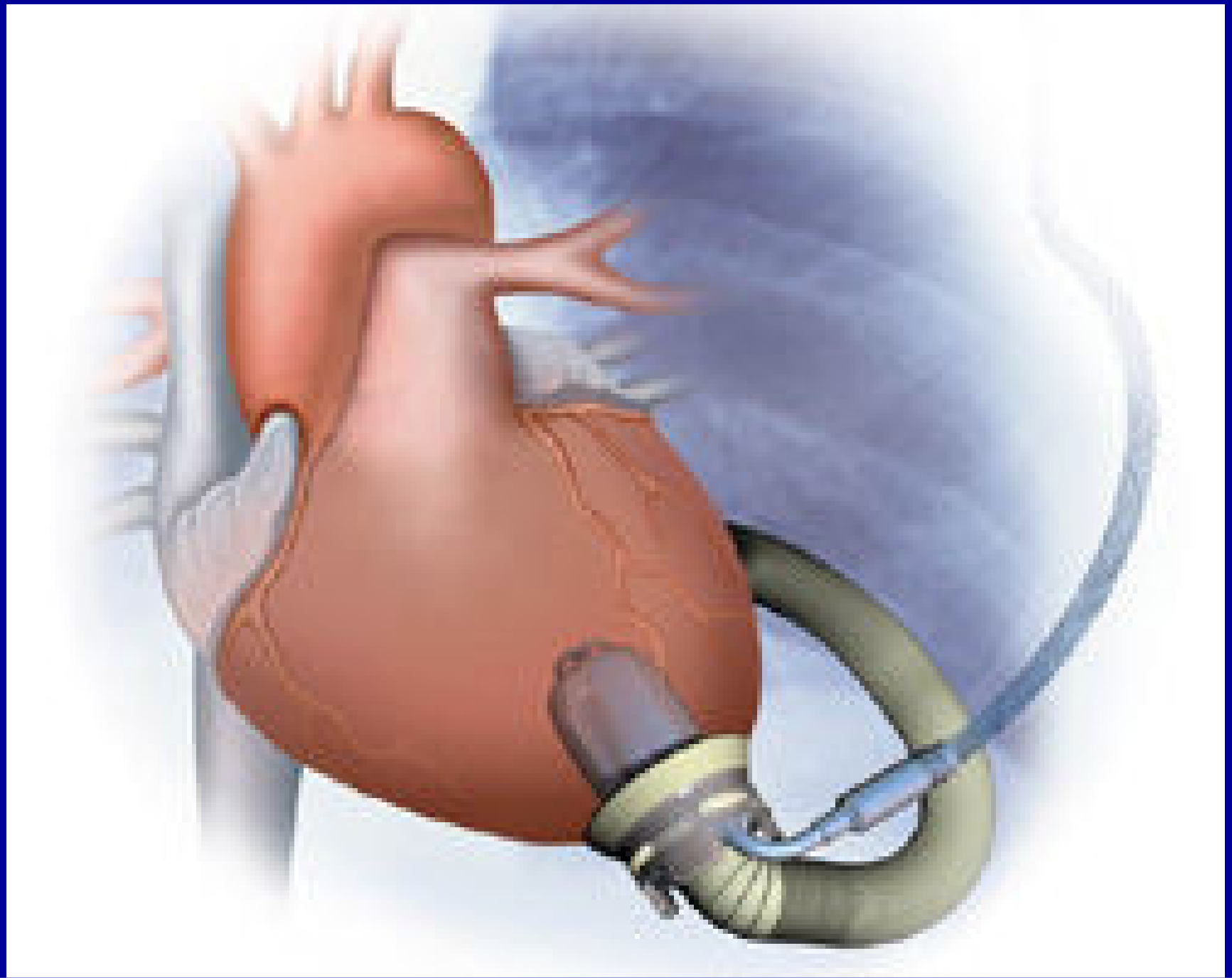
No benefit in early survival from VAD

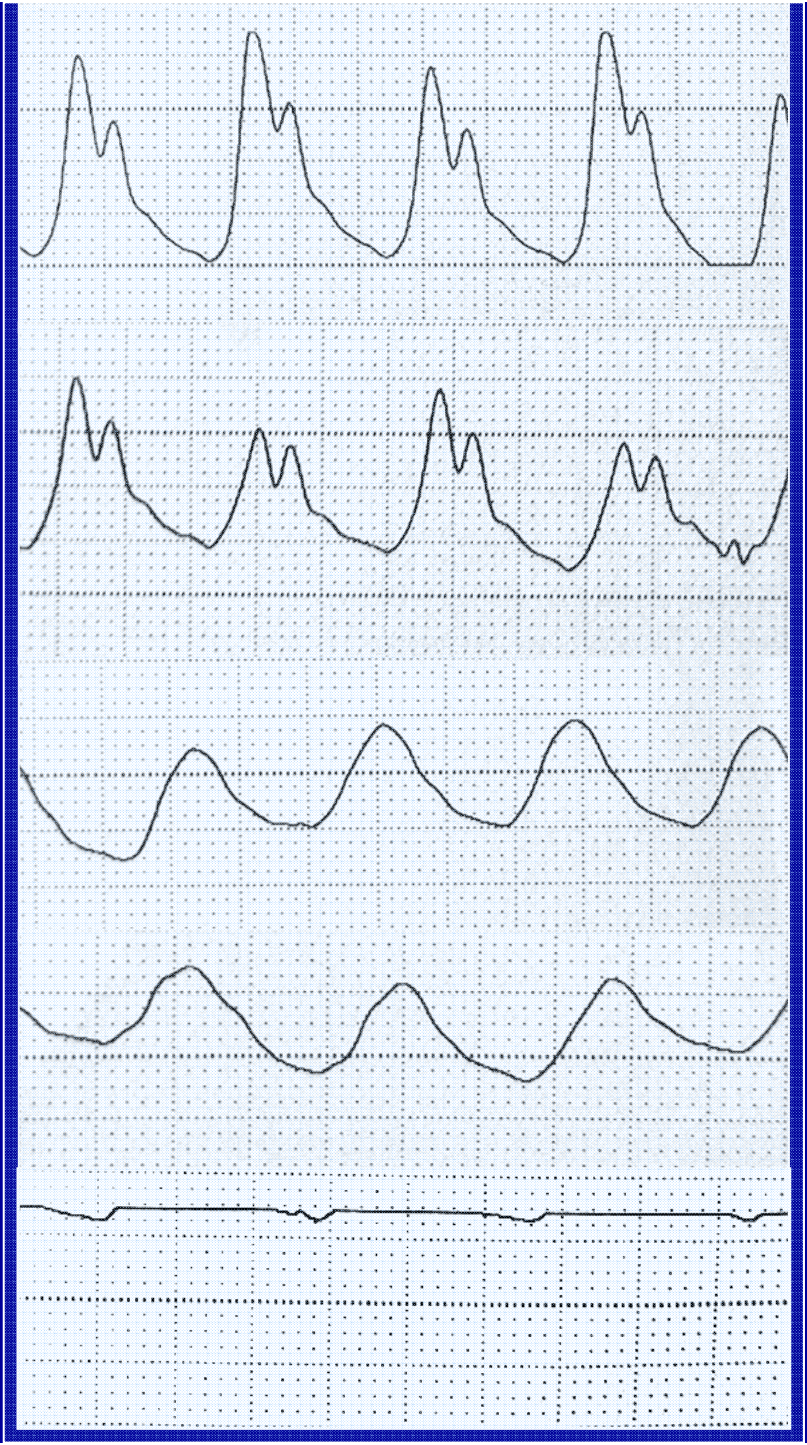
Limitations of Pulsatile Heartmate-XVE

- Bulky device
- Large external driveline
- Limited VAD life span
  - Inflow valve wear/tear
  - Motor failure
- New technology platform LVAD

HeartMate II with High-Speed Rotor

Comparison
HeartMate XVE & HeartMate II



8,000 RPM		Cardiac Output = 4.3 Pulse Pressure = 23 Mean BP = 68
9,000 RPM		Cardiac Output = 4.4 Pulse Pressure = 16 Mean BP = 70
10,000 RPM		Cardiac Output = 4.5 Pulse Pressure = 12 Mean BP = 74
11,000 RPM		Cardiac Output = 4.9 Pulse Pressure = 9 Mean BP = 82
12,000 RPM		Cardiac Output = 5.1 Pulse Pressure = 6 Mean BP = 87

Axial LVAD

- Small in size
- No need for large vent/drive line, totally implantable (reduced device infection)
- Durable (> 7 years of ongoing support)
- Continuous flow support with reduced pulsatility (well tolerated)

Improvements

- High in-hospital mortality
  - Learning curve (adopt better practices)
  - Risk factors
  - Better patient selection
- LVAD pumps – different technology platform
  - Small (easier to implant, patient friendly)
  - Low risk of infection (lack of large vent/drive line)
  - Durable (motor failure, valve or membrane rupture)

