



70th ESCVS
International congress of the European Society
for Cardiovascular and Endovascular Surgery



7th IMAD meeting



Universitätsmedizin Essen
Westdeutsches Herz- und
Gefäßzentrum Essen (WHDZ)
Klinik für Thorax- und
Kardiovaskuläre Chirurgie



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New VAD Concepts as bridge to heart transplantation

Bastian Schmack
Arjang Ruhparwar



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COI

- Proctor / Speaker für Abiomed (BS)
- Proctor / Speaker für Abbott (BS)
- Proctor / Speaker für Berlin Heart GmbH (BS)



THE MACHINE-HEART

A wrong track in medical treatment ?

Gold standard in terminal heart failure treatment

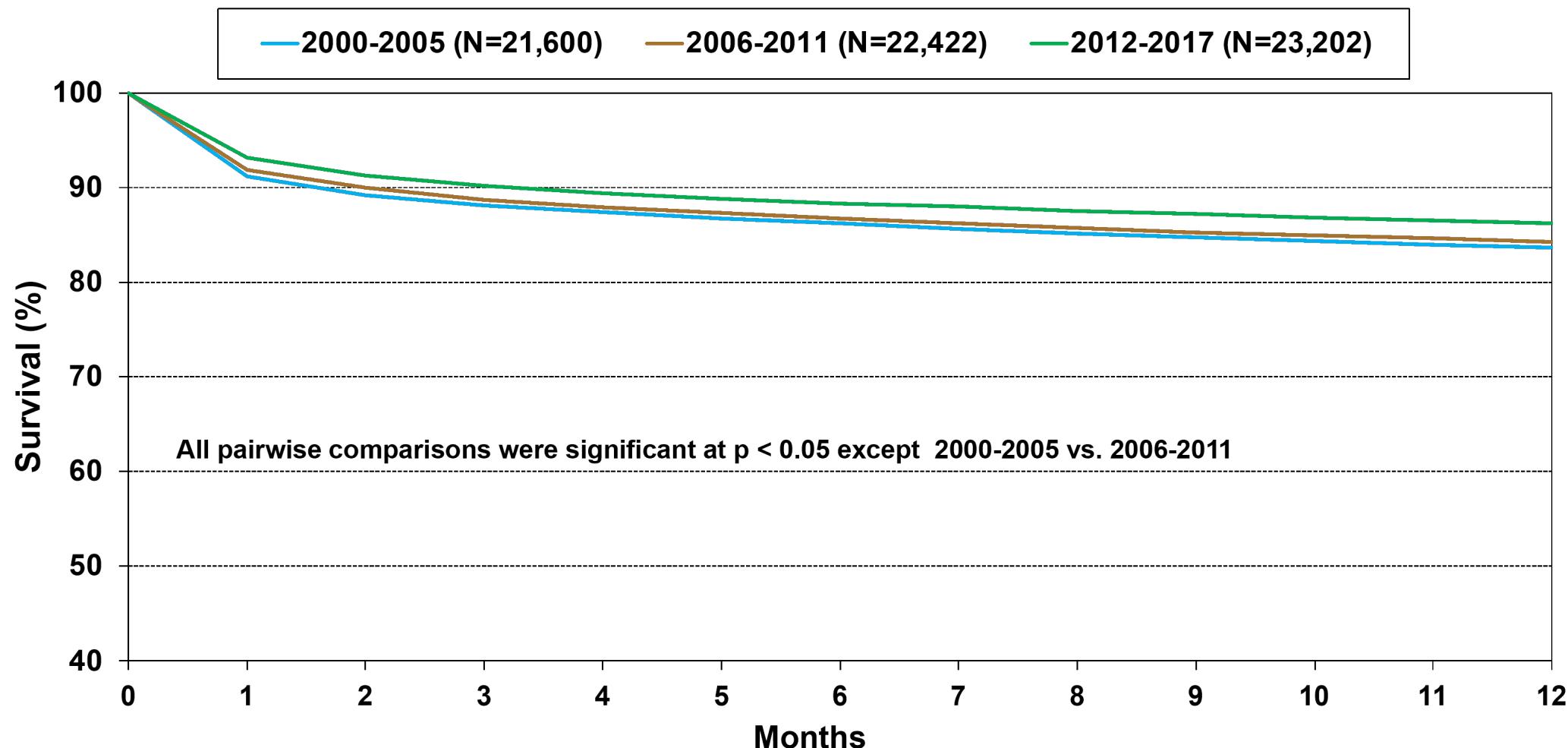


"OK, the old one's in my right hand,
the donor's in my left. Right?"

