Dlouhodobé mechanické podpory oběhu

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Klinika kardiovaskulární chirurgie

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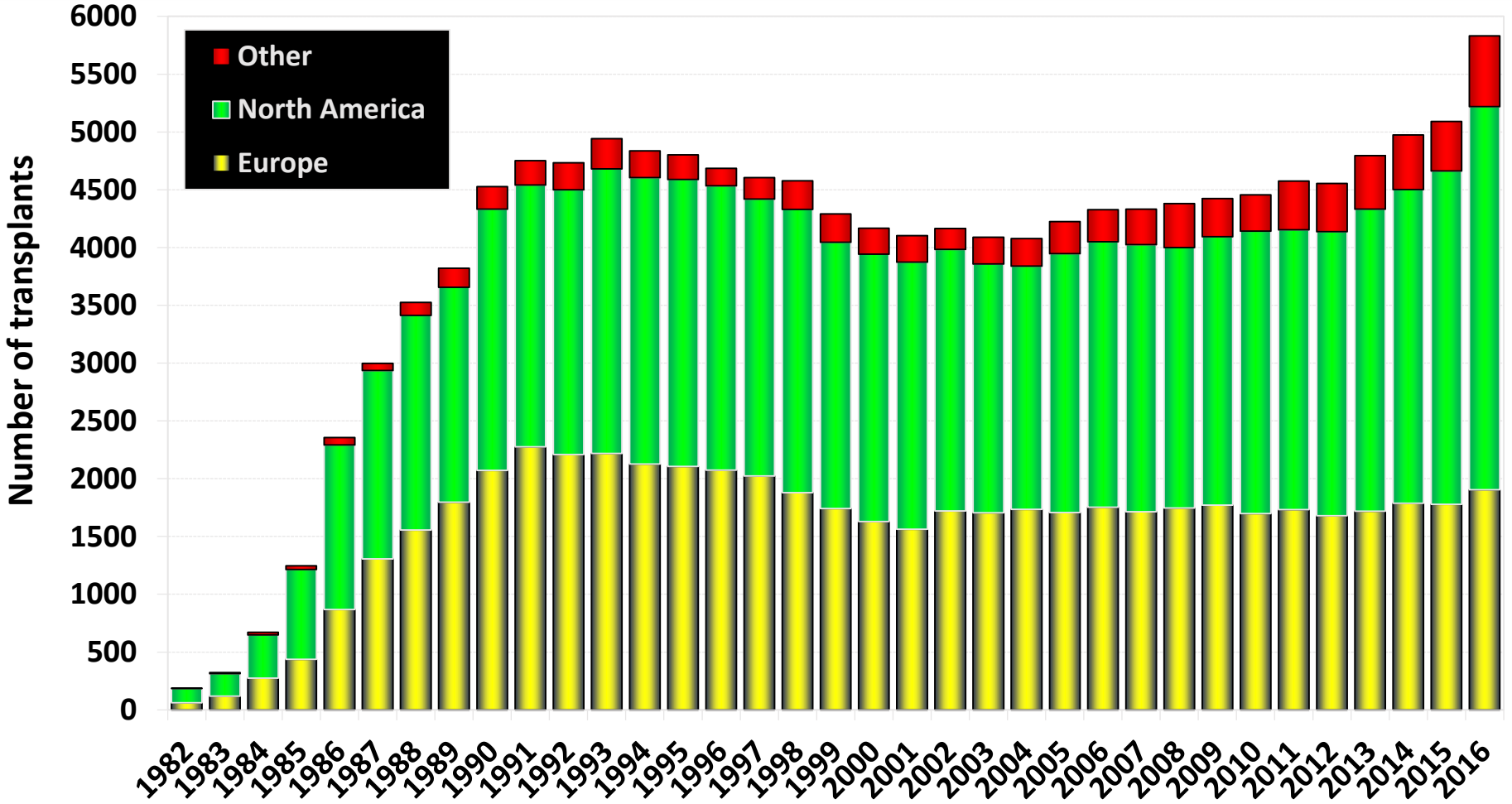
Úvod