Better Patient Selection
Improved LVAD device

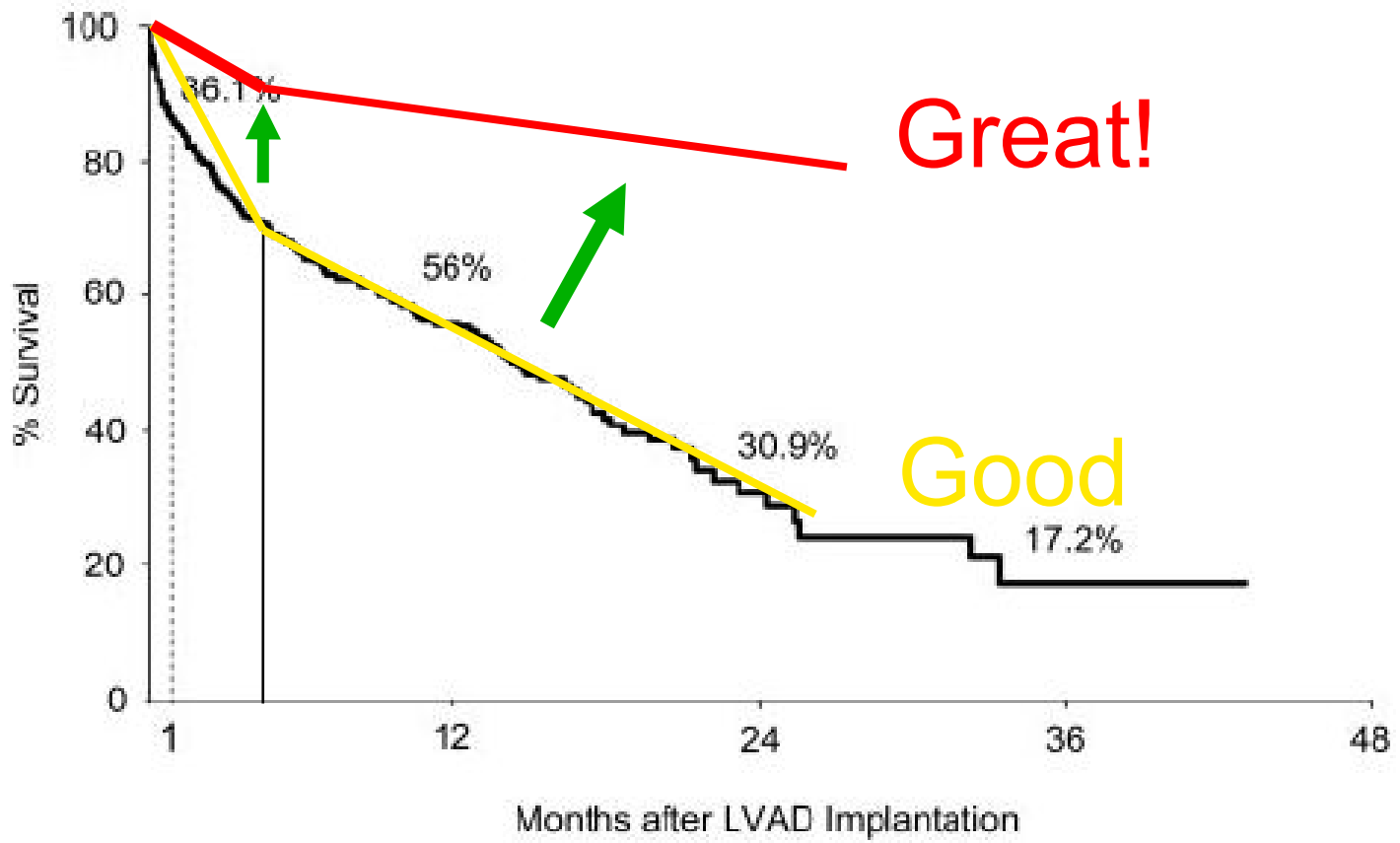
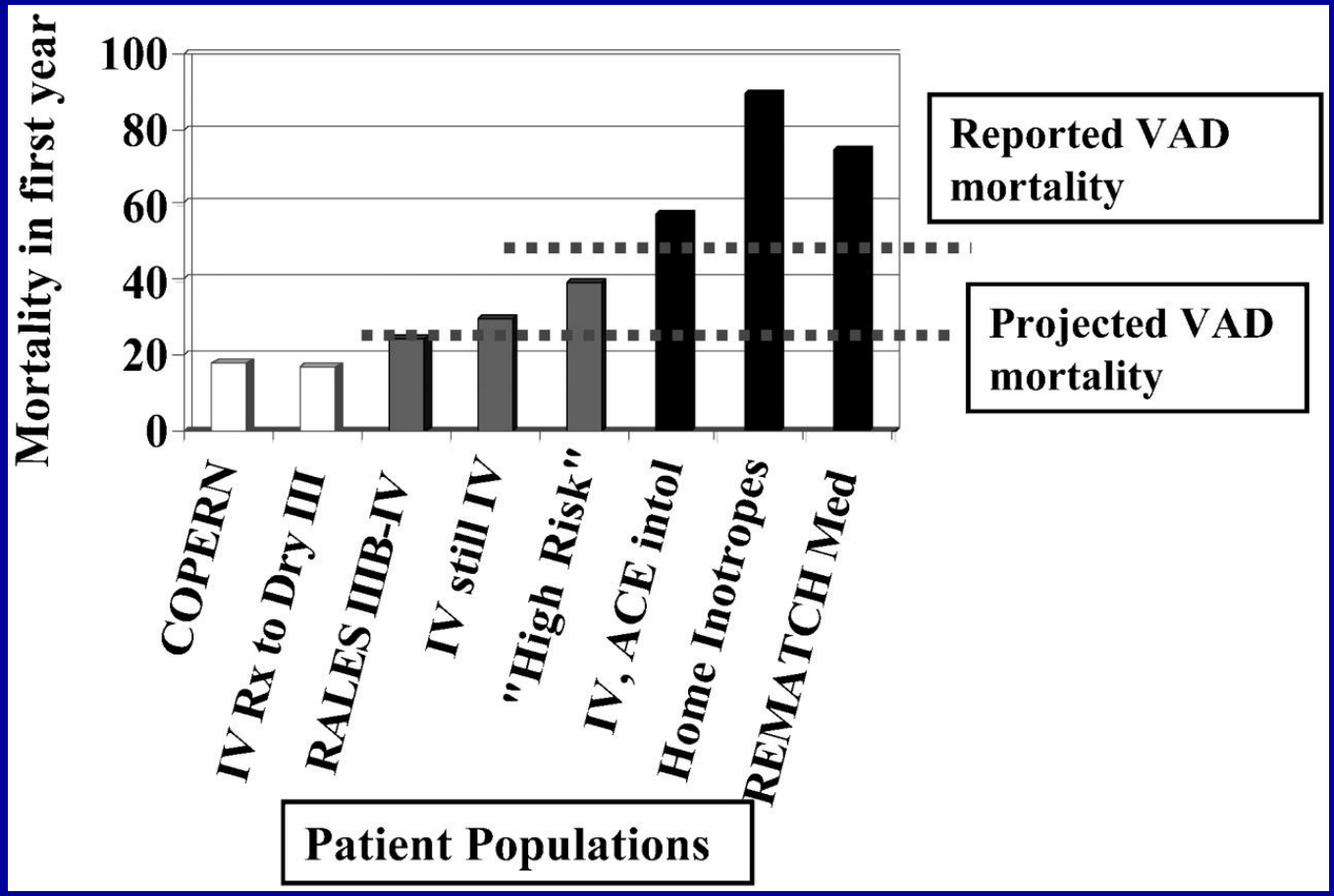


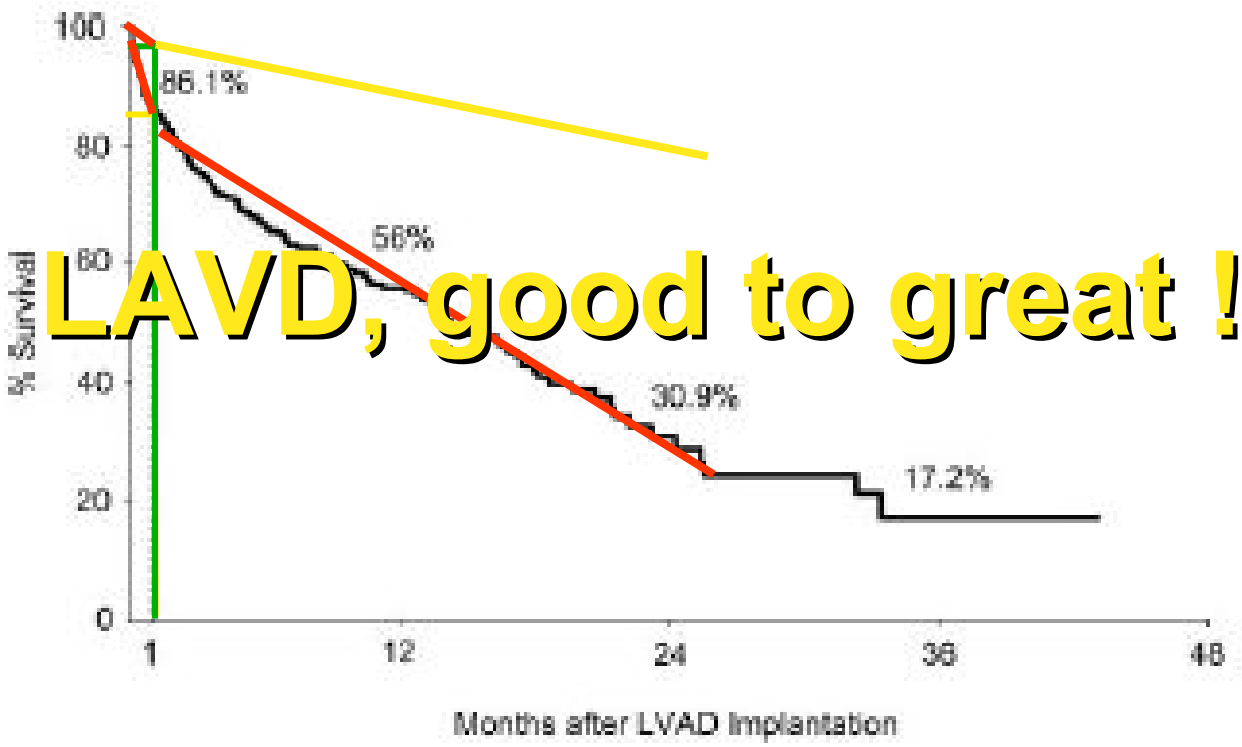
Figure 1. Survival after LVAD implantation as DT in the post-REMATCH era.

Comparison of estimated 1-y mortality of different heart failure populations



Stevenson, L. W. et al. Circulation 2005

Post REMATCH era – potential With better patient selection… and a better device achievements…..



LAVD, good to great !