Adult Heart Transplants

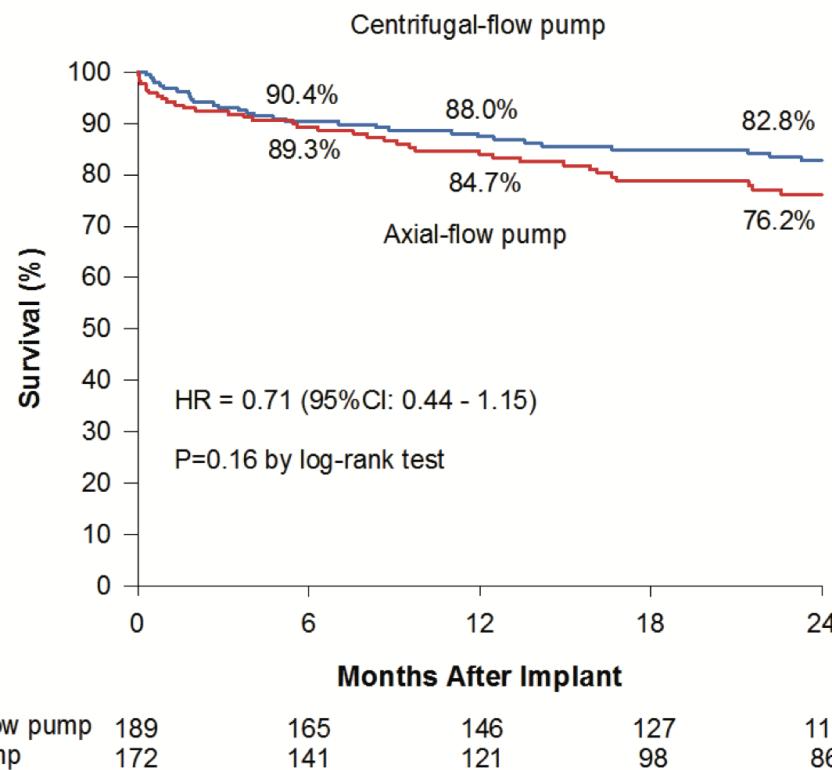
Kaplan-Meier Survival within 12 Months by Era

(Transplants: Jan 2000 – Jun 2017)



MOMENTUM 3 – A reason to shift paradigm ?!

Figure S3. Actuarial All Cause Survival (Per Protocol Population)



Actuarial 2y Survival equal to
(European) HTx survival!

Key Adverse Events: Pump Thrombosis, Neurological Events, Bleeding

	HeartMate 3 (n=151)		HeartMate II (n=138)				
	n (%)	no. of Events	n (%)	no. of Events	RR	95% CI for RR	P Value
Suspected or Confirmed Pump Thrombosis	0 (0)	0	14 (10)	18	N/A	N/A	< 0.0001
All Stroke	12 (7)	12	15 (10)	17	0.73	0.35-1.51	0.39
Hemorrhagic Stroke	4 (2)	4	8 (5)	8	0.46	0.14-1.48	0.18
Ischemic Stroke	8 (5)	8	9 (6)	9	0.81	0.32-2.05	0.66
Disabling Stroke	9 (6)	9	5 (3)	5	1.65	0.57-4.79	0.36
Other Neurologic Events*	9 (6)	9	8 (5)	8	1.03	0.41-2.59	0.95
Bleeding	50 (33)	100	54 (39)	98	0.85	0.62-1.15	0.29
Bleeding Requiring Surgery	15 (9)	15	19 (13)	21	0.72	0.38-1.36	0.31
Gastrointestinal Bleeding	24 (15)	47	21 (15)	36	1.04	0.61-1.79	0.87

No Pump Thrombosis in the HeartMate 3 LVAS group

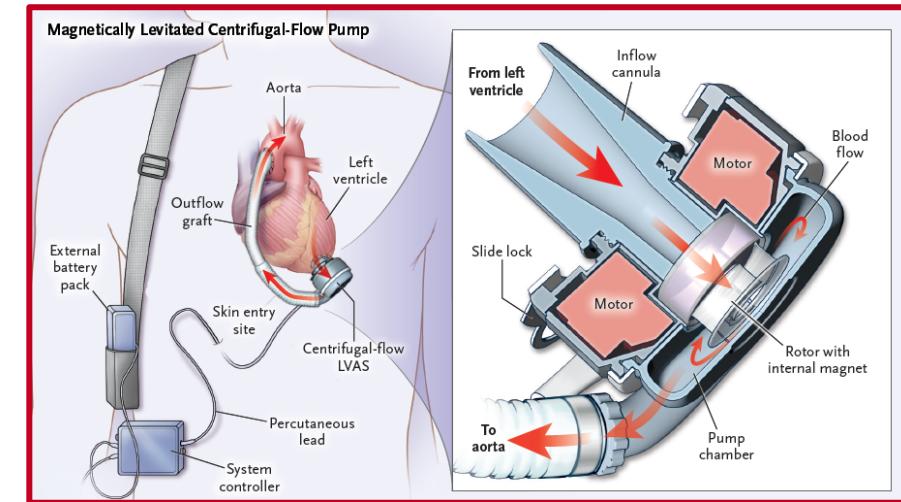
Similar Stroke and Bleeding rates in both groups

RR denotes Relative Risk and CI, confidence interval

*Includes transient ischemic attacks and neurologic events other than stroke

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

SJM-HM3-1116-0003 | Item approved for global use.