- Chronické srdeční selhání: 1–2% evropské populace[1]
- Faktory: demografické, životní styl, pokroky moderní komplexní kardiovaskulární léčby
- Vyčerpání možností konvenčních léčebných postupů
- → terminální srdeční selhání
- Transplantace srdce – prokazatelný přínos

Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location



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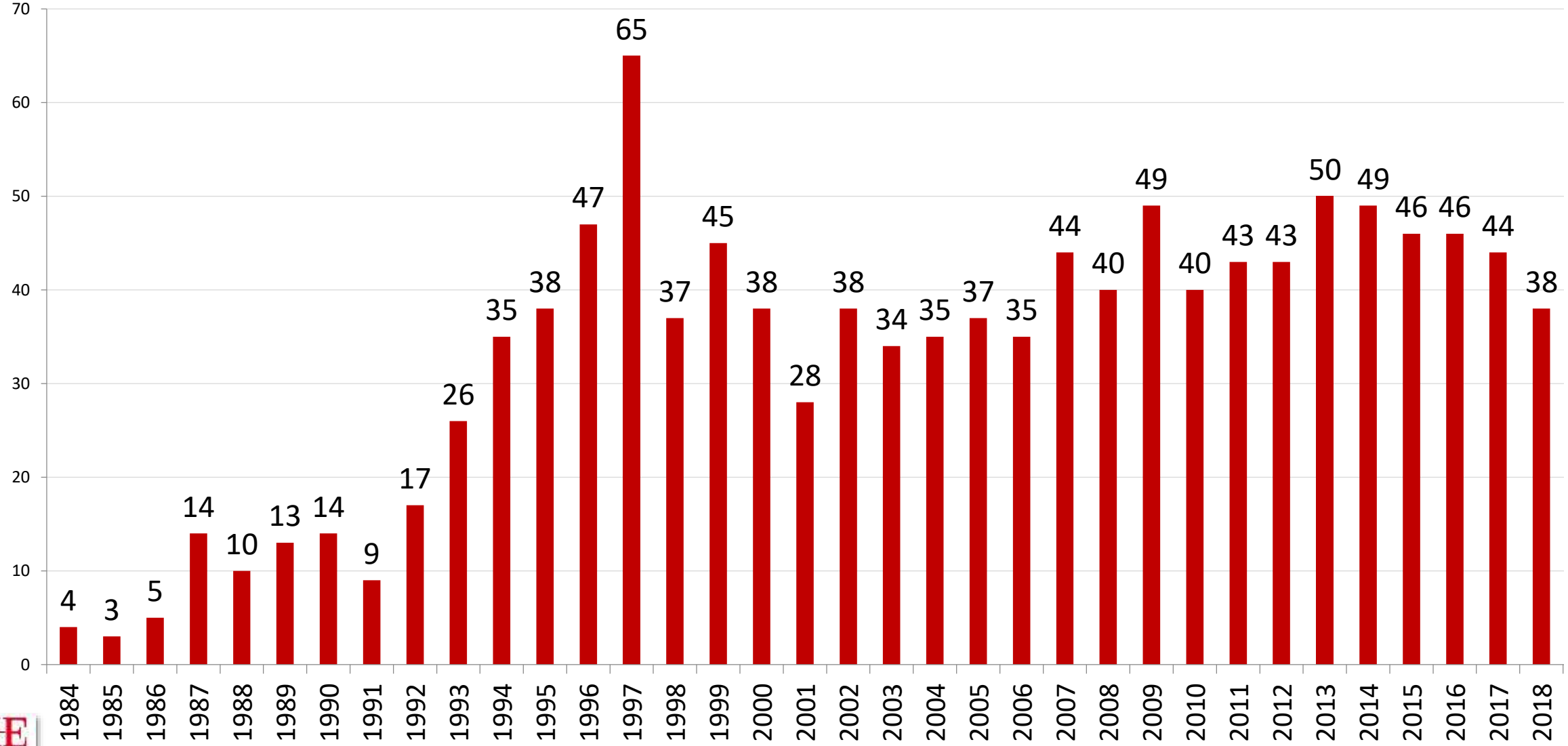
Transplantace srdce v IKEM



