Left Ventricular Assist Devices: Where do we Fit In

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Financial Disclosure

I do not have any financial disclosure related to this talk.

I will not be discussing off-label use.

Barriers to LVAD Implantation

Barriers

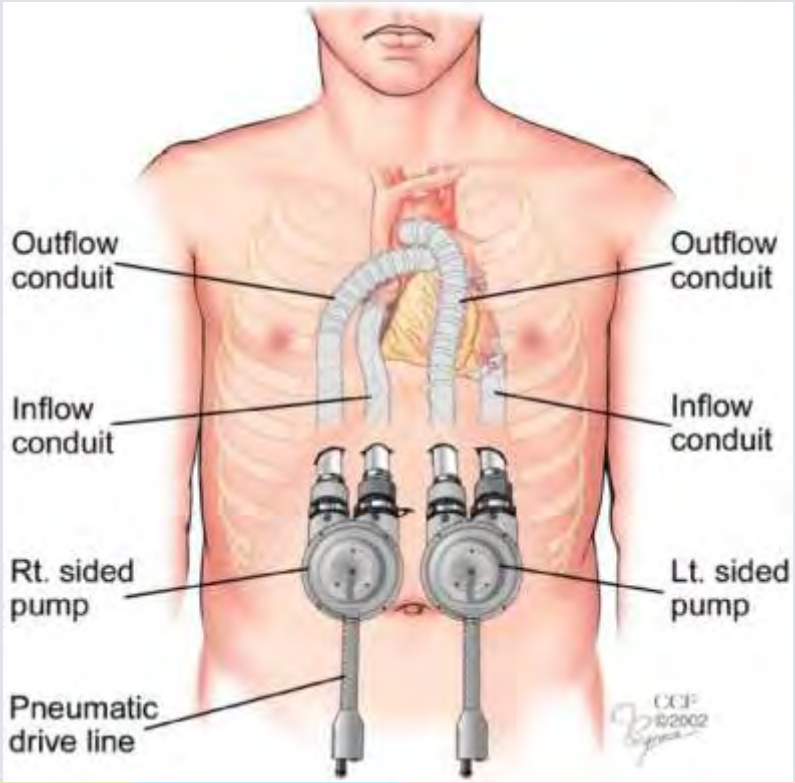
From Patients:

- “I only want one surgery”
- “I don’t want something hanging outside my body”
- “I don’t want to carry all that stuff around”

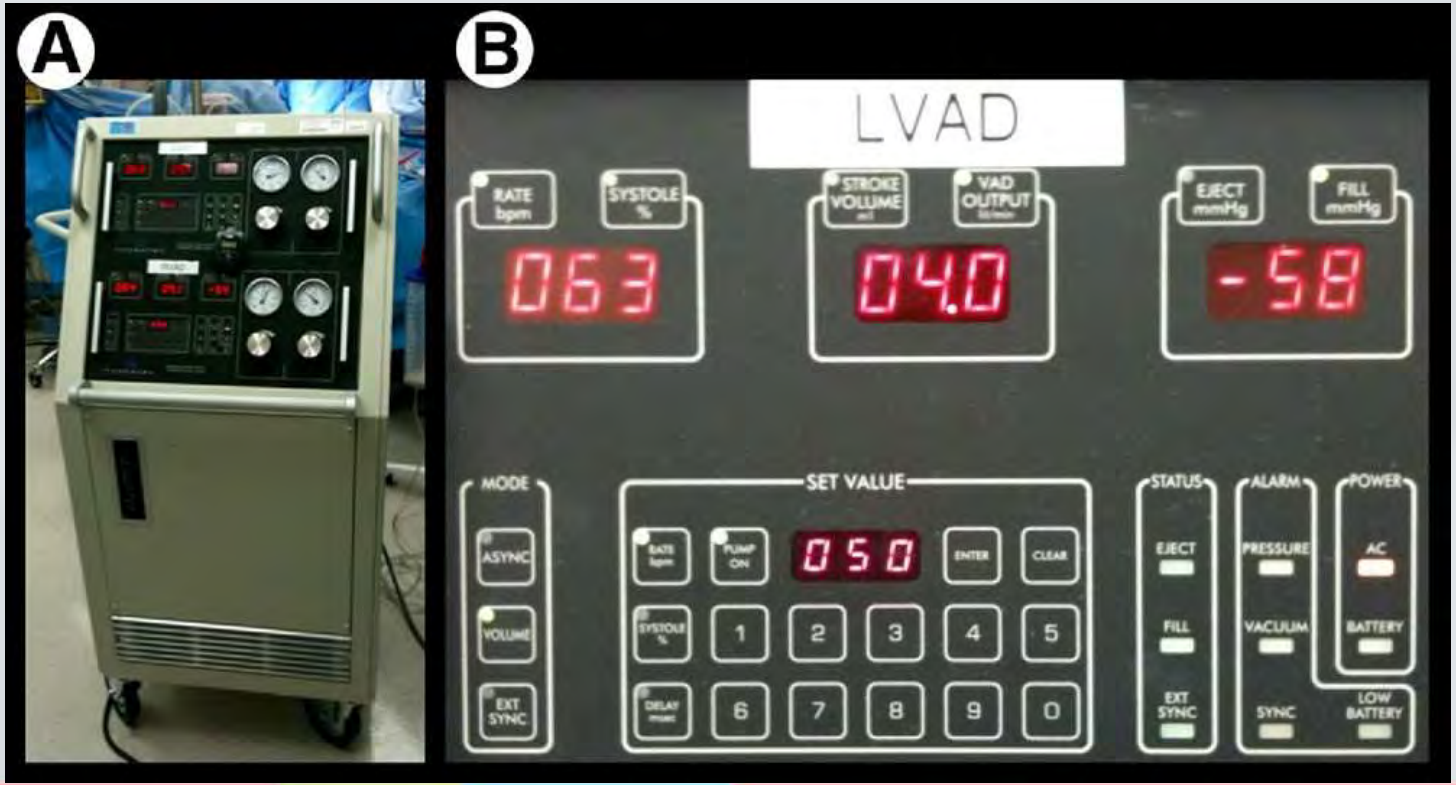
From Physicians/Providers:

- “Those things are unreliable”
- “They only last a few years”
- “They cannot leave the hospital with one of those”
- “Will it really make them live longer?”

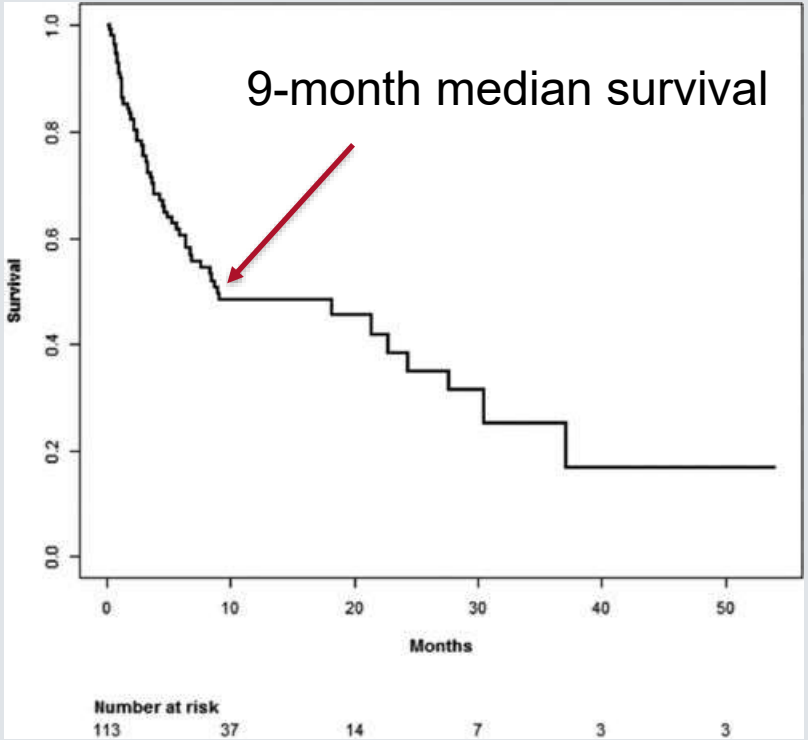
Early Days of VAD Therapy



Early Days of VAD Therapy

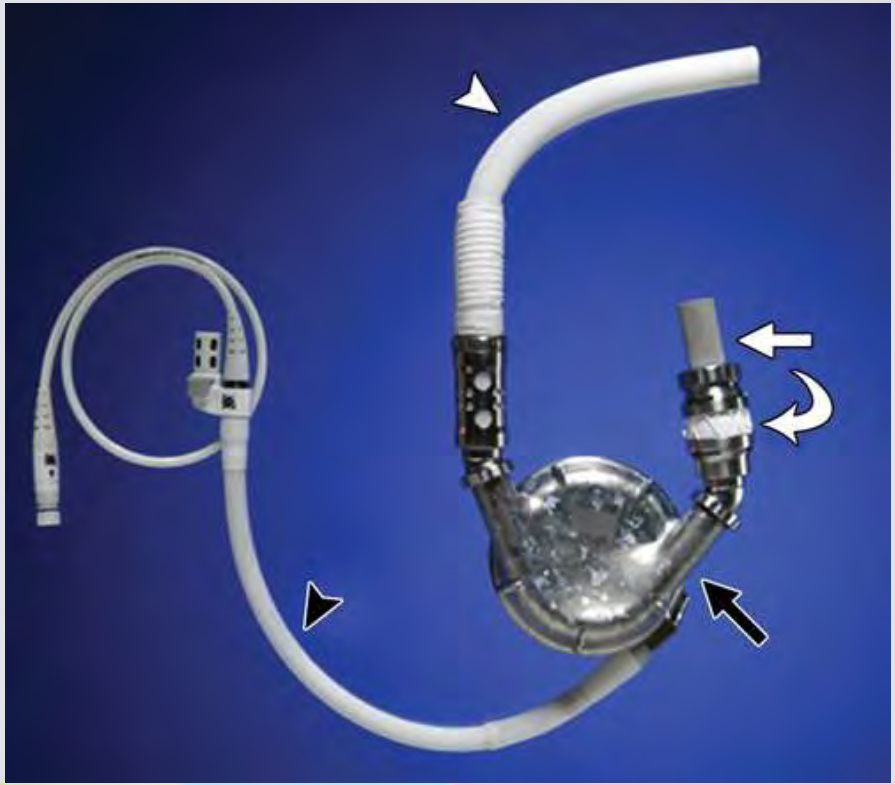


Treating with IV Inotropes

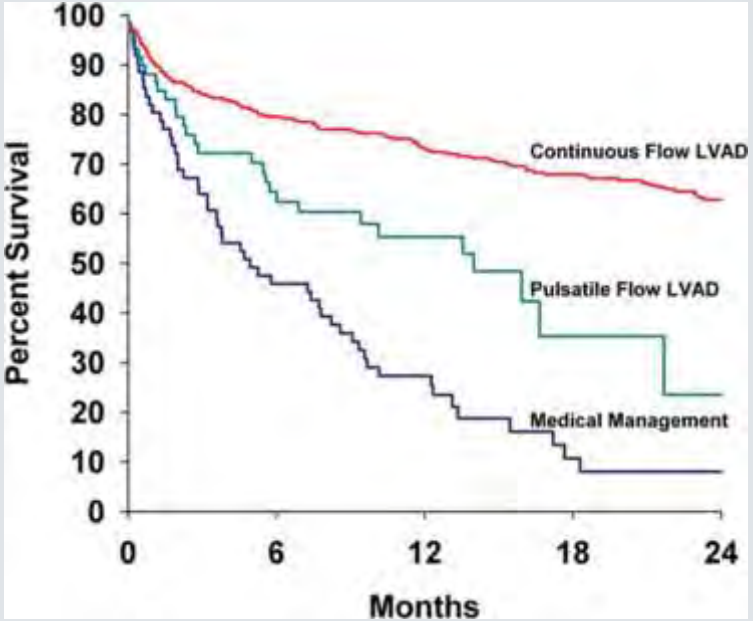


Hashim et al. Clinical Characteristics and Outcomes of Intravenous Inotropic Therapy in Advanced Heart Failure . *Circ Heart Fail.* 2015;8:880-886.

A Better Pump??



Survival with LVAD



DOI: 10.1161/CIRCULATIONAHA.112.139824

The evolution of LVADs

HeartMate XVE™

1998

BTT 1998 | DT 2003

Pulsatile flow

First LVAD FDA-approved for DT

HeartMate II™ LVAD

2008

BTT 2008 | DT 2010

Continuous flow (axial)

>27,000 patients implanted, with patients on therapy out to 10+ years[1]

HeartMate 3™ LVAD

2017

ST (BTT) 2017 | LT (DT) 2018

Continuous flow (centrifugal) with Full MagLev™ Flow Technology

>23,000 patients implanted, with patients on therapy out to 5+ years[1]

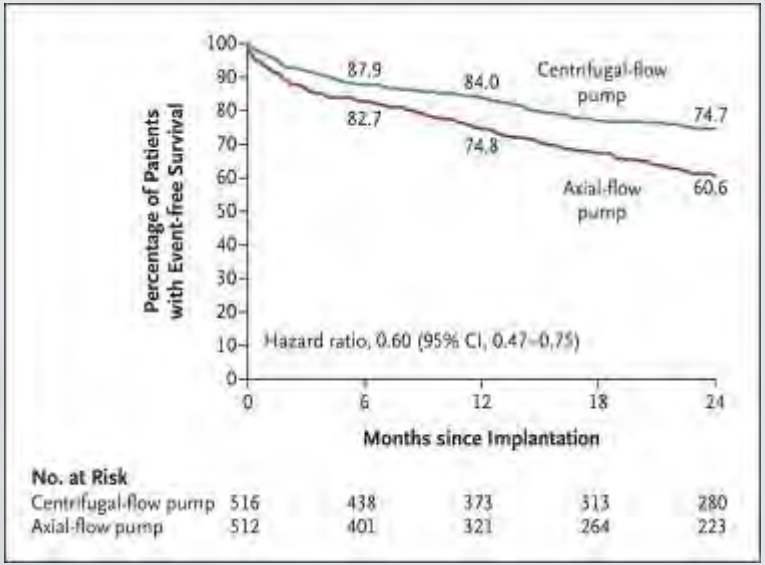
*This product is no longer available for sale or use.