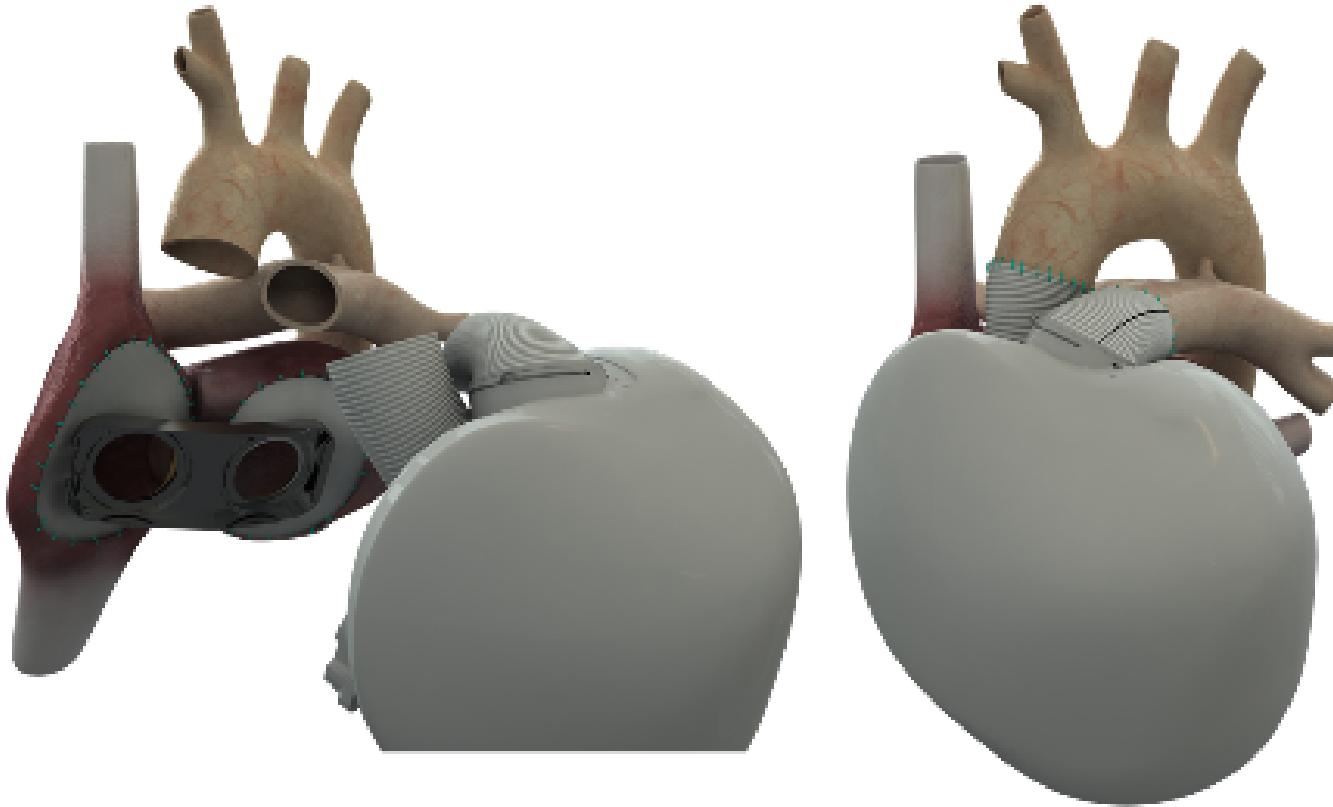
Key limitations in durable VAD-Therapy

- Haemocompatibility
 - Anticogulation medication
 - Stroke
 - Bleeding
 - Aquired Van Willebrand Disease (aVWD)
 -
- Driveline associated complications
 - Infection !!!
 - → stroke / bleeding
 - Dysfunction
- Pulsatility deficit
 - Risk for the development of AV-malformation

Key factors to improve durable VAD-Therapy

- Hemocompatibility
 - Decrease intensity of anticoagulation therapy
 - Delete immediate contact of the VAD to blood
- Driveline associated complications
 - Delete Driveline from the product design → Transcutaneous Energy Transfer (TET)
- Pulsatility deficit
 - Become pulsatile

CARMAT Total Artificial Heart



- Haemocompatibility
 - Bioprosthesis, all surfaced with blood contact made from biocompatible (xeno-pericardium) materials
 - Only ASA 75mg/day
- Driveline associated complications
 - Still present!
 - Electrohydraulic actuation
- Pulsatility deficit
 - Fully pulsatile