Recommendations for surgical implantation of LVADs in patients with systolic heart failure

Recommendations	Class[a]	Level[b]	Ref[c]
An LVAD or BiVAD is recommended in selected patients[d] with end-stage HF despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplantation, to improve symptoms and reduce the risk of HF hospitalization for worsening HF and to reduce the risk of premature death while awaiting transplantation.	I	B	254, 255, 258
An LVAD should be considered in highly selected patients[d] who have end-stage HF despite optimal pharmacological and device therapy and who are not suitable for heart transplantation, but are expected to survive >1 year with good functional status, to improve symptoms, and reduce the risk of HF hospitalization and of premature death.	IIa	B	254

BiVAD = bi-ventricular assist device; HF = heart failure; LVAD = left ventricular assist device.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.
[d]See text and *Table 25*.

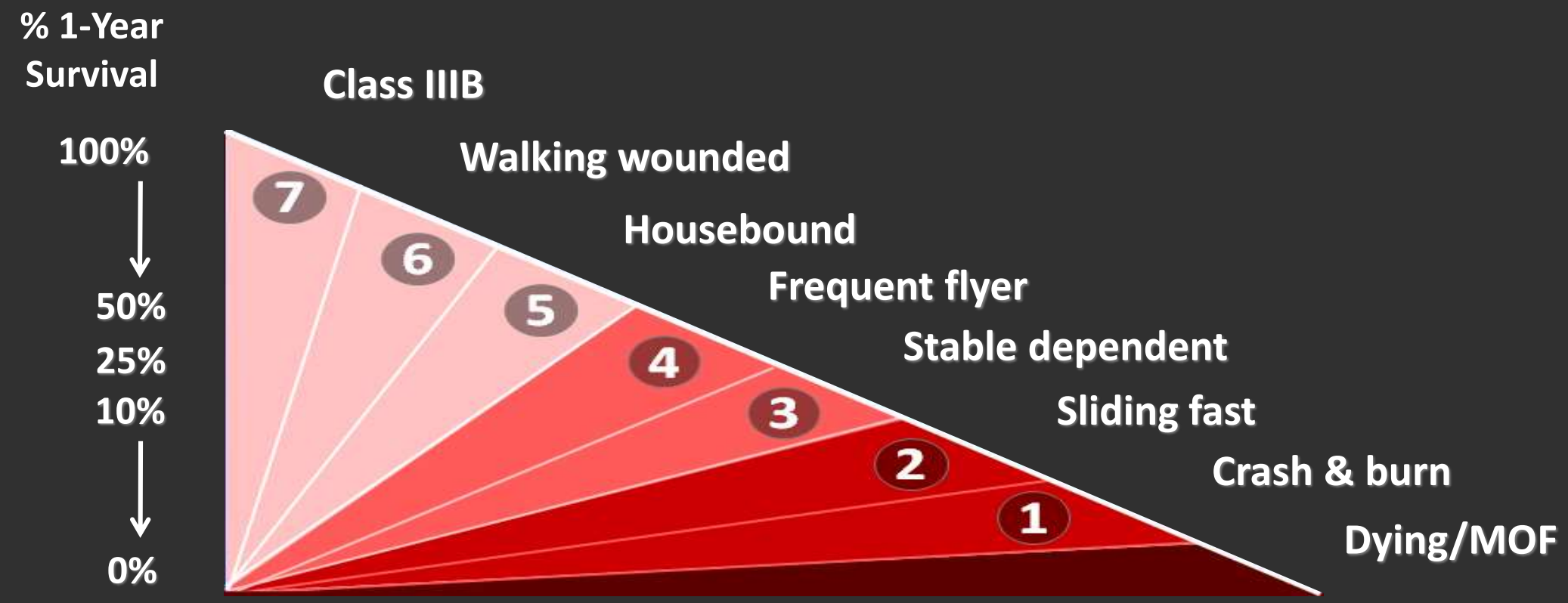
References
254. Rose EA, et al, NEJM 2001
255. Slaughter MS et al, NEJM 2009
258. Pagani FD, et al, JACC 2009

Table 25 Patients potentially eligible for implantation of a ventricular assist device

Patients with >2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:
• LVEF <25% and, if measured, peak VO_2 < 12 mL/kg/min
• ≥3 HF hospitalizations in previous 12 months without an obvious precipitating cause
• Dependence on i.v. inotropic therapy
• Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP ≥20 mm Hg and SBP ≤80–90 mmHg or CI ≤2 L/min/m²)
• Deteriorating right ventricular function

CI = cardiac index; HF = heart failure; i.v. = intravenous; LVEF = left ventricular ejection fraction; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure.