1. Abbott data on file. Based on clinical and device tracking data as of May 2, 2022

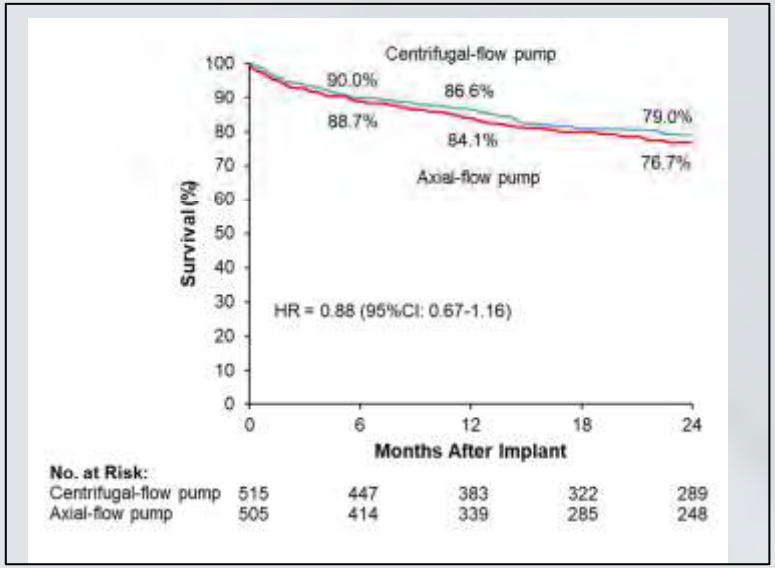
MOMENTUM 3 5-YEAR FOLLOW-UP

Key Outcomes of MOMENTUM 3 at 2 Years

Composite of survival free of disabling stroke or reoperation to replace or remove a malfunctioning device



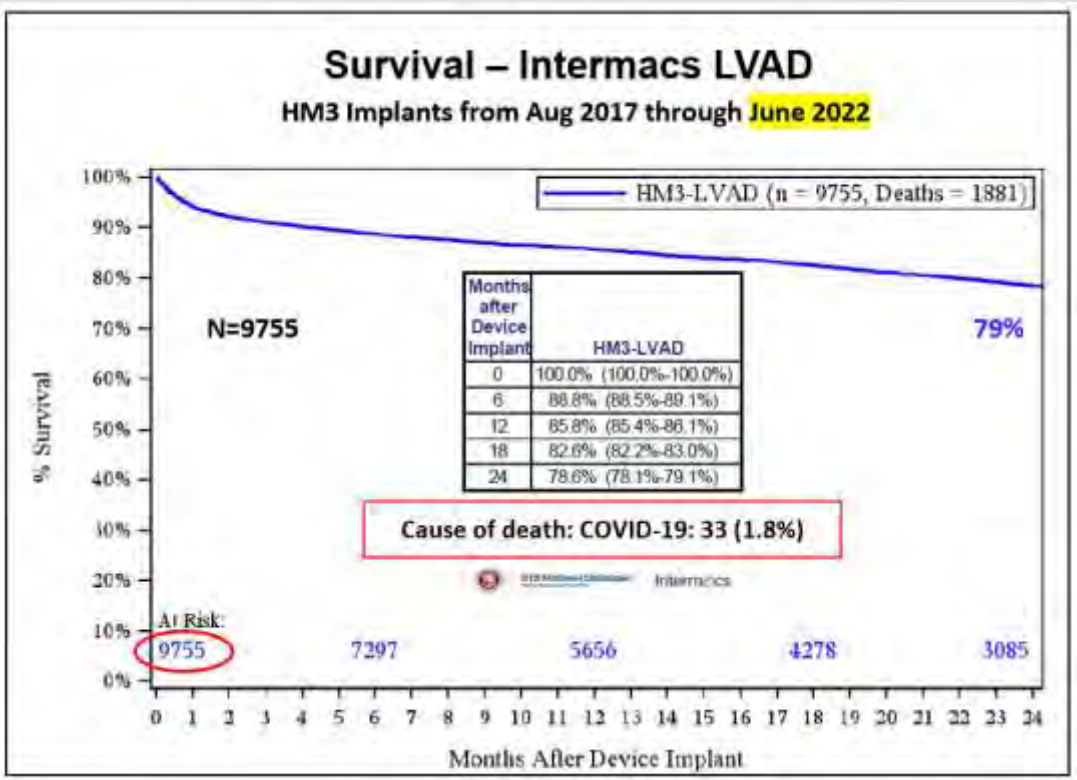
Overall Survival



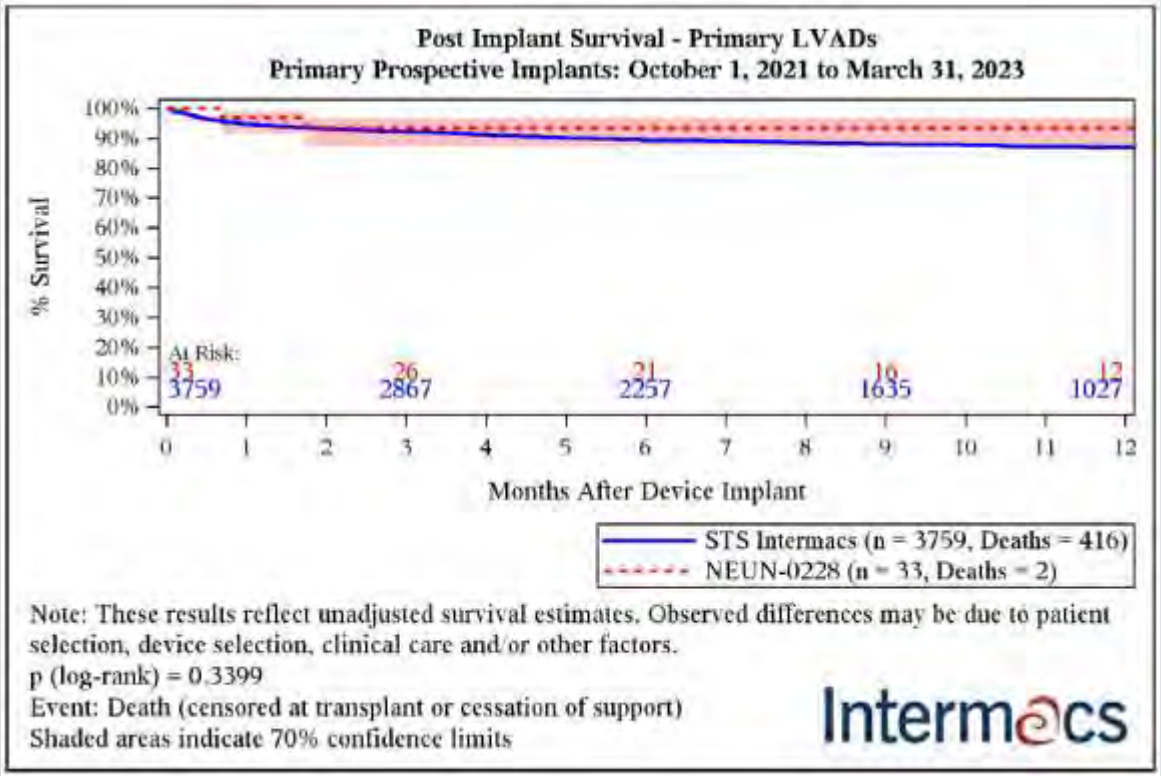
Superiority of HeartMate 3 over HeartMate II LVAD was driven by significant reduction in Hemocompatibility Related Adverse Events (HRAEs), specifically: pump thrombosis, strokes, bleeding, including GI bleeding