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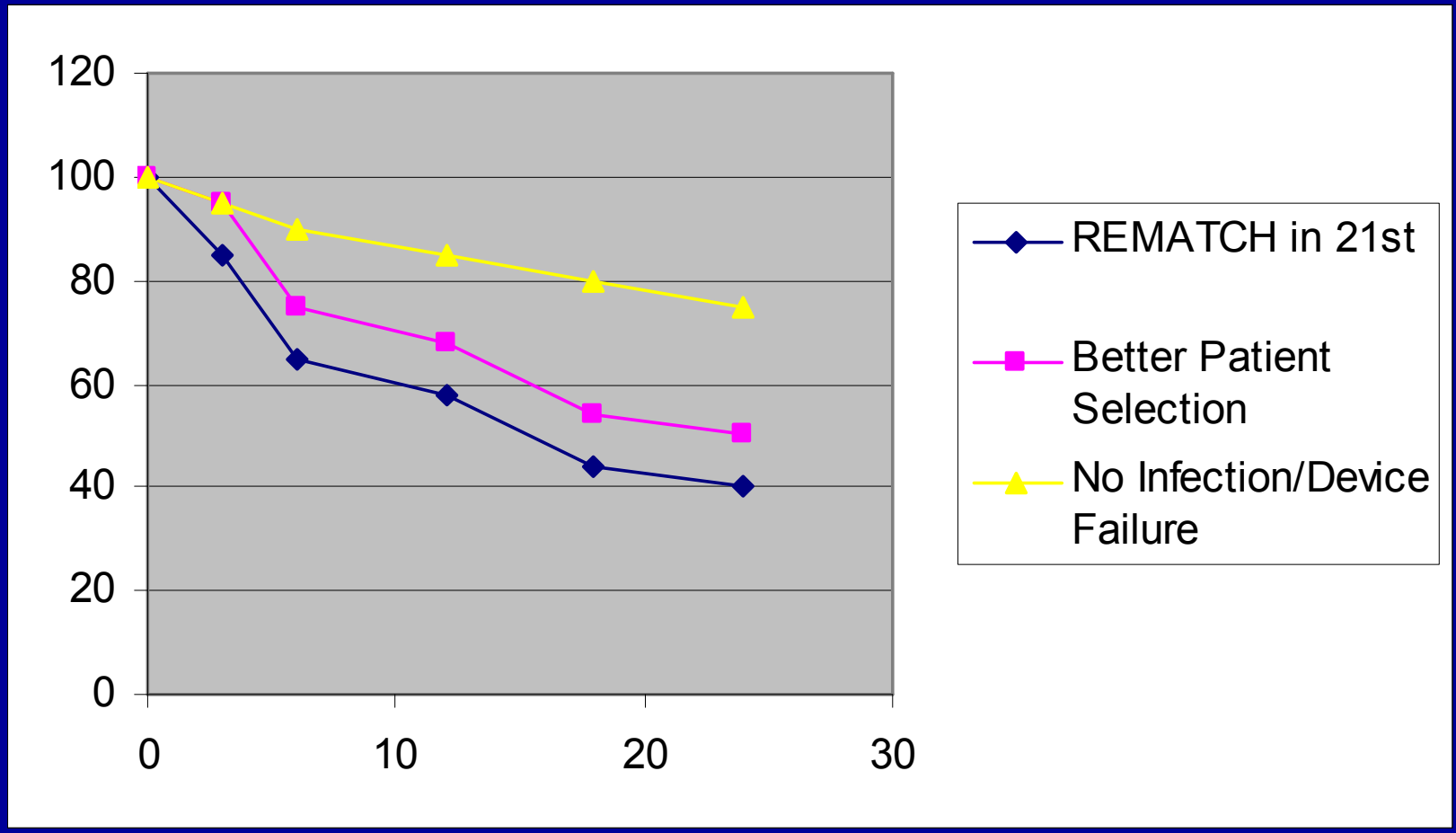
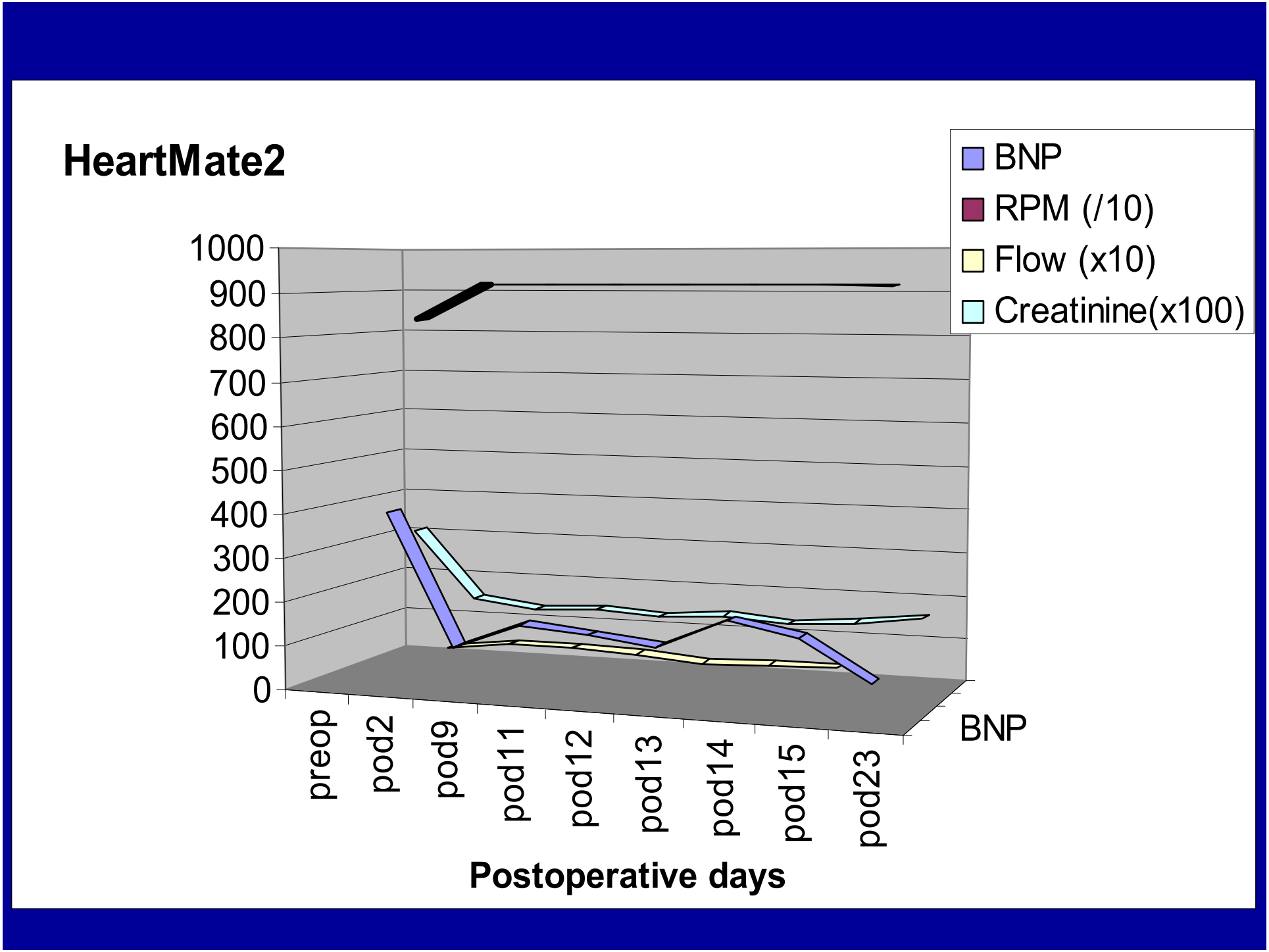
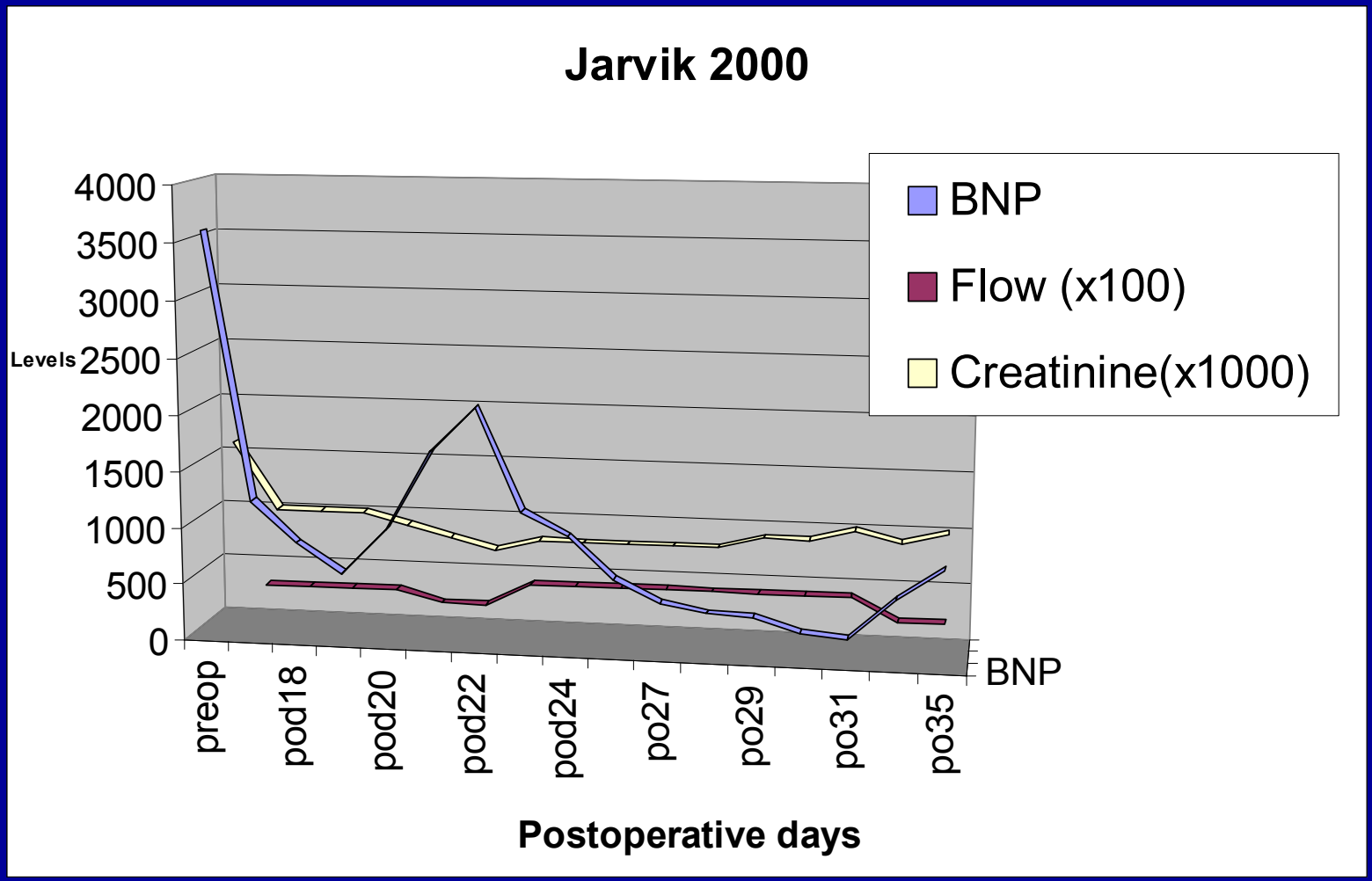
Estimated Improved Survival