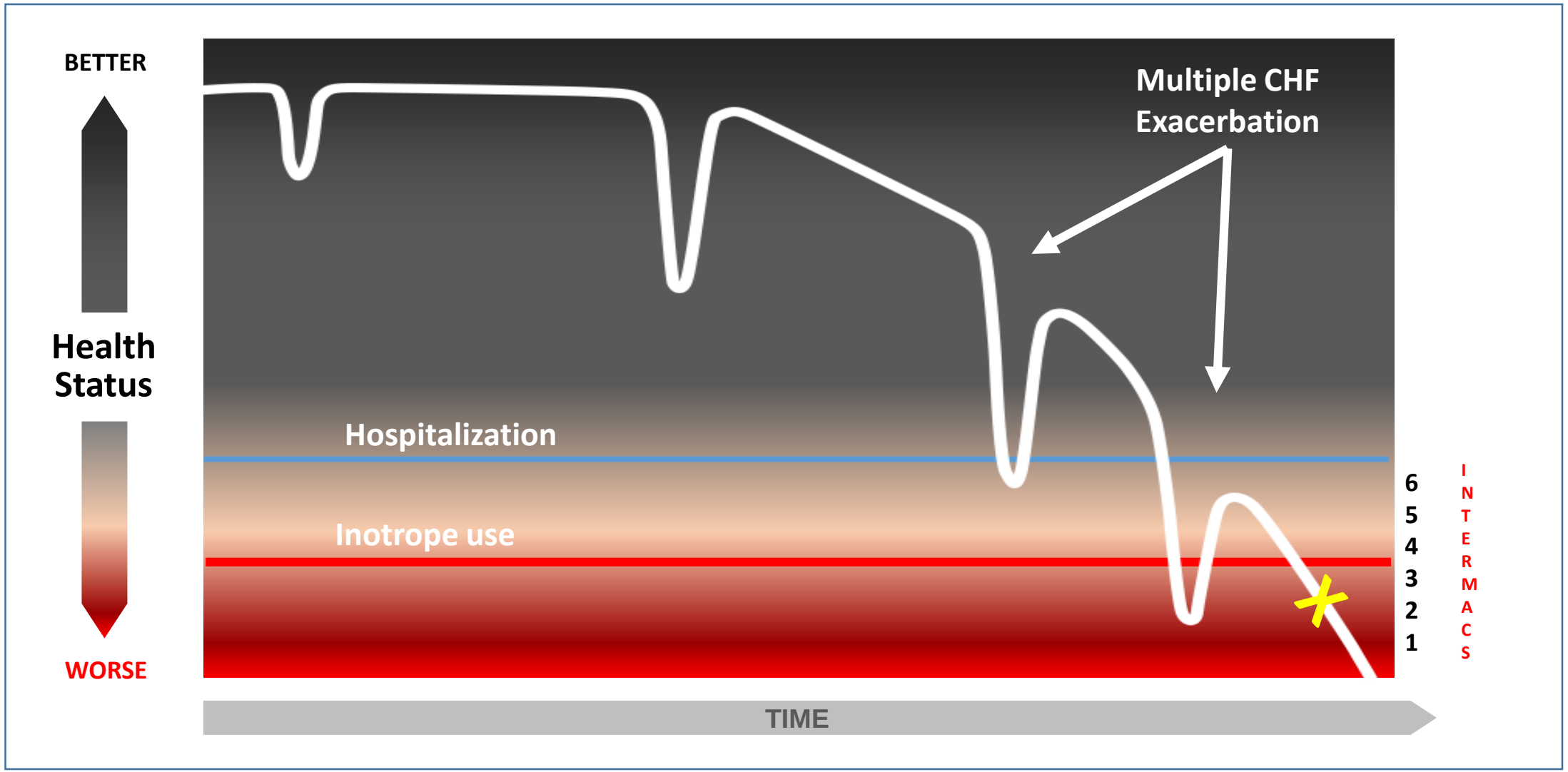
Klasifikace pokročilosti srdečního selhání a načasování MSP (Profily INTERMACS)