Mehra MR et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. *N Engl J Med.* 2019;380:1618-1627

Survival


Survival – Intermacs LVAD
HM3 Implants from Aug 2017 through June 2022
HM3-LVAD (n = 9755, Deaths = 1881)
N=9755
79%
Months after Device Implant
HM3-LVAD
0
100.0% (100.0%-100.0%)
6
88.8% (88.5%-89.1%)
12
85.8% (85.4%-86.1%)
18
82.6% (82.2%-83.0%)
24
78.6% (78.1%-79.1%)
Cause of death: COVID-19: 33 (1.8%)
Intermacs
At Risk:
9755
7297
5656
4278
3085
% Survival
Months After Device Implant

Survival



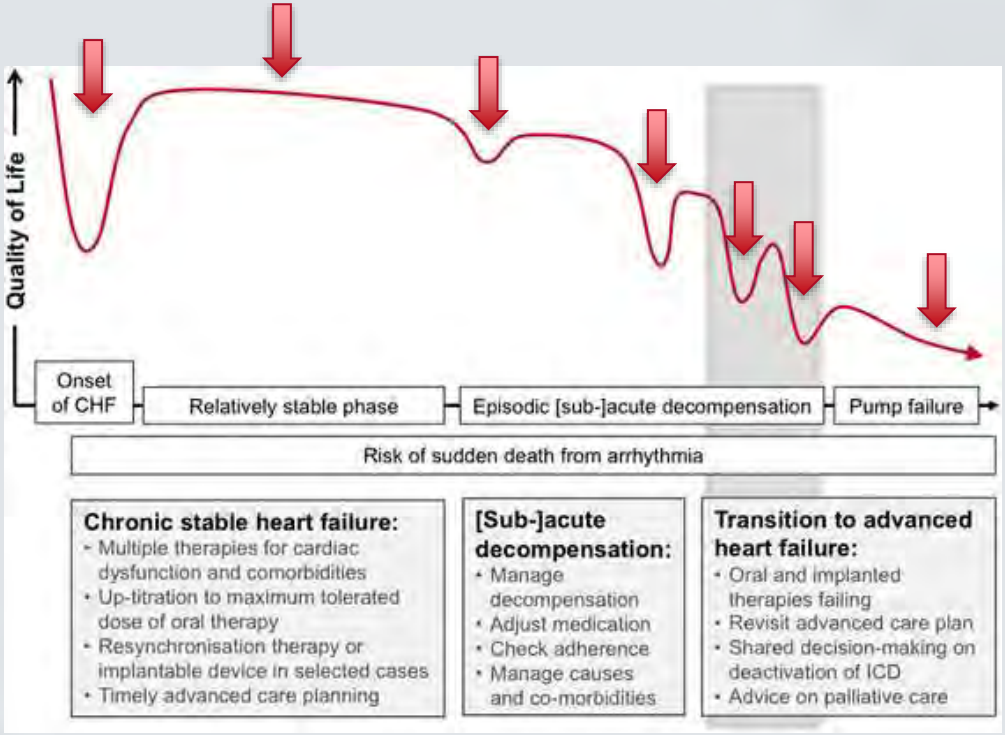
Months after Device Implant	STS Intermacs		NEUN-0228	
1	94.6%	(94.2%-95.0%)	96.9%	(91.7%-98.8%)
3	92.1%	(91.6%-92.5%)	93.4%	(87.1%-96.7%)
6	89.4%	(88.9%-89.9%)	93.4%	(87.1%-96.7%)
9	88.0%	(87.4%-88.5%)	93.4%	(87.1%-96.7%)
12	86.9%	(86.2%-87.5%)	93.4%	(87.1%-96.7%)

So now what?