CARMAT is no VAD, but a Heart replacement therapy

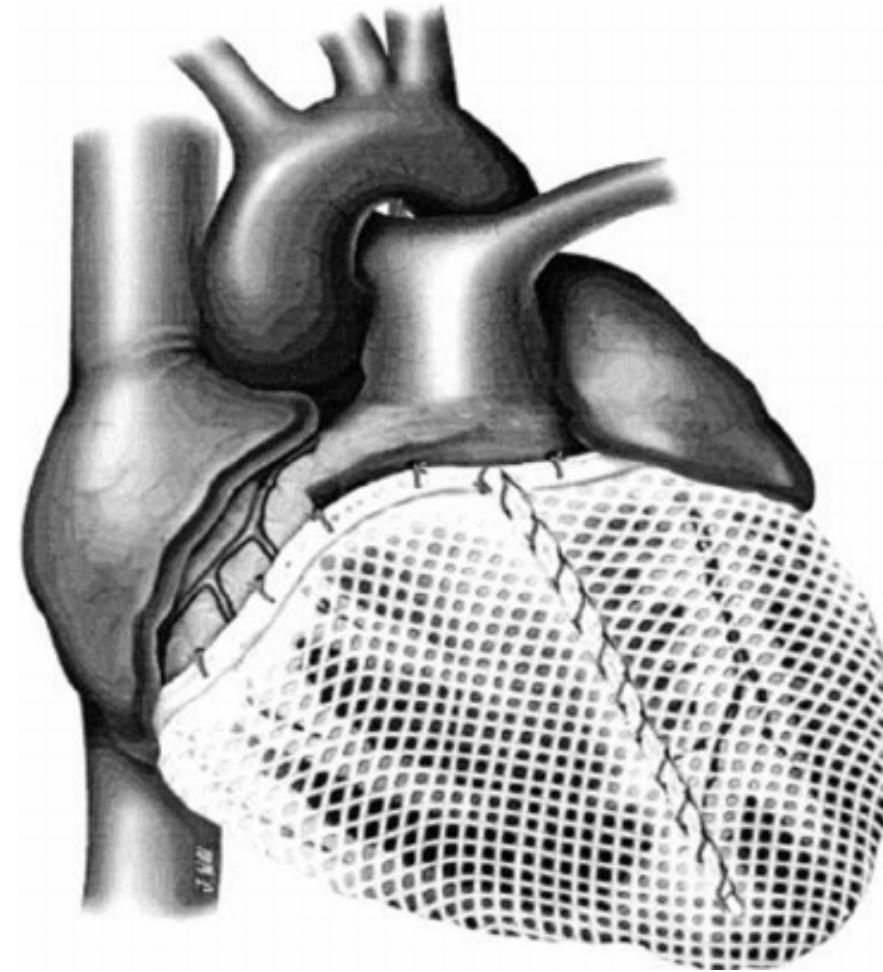


reBEAT Mechanical Circulatory Support without Blood Contact

A revolutionary technology for end-stage heart failure patients