HeartMate2
BNP
RPM (/10)
Flow (x10)
Creatinine(x100)
1000
900
800
700
600
500
400
300
200
100
0
preop
pod2
pod9
pod11
pod12
pod13
pod14
pod15
pod23
BNP
Postoperative days


Jarvik 2000
4000
3500
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2000
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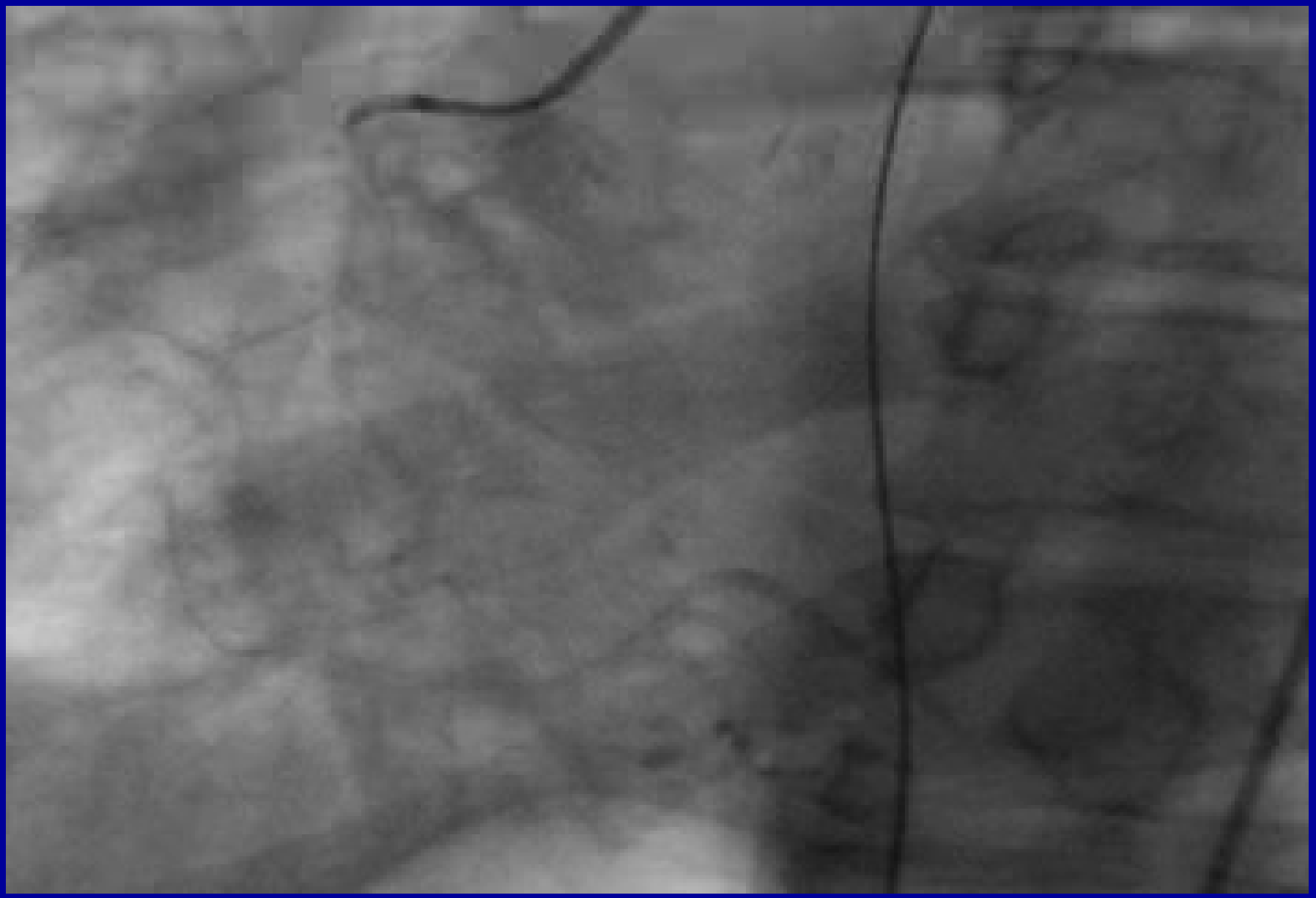
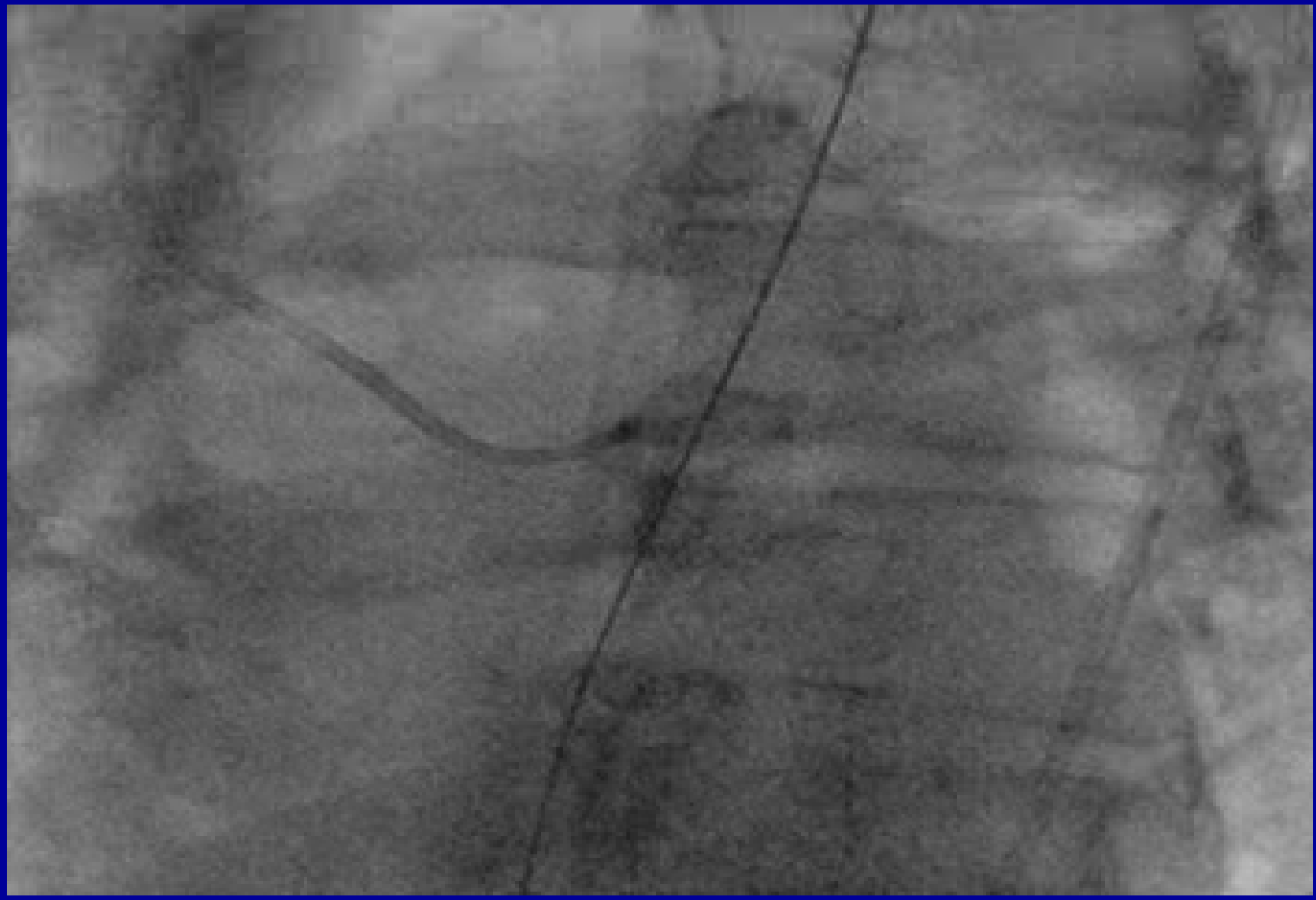
500
0
Levels
BNP
Flow (x100)
Creatinine(x1000)
preop
pod18
pod20
pod22
pod24
po27
po29
po31
po35
BNP
Postoperative days