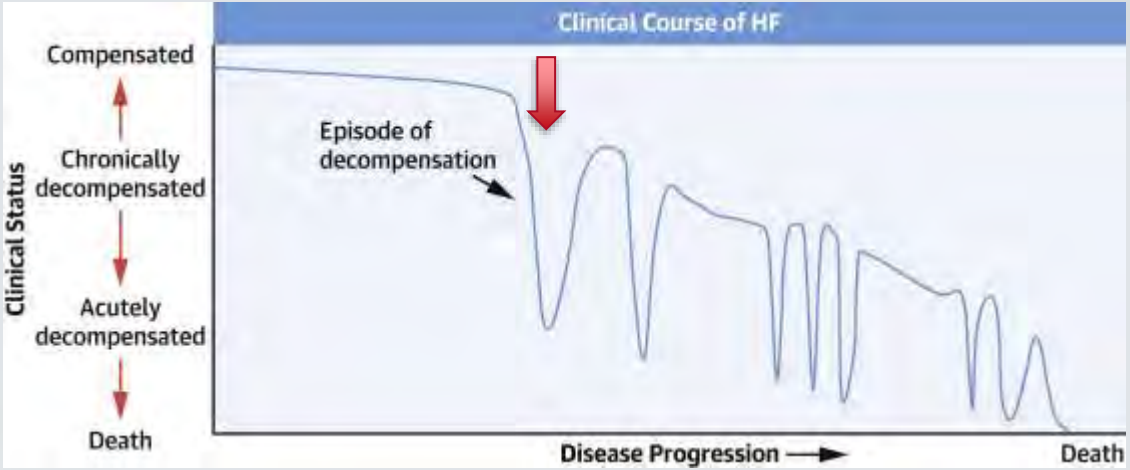
The number one question we get is…..

When do I refer my patient for evaluation?