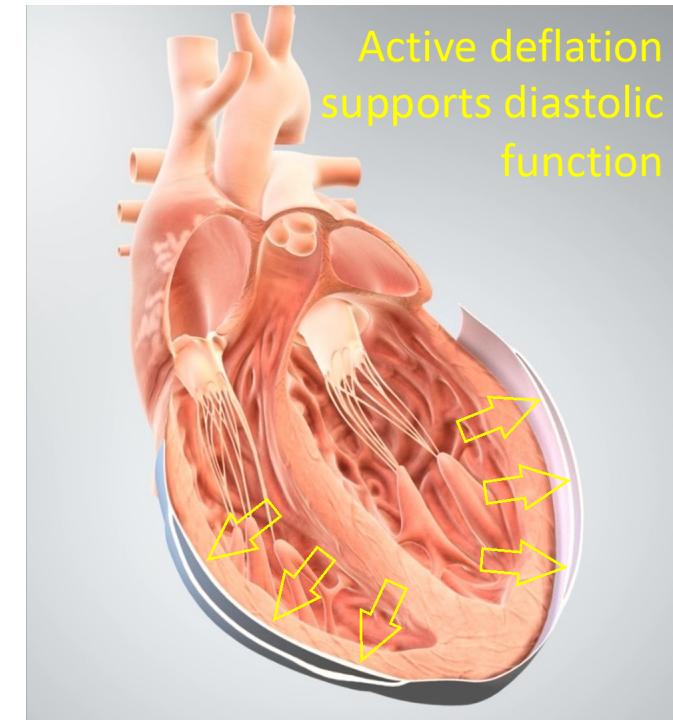
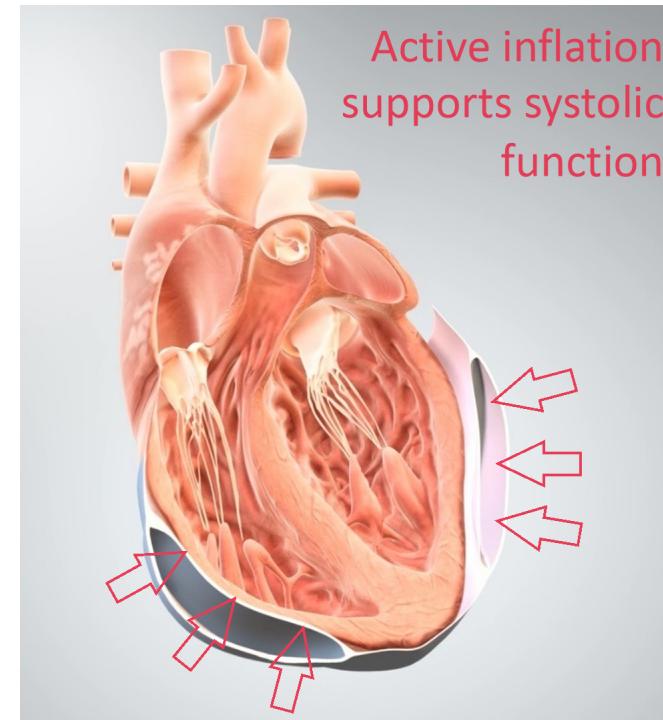
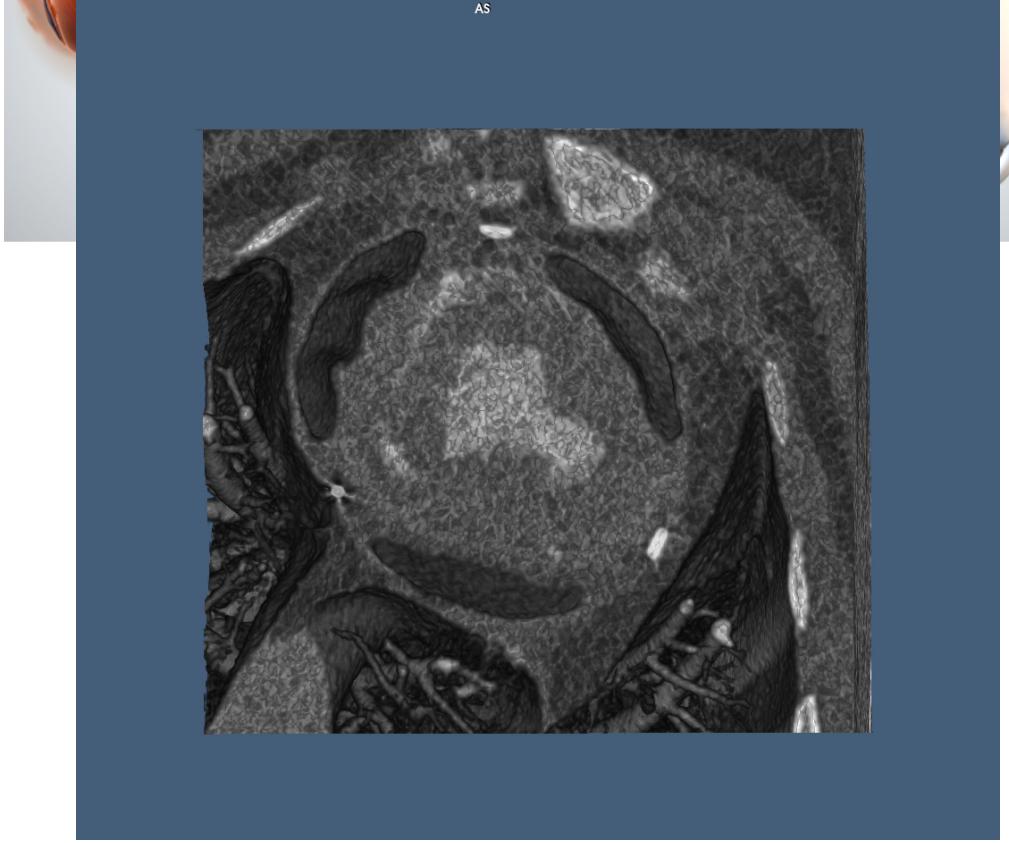
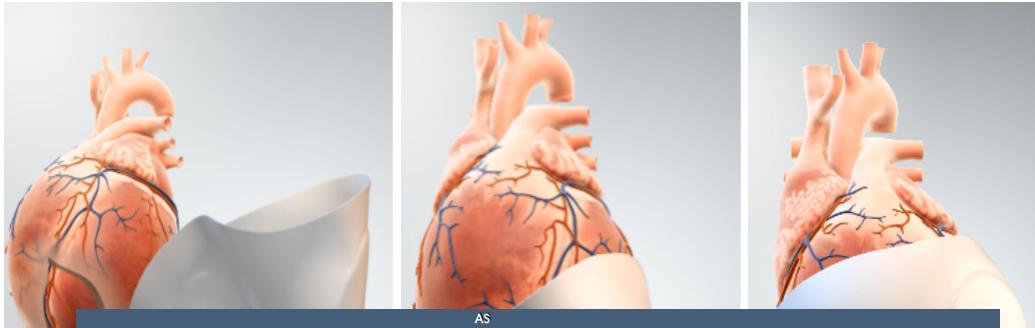
www.aducor.com