AMI in Cardiogenic Shock

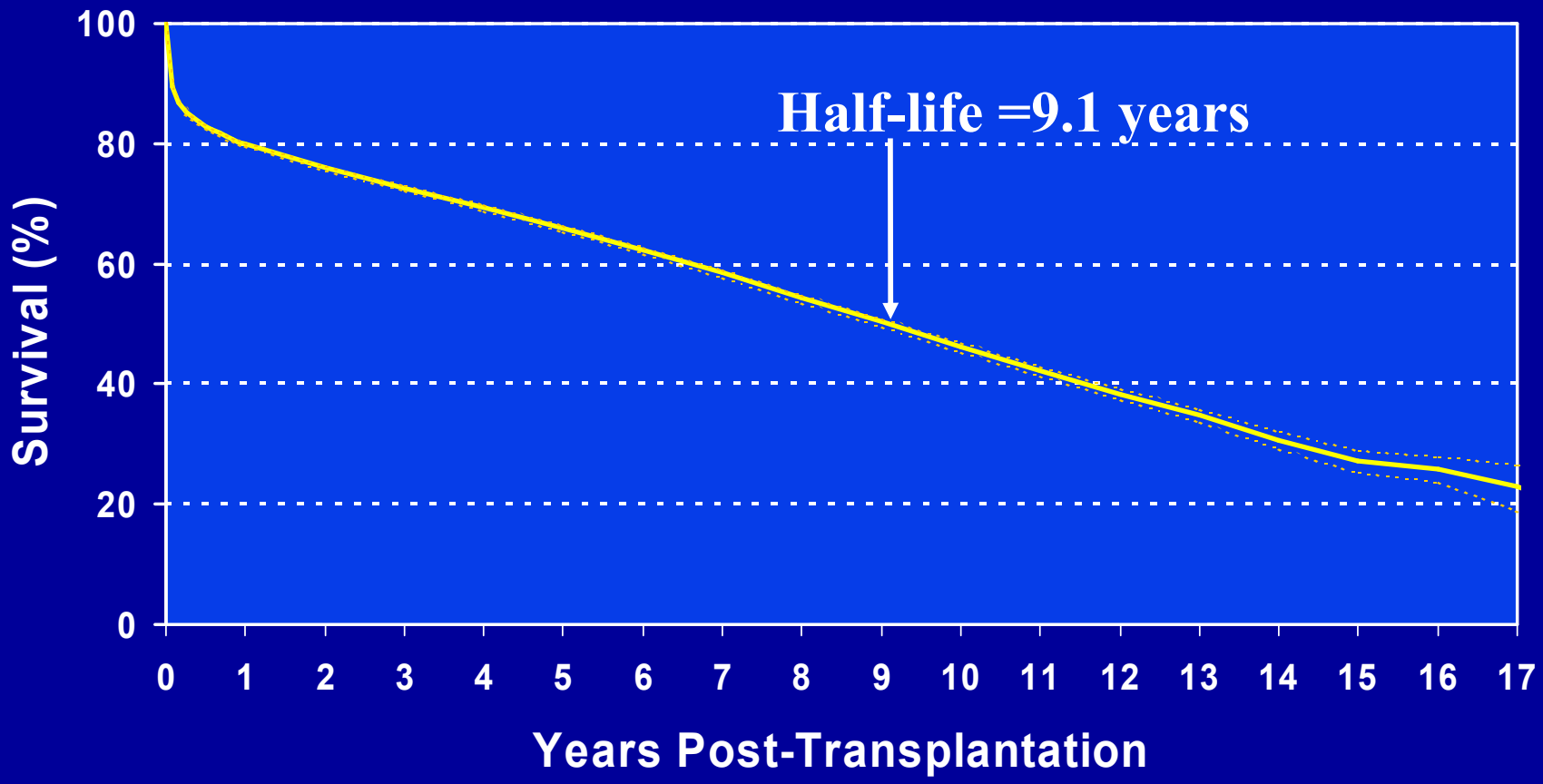
- 7-10% of all AMI
- Leading cause of death in hospitalized patients
- 10-30% survival rate at 30 days






CAT
95E

Heart Transplant Survival (ISHLT N =52,195)



September 15, 2002

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Damaged hearts beat the odds

By Josephine Marcotty
Star Tribune Staff Writer

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For months, Voigt, 42, waited for a transplant while an implanted titanium pump did the work of her own heart, which stopped suddenly last September from a viral infection.

The call for a transplant came one night in June. At midnight her family gathered in the waiting room at Fairview-University Medical Center in Minneapolis. Her surgeon, Dr. Soon Park, made the incision in her chest and prepared to hook her up to the heart-lung machine.

He switched off the titanium pump, then watched in surprise: Voigt's own heart started to beat.

Duane Braley/Star Tribune

A viral infection damaged Mary Voigt's heart, but the organ repair itself with help from an implanted pump .

For two hours he watched it work. Then he took off his mask and went to tell her family that she didn't need a transplant after all.

HEART continues on A8

Can a heart heal itself?

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Can a heart heal itself?

Yes!

"All the News That's Fit to Print"

The New York Times

VOL. CLII . . . No. 52,519 NEW YORK, TUESDAY, JUNE 10, 2003 ONE DOLLAR

Science Times

When Her Heart Failed, a Pump Gave Her Life

A 'Bridge to Transplant' Becomes a Bridge to Recovery; Now, Doctors Wonder How Many Could Benefit

By DENISE GRADY

It was the kind of phone call every parent dreads. Late one night last December, Megan Ivers, a freshman at the University of Minnesota, called home to say her friends were taking her to the emergency room.

She had been sick for about a week with what she thought was the flu. Yesterday, the infirmary had diagnosed pneumonia. Now, she was having trouble breathing and was feeling so weak and faint that she could barely stand up.

Her parents, Marcia and Wayne Ivers, high school teachers in Marshall, Minn., said they would meet her at the hospital, and started the three-hour drive east to Minneapolis.

Megan's friends sat her in a desk chair with wheels, rolled it down a corridor, loaded her into a car and drove the block or so from their dormitory to Fairview University Hospital.

Her memories of what happened next are hazy.

"They did an echo of my heart, and I knew it was bad when they started calling people in," Megan, 18, said. "Some came from home. One had been going to bed. About 10 people were sitting there watching. I knew something was bad when they did that."

Megan's heart was failing, pumping so little blood that she was near death. The virus that had made her ill had probably attacked her heart, causing viral myocarditis. Dozens of common viruses have been linked to this heart ailment, but no one understands why. In a few unfortunate people, a viral infection can rapidly shut down the heart.

Such cases are uncommon, but when a previously healthy young person suddenly needs a heart transplant, viral myocarditis is often the reason.

The one hope of saving Megan's life was an operation to implant a mechanical pump that would assist her heart. It was not an artificial heart, and would not replace her own heart. Instead, it would be attached to her heart to do the work of its main pumping chamber, the left ventricle.

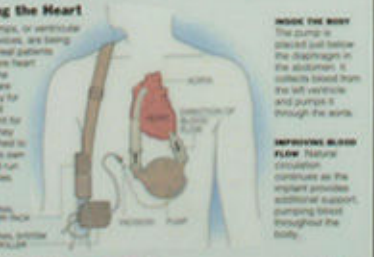
Such pumps, called ventricular assist devices, or VADs, are most often used as a "bridge to transplant" to keep people with failing hearts alive

Continued on Page 6

Dr. Soon Park, far right, with the surgical team, left to right, Dr. Ken Lain, Leslie Micho, a nurse, and Christine Spence, surgical technician, preparing to remove a heart pump from Megan Ivers at Fairview University Hospital in Minneapolis. Megan, a freshman at the University of Minnesota, is shown in the photograph at right along with her father, Wayne, and Peter Maiza, her boyfriend.

Helping the Heart

Heart pumps, or ventricular assist devices, are being used to treat patients with severe heart failure. The devices are temporary for some and permanent for others. They are attached to a patient's own heart and run by batteries.



INSIDE THE BODY The pump is placed just below the diaphragm in the abdomen. It collects blood from the left ventricle and pumps it through the aorta.

IMPROVING BLOOD FLOW Natural circulation continues as the implant provides additional support, pumping blood throughout the body.

Sources: New England Journal of Medicine; FirstHealth Inc.

The New York Times

When Her Heart Failed, a Pump Gave Her Life

Continued From First Science Page

until they can get a transplant. Megan would be put on the waiting list for a heart.

But Dr. Soon Park, a heart surgeon, and Dr. Andrew Boyle, a cardiologist, had higher hopes for her. They had seen VADs do something extraordinary: act as a bridge to recovery, rather than to transplant. There was a chance that Megan's heart, given a rest while the pump did its work, would recover. If it did, she would not need a transplant, and the device would be removed.

But only time would tell. The Minnesota team had four other patients with sudden and mysterious cases of heart failure whose hearts recovered after a few months on a pump, and there have been a handful of cases at other hospitals as well, using various types of assist pumps. Initially, doctors were surprised. But now, instead of assuming that a transplant is inevitable, doctors have begun to look for signs that the heart is healing.

Patients like Megan — young, previously healthy people who suddenly develop heart inflammation and heart failure — seem to have the best chances of recovering if they are given assist pumps. It remains to be seen whether a majority of people who need assist pumps — older patients with chronic heart failure — can also regain a useful amount of heart function from being on a pump.

There are hints that at least some of them might be helped. VADs are coming into wider use and being used for longer periods of time, and if they live up to their promise of helping the heart to heal, they could enable a significant number of people to avoid or postpone heart transplants.

The question is important because donor hearts are in short supply, and doctors and patients are desperate for other options. About 3,700 people are on the waiting list for a heart in the United States, but only 2,154 received heart transplants last year. Many people die waiting, and many never even make the list because they are too old or too sick to qualify.

Ventricular assist devices have been used since the 1990's. Most recipients have advanced heart failure, a chronic disorder in which the muscle becomes too weak to pump efficiently. It is usually caused by coronary artery disease, heart attacks or longstanding high blood pressure.

The VAD is implanted below the heart. Blood drains into the device from a tube in the left ventricle and is then pumped out through another tube to the aorta, a large artery, to circulate through the body. Another tube comes out through the skin to connect the pump to a battery pack and a set of controls worn on a belt.

One company, Thoratec of Pleasanton, Calif., sells 80 to 90 percent of the VAD's used as bridges to transplant in the United States. Its device, the HeartMate, costs about $65,000, and the surgery to implant it about $100,000. In 2002, Thoratec sold 1,400 to 1,500 HeartMates.

When doctors saw that some patients awaiting transplant survived years with VADs, they began to wonder whether the pumps could be used as a long-term or even permanent treatment for some people with severe heart failure.

A major study in 2001 suggested that VADs could help some of those people who did not qualify for transplants. In the study, 128 people who were dying from heart failure, but were too old or too sick for a transplant, were assigned at random to receive either the device or standard drug therapy. After two years, 23 percent who got the pump were still alive, as opposed to only 8 percent who took drugs. Even though they had more complications than people on drugs, those on the pump felt better and were more active.

Dr. Eric Rose, director of the study and chairman of surgery at Columbia-Presbyterian Medical Center, said that since the 2001 findings, as pumps have been improved and surgeons have become more experienced, survival statistics have improved.

> After nearly dying, a student now feels "pretty normal."

In November, the Food and Drug Administration approved the HeartMate as "destination" therapy, meaning long-term treatment for people who are not eligible for transplants. What would really open the door to destination use is approval by the federal Medicare program, which would then cover the pump for people 65 and over. A decision is expected in July.

If Medicare started paying, Dr. Rose estimated that 4,000 to 5,000 people a year would receive HeartMates as destination therapy. The cost could approach $1 billion a year. Eventually, according to a study by the National Institutes of Health, the number could increase to 100,000 a year.