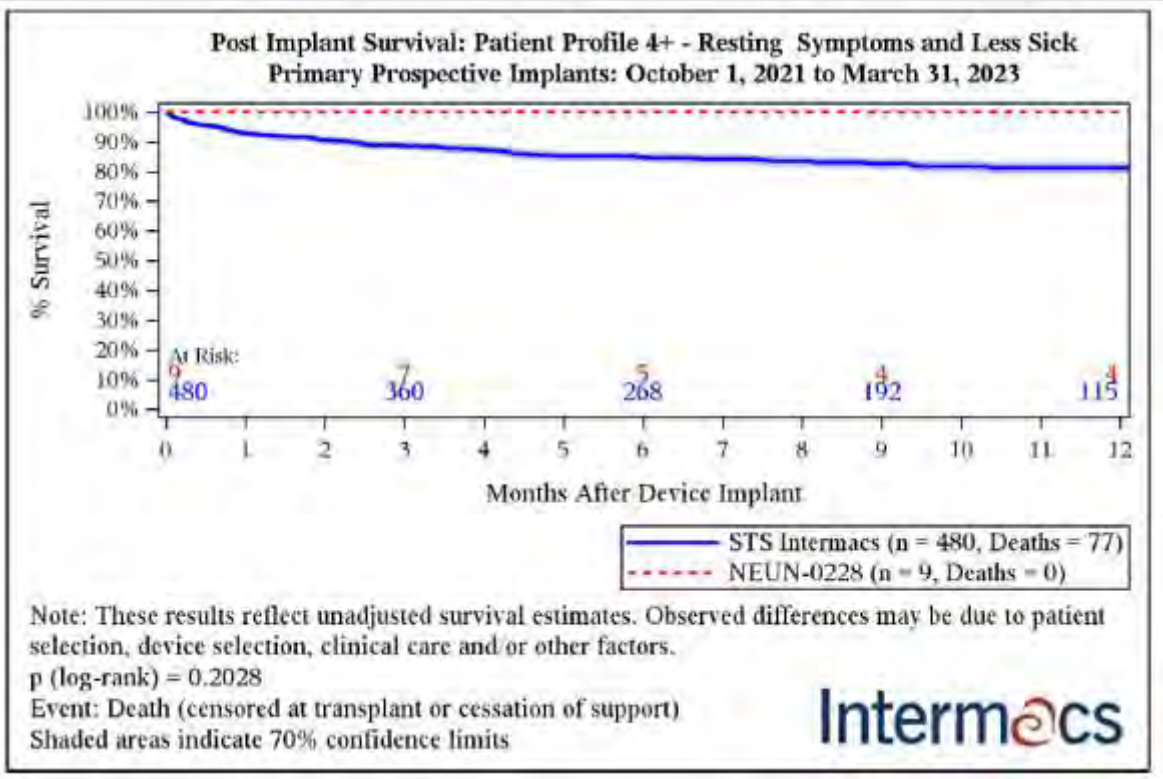
Progression of Heart Failure



Progression of Heart Failure



Survival with Early Referral

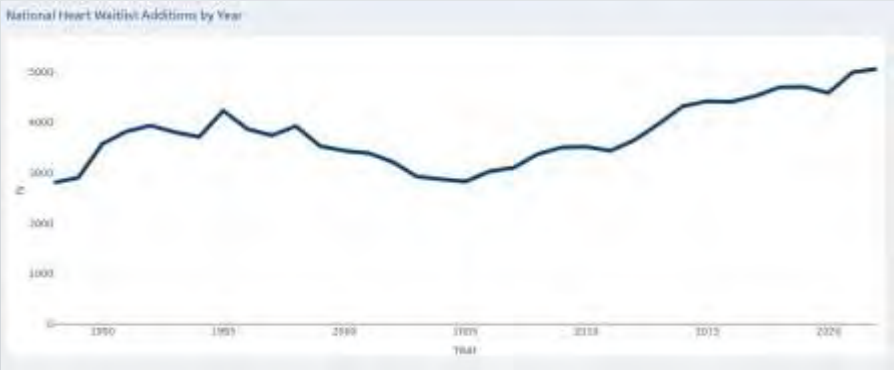


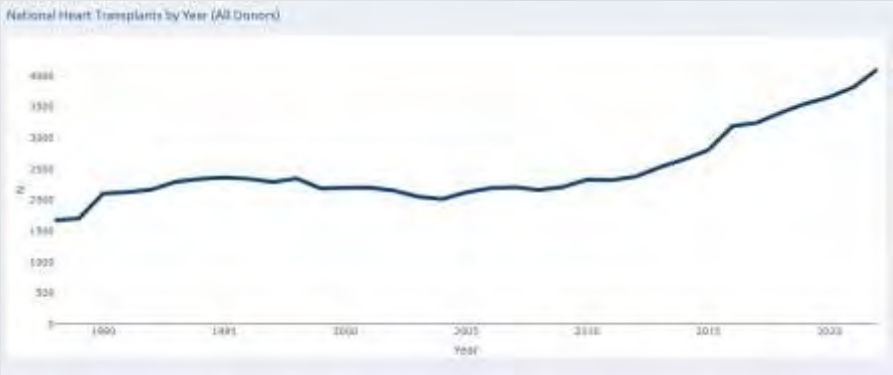
Months after Device Implant	STS Intermacs	NEUN-0228
1	92.7% (91.4%-93.8%)	100.0% (100.0%-100.0%)
3	88.6% (87.0%-90.0%)	100.0% (100.0%-100.0%)
6	84.8% (83.0%-86.5%)	100.0% (100.0%-100.0%)
9	82.7% (80.6%-84.5%)	100.0% (100.0%-100.0%)
12	81.2% (79.1%-83.2%)	100.0% (100.0%-100.0%)

Where do VADs fit in?

- Barriers to transplant
  - Obesity
  - High Pulmonary Pressures
  - Drug Use/Smoking
  - Cancer History