Some might feel reminded of.....

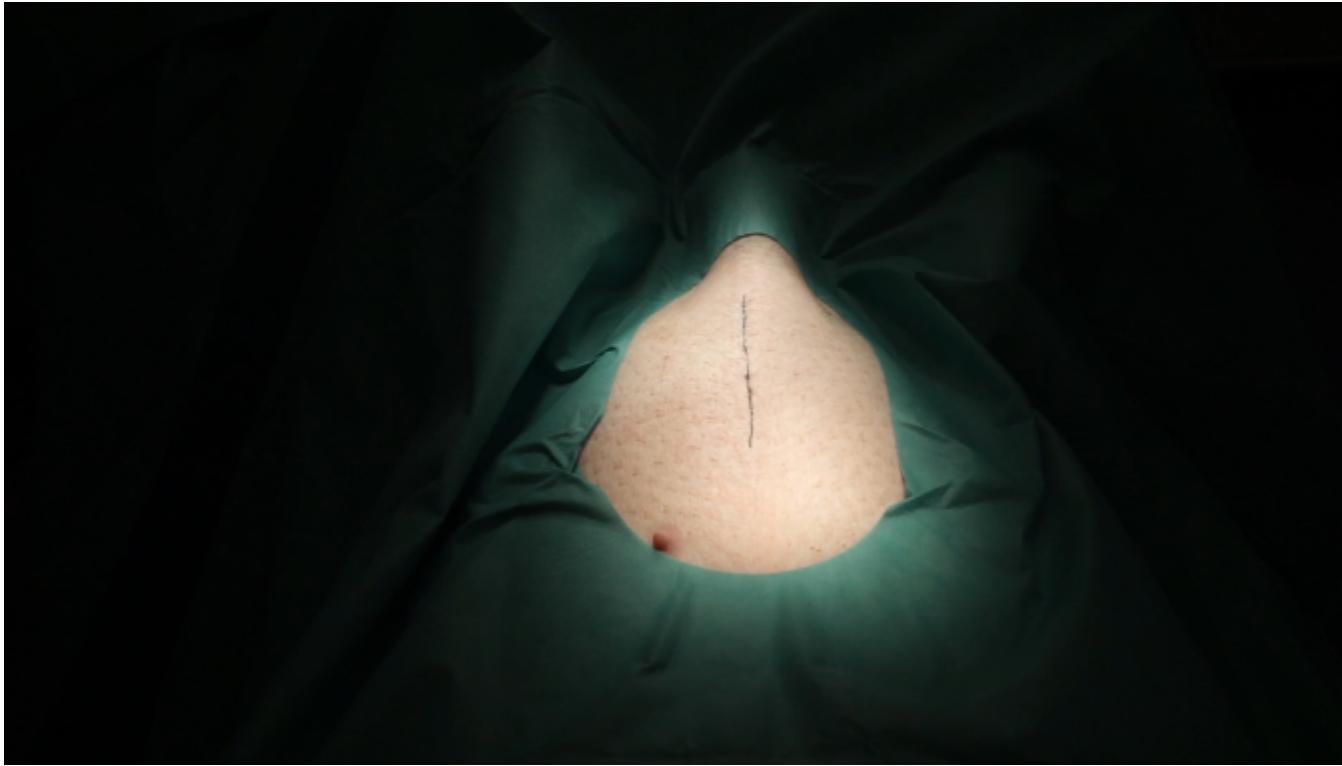


The CorCap support device

Timing of mechanical augmentation to heart cycle



Adjudcor Rebeat



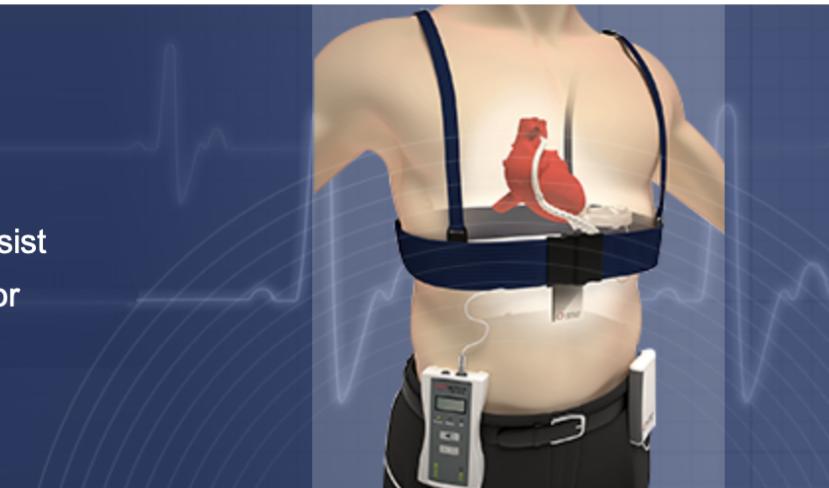
- Haemocompatibility
 - Excellent, no blood contact at all
 - No anticoagulation medication
- Driveline associated complications
 - Still present!
 - pneumatic actuation
- Pulsatility deficit
 - Full ECG-synchronized pulsatility
 - Adaptable biventricular support

How to get rid of the driveline...?! TET / CET

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The Leviticus FiVAD™ - a Fully Implantable Ventricular Assist Device

Leviticus Cardio's wireless power transfer technology, Coplanar Energy Transfer (CET), combined with an existing Ventricular Assist system, provides a new, robust, comprehensive hybrid solution for CHF patients. Leviticus FiVAD™ is wirelessly charged using an external belt along with an internal battery that lasts 6-8 hours. Patients may expect an improved Quality of Life with Leviticus FiVAD™ because they are free from external equipment for many hours per day.



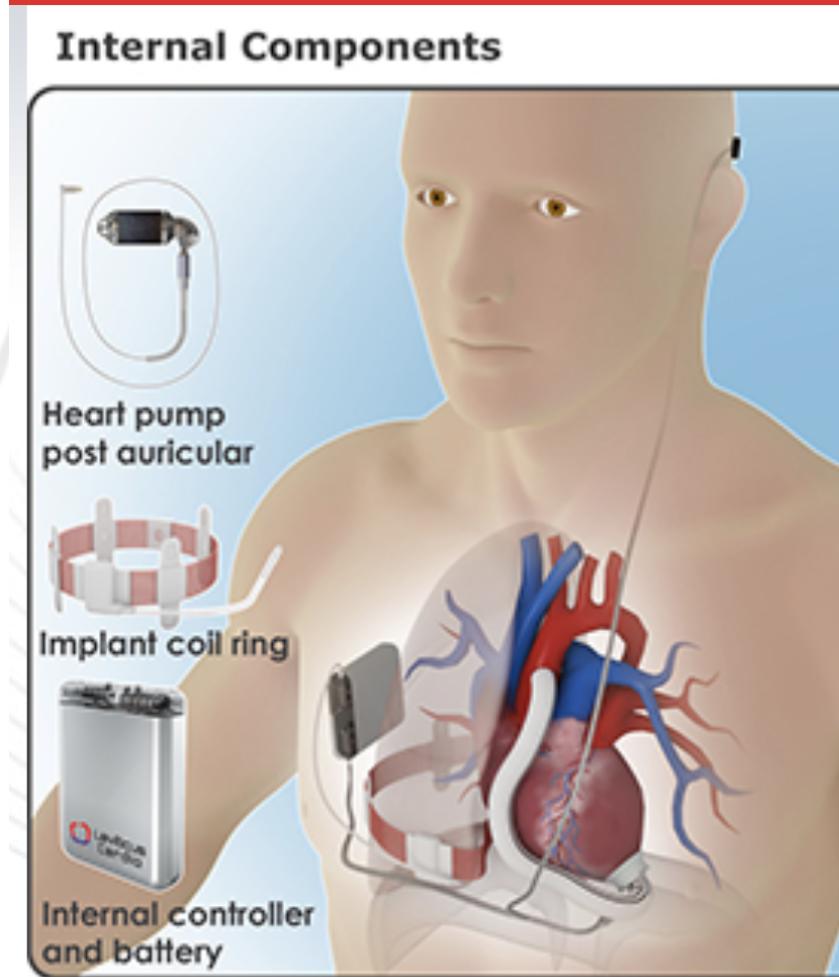
JHLT scientific paper
about the first patient >

Leviticus „FiVAD“



Levitinus Cardio Key CET Components

IMPLANT COMPONENTS



external Power
and fixated to the chest
inse structure technology

power receiver circuits,
inicates with the external
I controls the battery
ower backup and enables
Power Transmission

TET - the (still!!) missing feature in modern VADs

The LionHeart LVD-2000: A Completely Implanted Left Ventricular Assist Device for Chronic Circulatory Support