If VADs become more common and are used for longer periods, doctors may learn more about how often failing hearts can recover and which patients can benefit most. Experts say people with chronic heart failure are far less likely to regain normal heart function than acute cases like Megan's. Recovery is least likely in those who had heart attacks and have a lot of dead heart muscle.

And yet some healing does take place in many patients when they are put on pumps, even those with longstanding heart failure. Doctors have noticed improved heart function in some, and in some people whose hearts were removed as they could have transplants, doctors found that cells in the patient's original heart had begun to return to normal. It is not clear, though, that the improvement can ever progress far enough to help the patients.

"They all get better," said Dr. O. H. Frazier, a heart surgeon at Baylor who has been working on mechanical hearts for more than 30 years. "We see it in every patient."

Dr. Frazier said there was a great need for studies to find out how much recovery VAD's could produce and how to maximize it.

Other researchers have begun genetic studies on tissue from failing hearts and recovering ones treated with VAD's to learn which genes are turned on and off as hearts become diseased and as they heal. Ultimately, that work might lead to tests that would help predict which patients with heart failure might recover if given a VAD.

On the night of Dec. 17, Megan Ivers was feeling fast. Her heart was quivering uselessly instead of beating. Her skin was grayish, her lips white, her pulse thready, her skin beginning to cool from lack of circulation. She was awake, but could not think clearly, and was terrified.

"It was quite clear that she was barely alive," Dr. Park said.

Dr. Boyle warned Megan's parents that she might die even before surgeons could get the pump in place. She was rushed to the operating room in the early hours of Dec. 18, a Wednesday. She has no memory of the days between then and Saturday, when she awoke in the intensive care unit with a line of staples down her middle and a titanium pump pounding away inside her.

Grateful as she was for the device that had saved her life, she soon wanted to get rid of it.

The pump shuddered with each beat and made her whole body shake. The tube coming out through her skin felt uncomfortable, and when she stood or walked for more than 10 minutes she felt weighed down by the two and a half pounds of metal hanging off her ribs. The pump crowded her stomach and kept her from eating normal-size meals. She could sleep comfortably only on her back, with a pillow or blanket on her chest to muffle the sound of the machine.

By the time Megan left the hospital in January, her heart had already begun to recover. A series of tests in February, including one that crunked back the pump and finally turned it off, showed that her heart had recovered. It was time to take the pump out.

On Friday, March 7, as Megan lay anesthetized on an operating table, doctors turned off the assist pump and watched her heart on an echocardiogram monitor. The beat was strong.

"Look at that!" Dr. Park said, watching the monitor. "I love it."

It took about three hours to "explant" Megan's pump, a procedure that required some delicate dissection to free the components from tissue that had grown into them.

But the pump came out. Six days later, doctors implanted a defibrillator in Megan's chest, as a precaution in case she developed the kind of abnormal heart rhythm that can lead to sudden death. If an arrhythmia occurred, the defibrillator would emit a shock to restore normal rhythm. She was at risk because a piece of ventricle had been removed to attach the pump, and the scar could disrupt heart rhythm.

But, Dr. Boyle said, "I think she should have a full, normal life expectancy with no restrictions."

In a telephone interview on Sunday, Megan said she felt "pretty normal," though the defibrillator did fire once, in May, after she had climbed five flights of stairs to take a calculus final she missed last December. She felt the shock and knew what it meant, but she decided to tough it out and take the exam anyway. (She has yet to receive her grade.) Doctors said the problem was due to a dosing mistake in a drug she takes to stabilize her heart rhythm and was unlikely to occur again.

Megan said she was eager to get back to the university after taking a semester off. She is majoring in music education, plays trombone and baritone and has been selected as a section leader and rank lieutenant in the university's marching band.

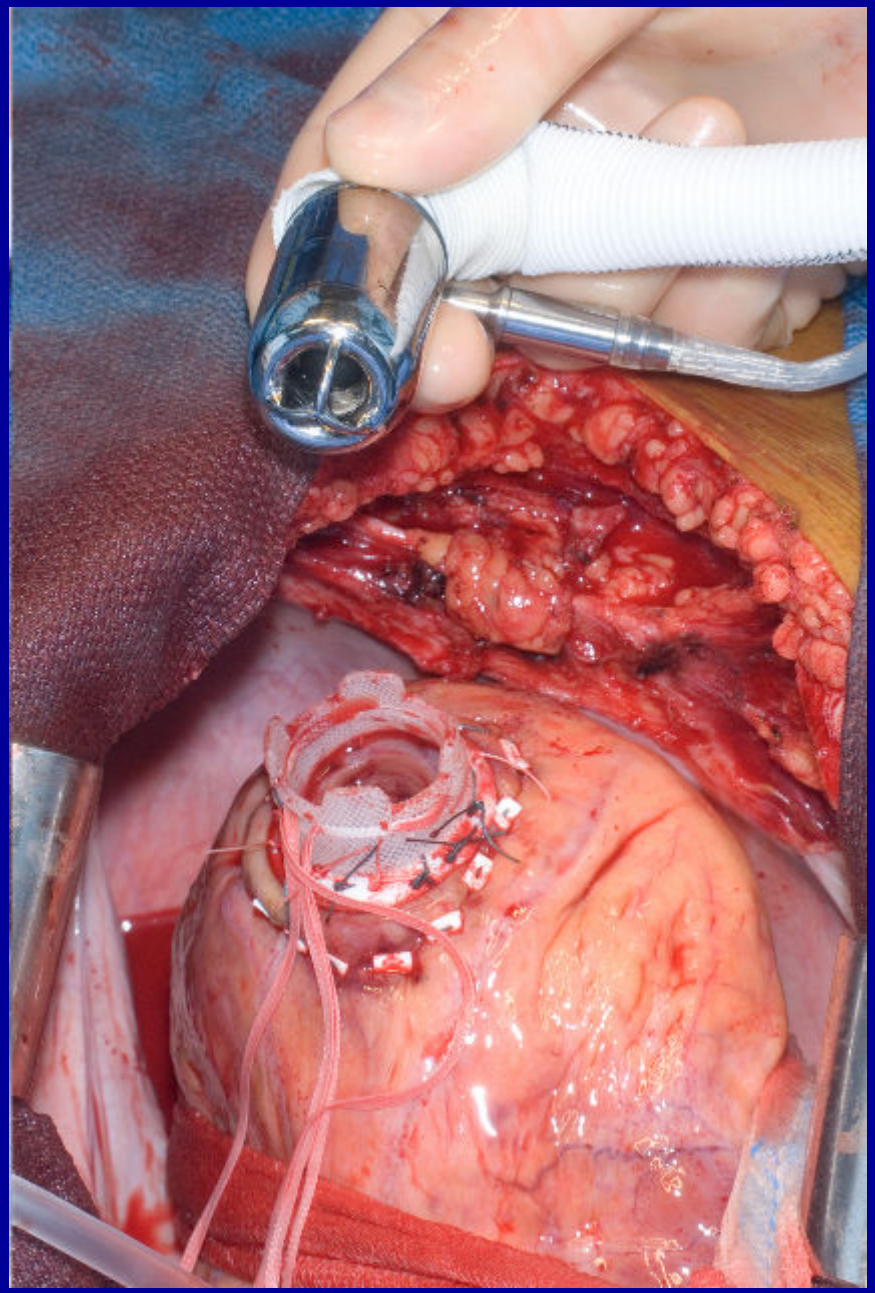
She said it was hard to believe how ill she had been, considering how good she feels now. And yet the memory of it is always with her.

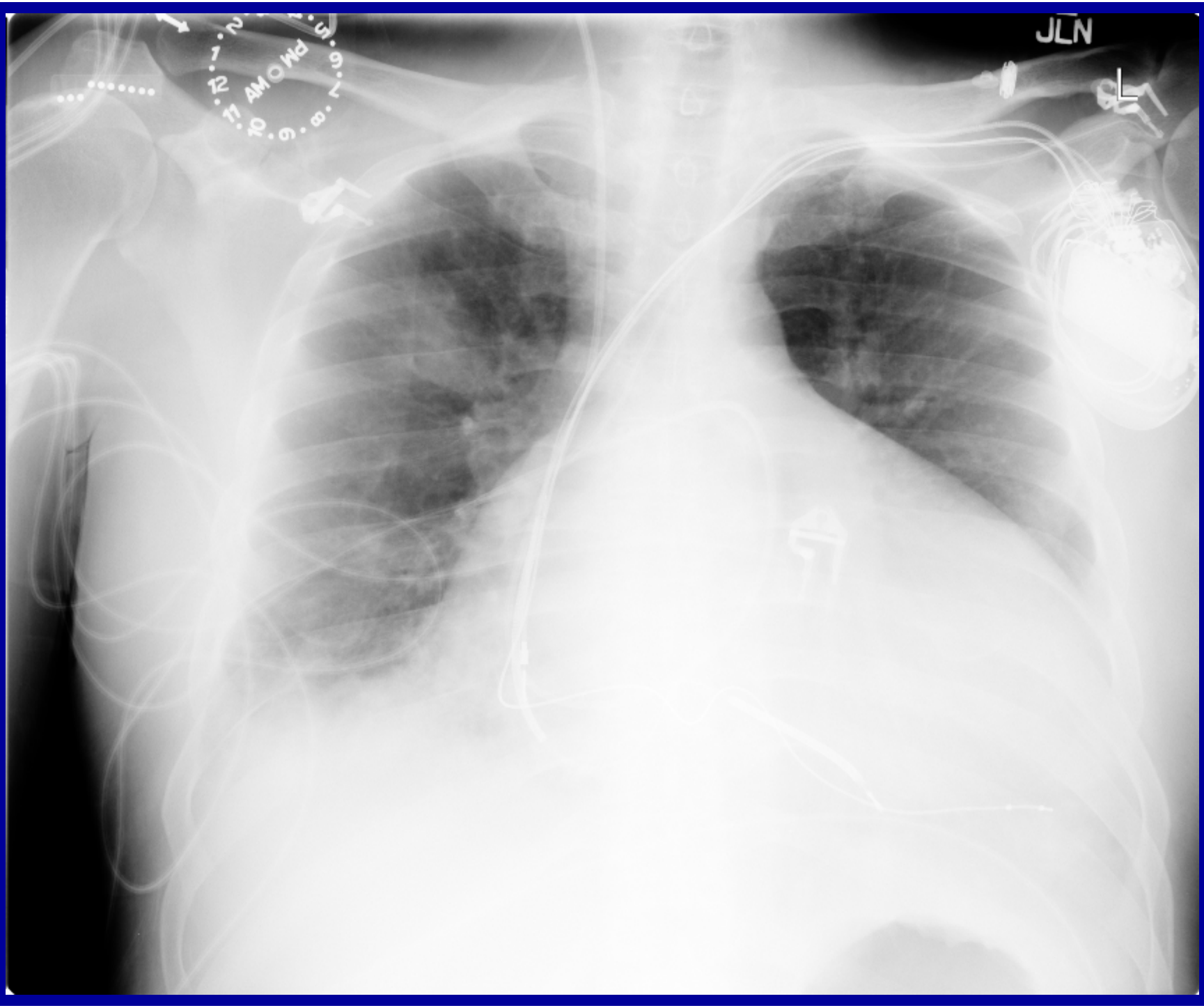
"I feel pretty much back to normal," she said. "As normal as I'll be after all this."