  - Age
  - Compliance Issues
  - Limited Organs

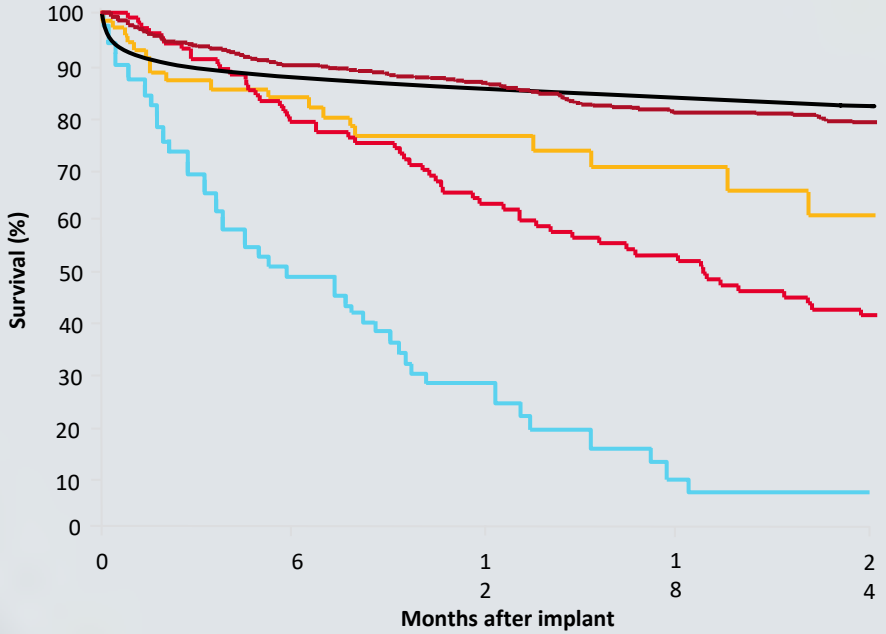
Transplant Numbers





OPTN Data as of 09-13-23

Heart Transplant vs LVAD Therapy



82% - Heart Transplant (2017)*[1]

79% - HeartMate 3 LVAD all-comers cohort (2019)[2]
Enrolled Sept 2014 - Oct 2015

61% - Medical Therapy Level 4 or 5 (2019)[6]
Enrolled May 2013 – Oct 2015

41% - ROADMAP OMM INTERMACS 4-7 (2017)
Enrolled Oct 2011 – July 2013

8% - OMM – REMATCH (2001)[5]
Enrolled May 1998 – July 2001

Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head to head comparison. Data presented for informational purposes only.