Sanjay M. Mehta, MD, Walter E. Pae, Jr, MD, Gerson Rosenberg, PhD,
Alan J. Snyder, PhD, William J. Weiss, PhD, Jeffrey P. Lewis, M Eng,
Daniel J. Frank, M Eng, James J. Thompson, and William S. Pierce, MD

Divisions of Cardiothoracic Surgery and Artificial Organs, The Milton S. Hershey Medical Center, The Pennsylvania State University, Hershey, Pennsylvania, and Arrow International, Reading, Pennsylvania

Management of patients with end-stage cardiac disease remains a vexing problem. Limitations in medical management and a fixed supply of donor organs for cardiac transplant have a continued impact on this growing population of patients. Mechanical circulatory support has proved very successful as a means of bridging patients to cardiac transplant when all medical options have been exhausted. The development of a chronic system of circulatory support has been underway at the Pennsylvania State University for nearly 30 years. These efforts have been recently merged with the industrial

partnership with Arrow International toward the development of the LionHeart LVD-2000 (Arrow International, Reading, PA) completely implanted left ventricular support system. We present an overview of the system, details of implantation, a review of preclinical studies, and a synopsis of the first European implants. Early results have demonstrated the system to be safe, effective, and reliable. Transcutaneous energy transmission and the compliance chamber have been validated.

(Ann Thorac Surg 2001;71:S156–61)

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Fig 1. Components of the LionHeart LVS-2000 including the motor controller, pump assembly, and compliance chamber.

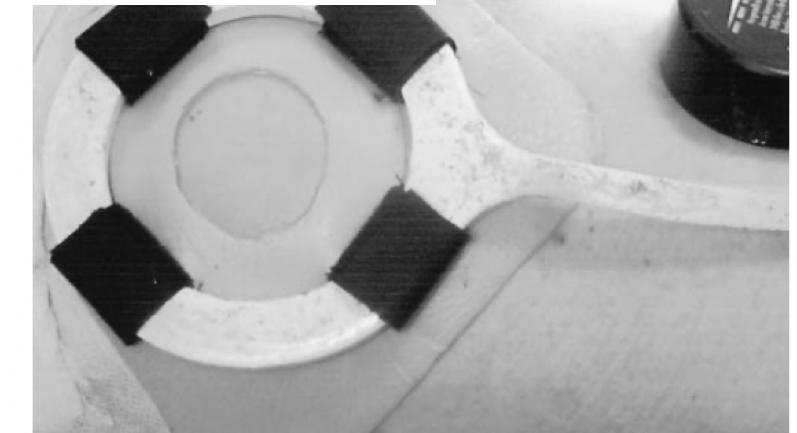


Fig 3. Transcutaneous energy transmission system coil is shown as it is secured in place by a nontraumatic skin adhesive.

TET - the (still!!) missing feature in modern VADs



@BSchmack_MD tweets:

.....I bet, @elonmusk will fail to develop #TET for durable #VAD therapy to fight #heartfailure within 24month from now.....

Summary

- HTx remains the standard of care in terminal heart failure whenever indicated
- Shortage in organ donation persists
- Contemporary LVAD help to bridge-2-HTx or allow for Destination therapy
- LVAD therapy remains limited by certain concerns, such as bleeding, embolism and infection (Driveline)
- “Driveline-less” Devices may evolve soon once TET is safe and feasible
- Modern devices enhance haemocompatibility or may even avoid blood contact, whatsoever

Thank you so much for your attention

Bastian Schmack, MD, PhD

Senior Consultant Cardiac Surgeon
Head of Heart Failure Surgery
University Hospital Essen
Westgerman Heart & Vascular Center