Megan Ivers and her surgeon, Dr. Soon Park, left, and Dr. Andrew Boyle, a cardiologist, look at a ventricular assist device like one she used.

Good to Great!

Think VAD!



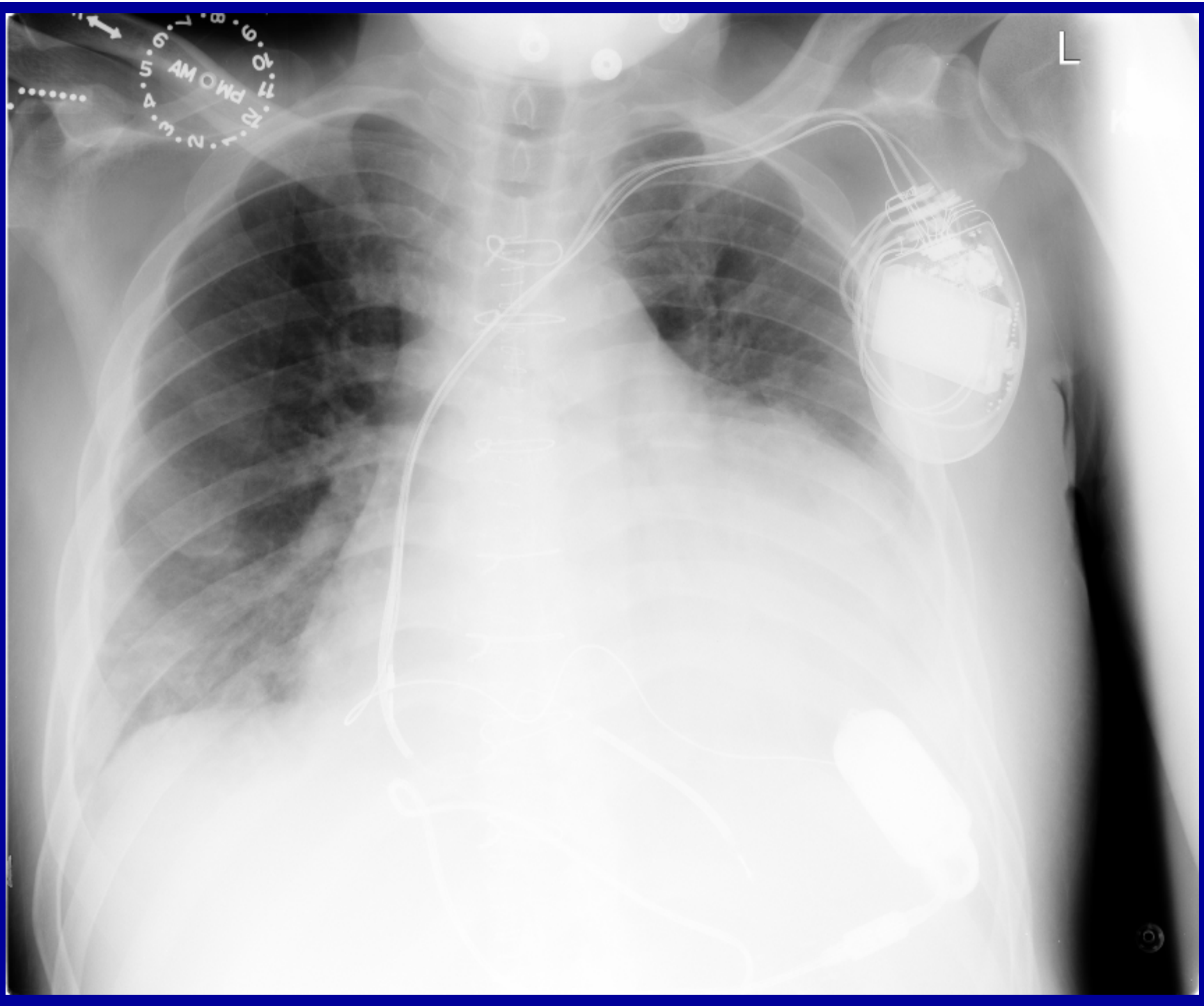

JLN

FlowMaker™ Controller

Only One Adjustment: Speed Setting

Speed Setting	Pump Speed (rpm)	Flow (L/min)
1	8,000	1-2
2	9,000	2-4
3	10,000	3-5
4	11,000	4-6
5	12,000	5-7

8 HOUR PORTABLE POWER SYSTEM – 2 lbs.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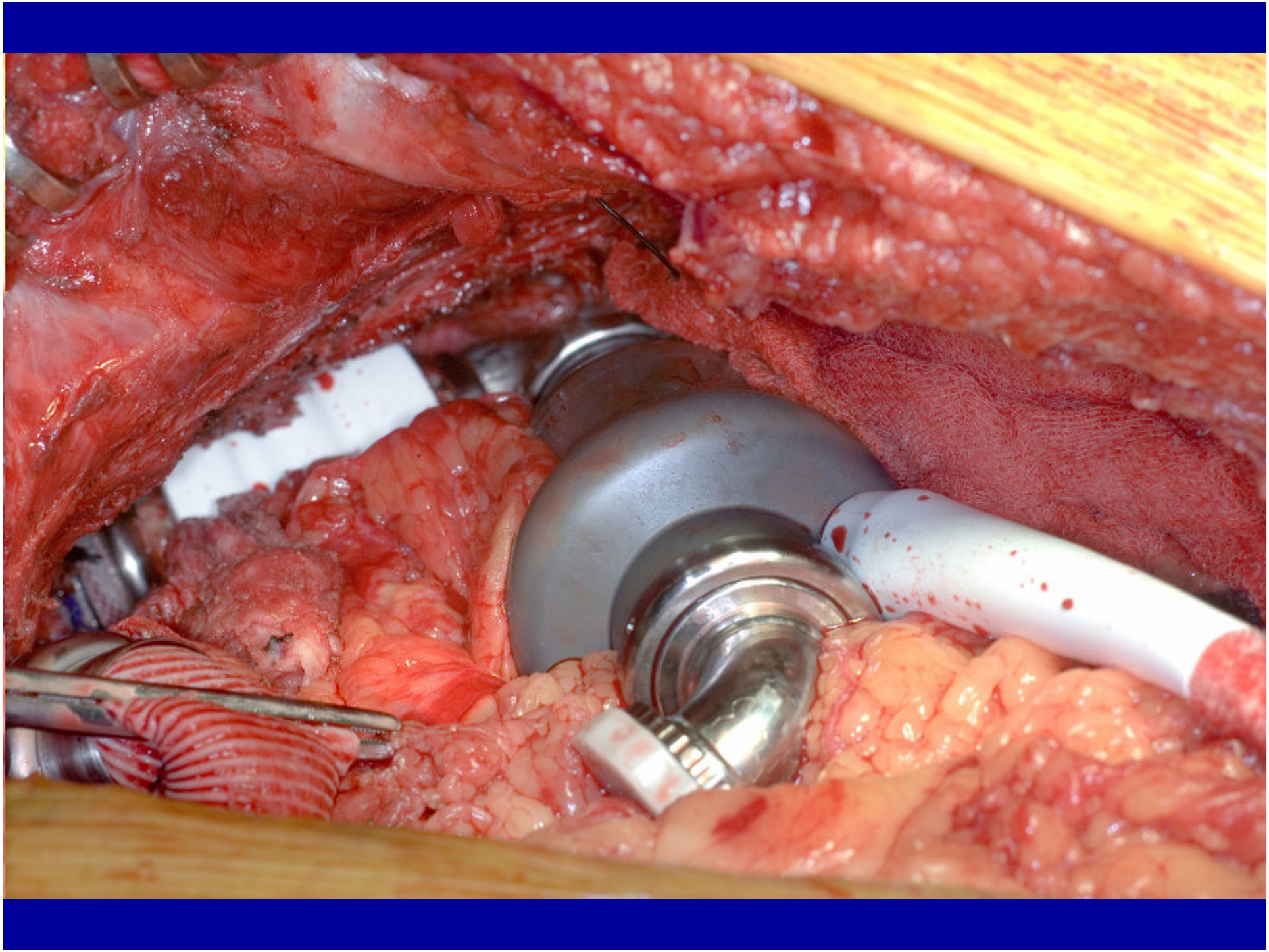
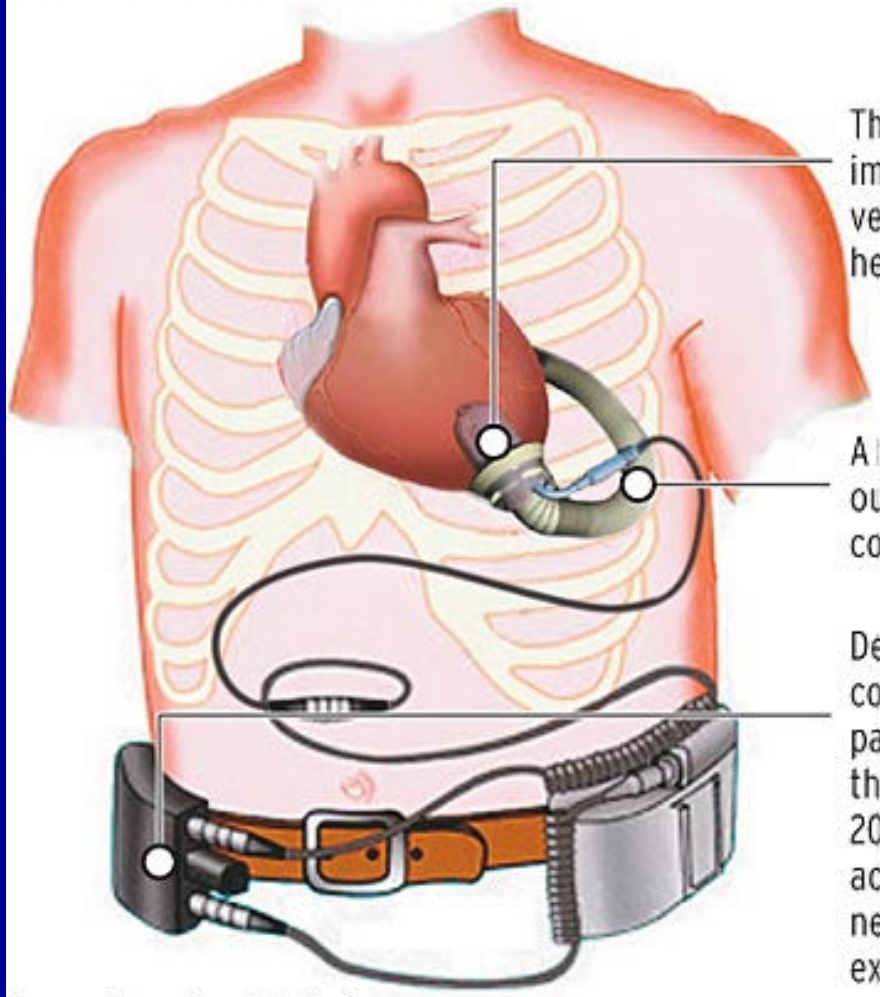