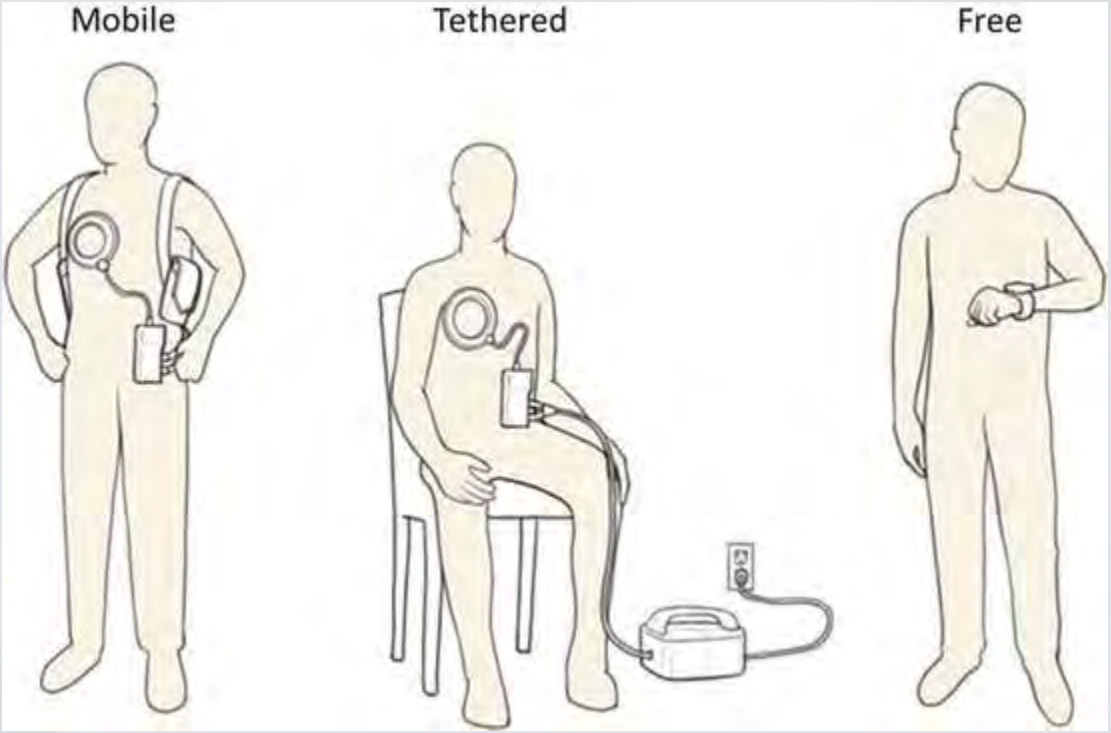
*82% 2-year survival for adult heart transplants patients between 2009 and 2015[1]

References: 1. Lund LF, Khush KK, Cherikh WS, et al. The Registry of the International Society for Heart and Lung Transplantation: Thirty-fourth Adult Heart Transplantation Report—2017; Focus theme: allograft ischemic time. *J Heart Lung Transplant*. 2017;36:1037-1046. **2.** Mehra MR, Uriel N, Naka Y, et al. A Fully Magnetically Levitated Ventricular Assist Device-Final Report. N Engl J Med. 2019. **3.** Rogers JG, Pagani FD, Tatooles AJ, et al. Intrapericardial Left Ventricular Assist Device for Advanced Heart Failure. *N Engl J Med*. 2017;376:451-60. **4.** Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009;361:2241-2251. **5.** Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med.* 2001 Nov 15;345(20):1435-43.

Future of VAD Therapy

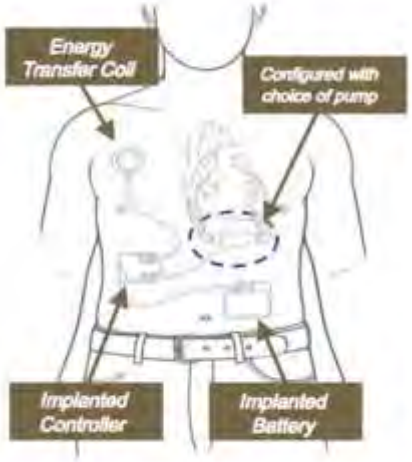
- Wish list for the future
  - Get rid of driveline
  - Can get wet
  - Don’t look like I am carrying guns
  - Talks to other implanted devices

Fully Implantable VAD



Fully Implantable VAD

Fully-Implantable LVAS (FILVAS)



Fully Implantable System
(Finalizing Design)

- No percutaneous lead – improved infection and system durability profile
- Quality of life
  - No daily dressings
  - Ability to swim and shower
  - Less limitations on movement
- Advanced battery technology
  - Custom cell technology tailored for implantable LVAD application
  - Targeting "untethered" run times of ~3 hours initially and ~2 hours at 3-year mark
- Reduced size implanted components with highly reliable electronics

THORATEC

In Summary…

- LVAD therapy continues to be a viable treatment option for heart failure
- LVAD technology continues to evolve with improved outcomes in survival, stroke and GI bleeding
- Referral timing is imperative for successful outcomes with LVAD therapy
- Outcomes with LVAD therapy at 2-years are similar to outcomes with cardiac transplantation

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