bastian.schmack@uk-essen.de

Phone. +49 201 - 723 - 4901



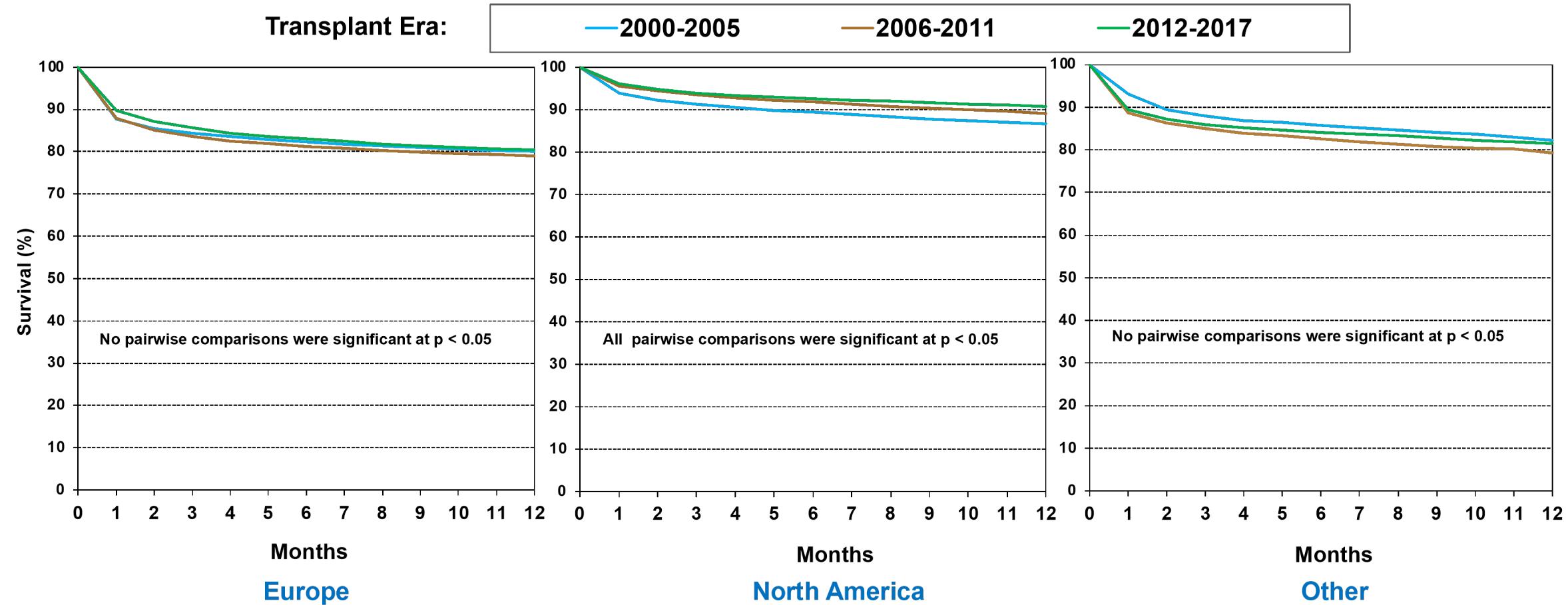


Artificial Muscle - Boston

Adult Heart Transplants

Kaplan-Meier Survival within 12 Months by Location and Era

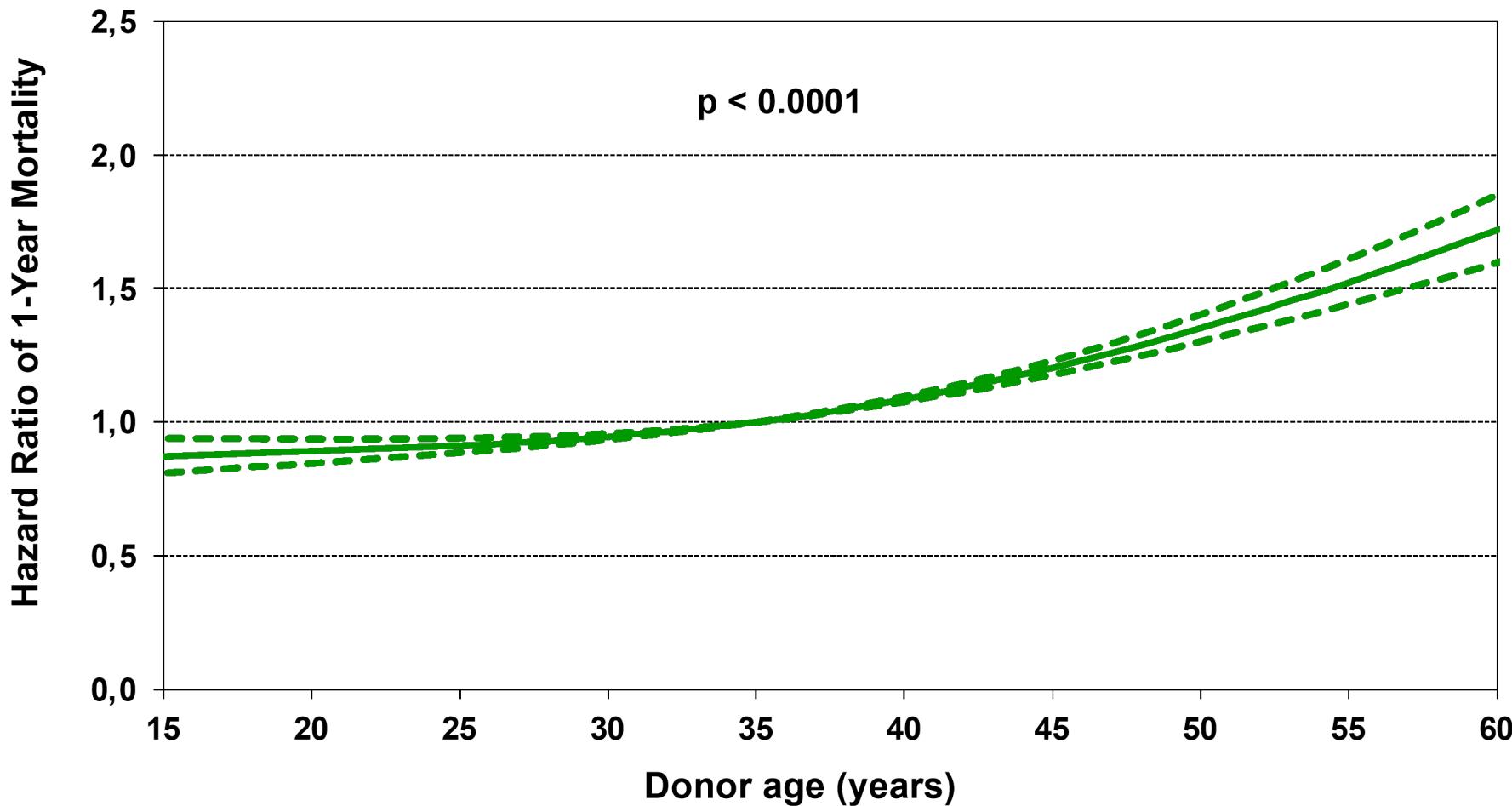
(Transplants: Jan 2000 - Jun 2017)



Adult Heart Transplants (2000-6/2017)

Statistically Significant Risk Factors For 1-Year Mortality with 95% Confidence Limits

Donor age (years)



Adult Heart Transplants (2000-6/2017)

Risk Factors For 1-Year Mortality with 95% Confidence Limits Transplant era and MCS device type interaction