JARVIK 2000

Unlike the natural heart, the Jarvik 2000 pump does not "beat." Instead, it uses a spinning rotor to propel blood from the left ventricle into the aorta. But the patient's heart continues to contract and relax, and the volume of blood moved by the spinning rotor rhythmically increases and decreases in synchrony with those contractions.



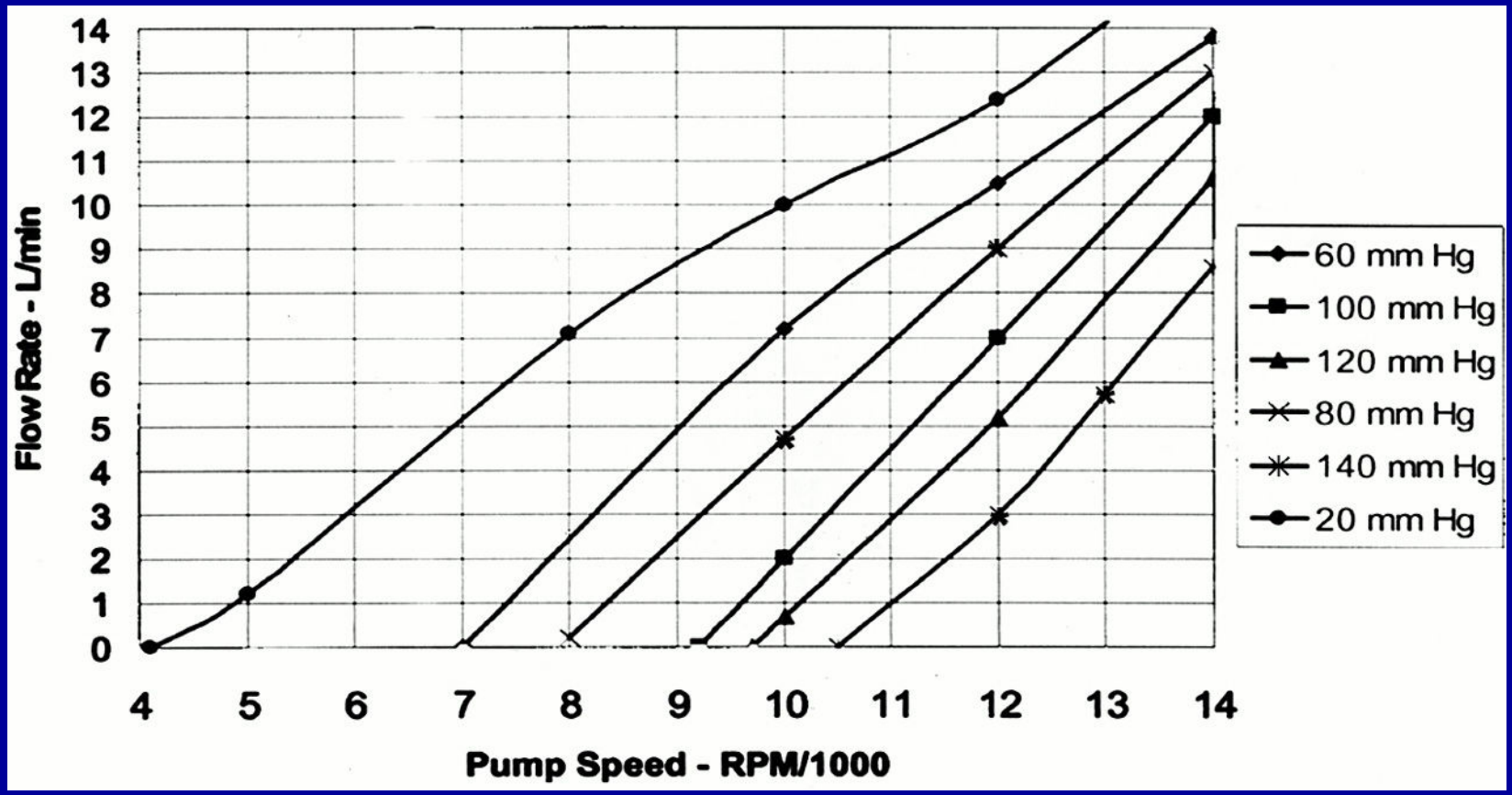
The Jarvik 2000 pump is implanted inside the left ventricle of the patient's heart.

A fabric tube from the outflow end of the pump connects it to the aorta.

Depending on the heart's condition and the patient's level of activity, the output of the Jarvik 2000 can be adjusted to accommodate patient needs using a small, external controller.

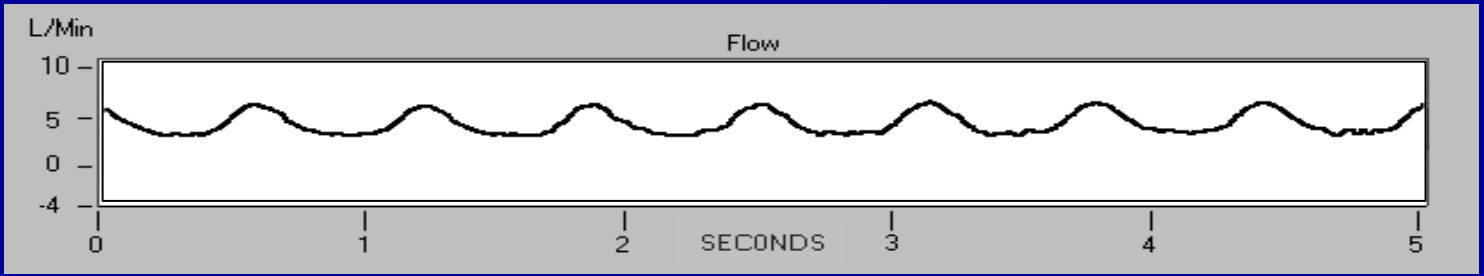
Source: Texas Heart Institute

The News & Observer

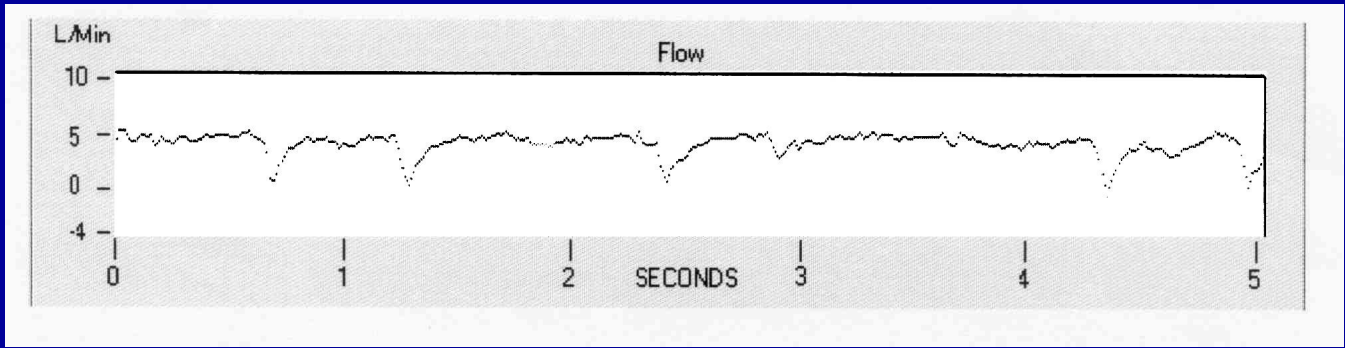


Pressure–flow relationship for HeartMate II axial flow pump P is measured from inlet and outlet cannulas. (*RPM* = revolutions per minute.)

Axial flow waveforms



Typical flow waveform



SUCTION WITH NO NATIVE VENTRICULAR FUNCTION

Adverse Events

	Rate per patient-year		
Event	**OMM (n=60)**	**LVAD (n=67)**	**Ratio (95% CI)**
All	2.75	6.45	2.35 (1.86-2.95)
Bleeding (Non Neurological)	0.06	0.56	9.47(2.3-38.9)
Neurologic Dysfunction	0.09	0.39	4.35(1.31-14.5)
Peripheral Embolic Event	0.06	0.14	2.29(0.48-10.8)
Sepsis	0.3	0.6	2.03(0.99-4.13)

LVAD-Specific AEs

Suspected LVAD Malfunction	0.75
Perioperative Bleed	0.46
Percutaneous Site/Pocket Infection	0.41
Pump, In- Or Outflow Tract Infection	0.23
LVAD-Related RHF	0.17
LVAD System Failure	0.08
Device Thrombosis	0.06
Perioperative MI	0