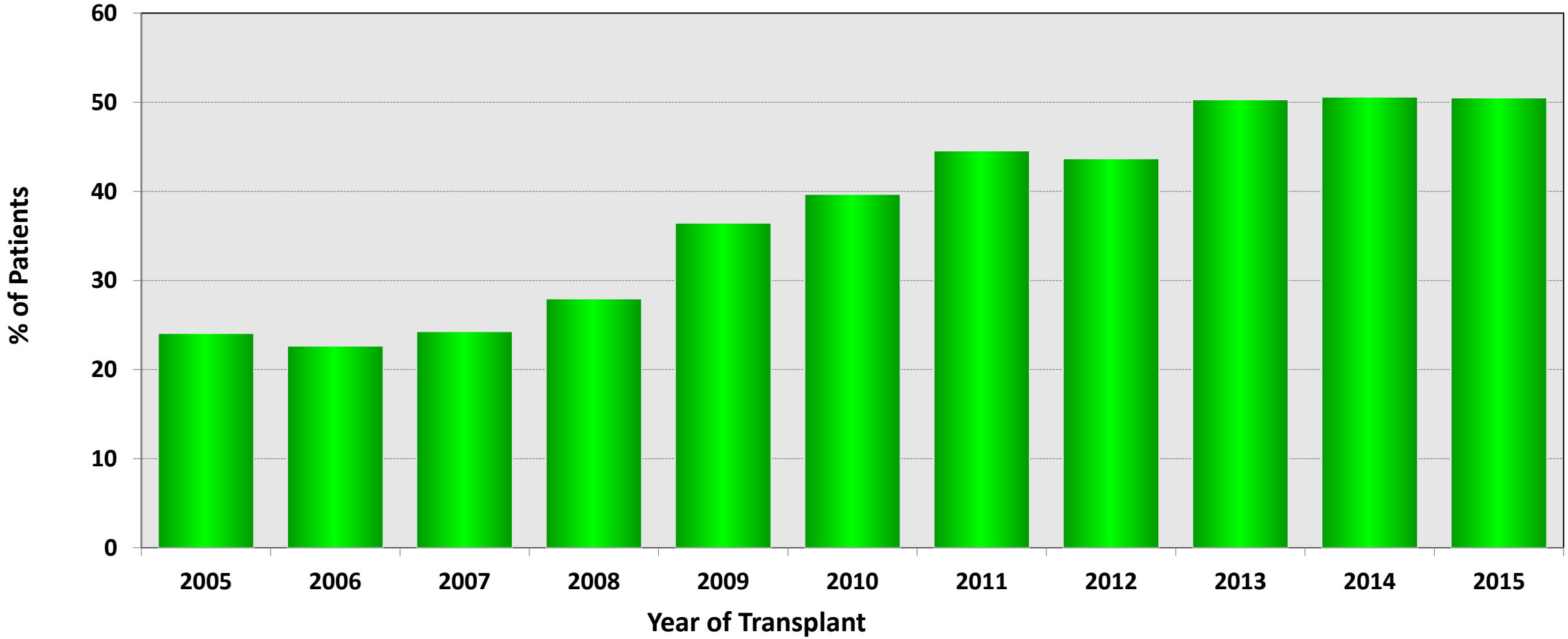
**Does not account for arrhythmia.*

Courtesy: K. Lietz

Kontinuita progrese srdečního selhání k LVAD



Přemostění k transplantaci srdce



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* LVAD, RVAD, TAH, ECMO

Permanentní (destinační) terapie

Indikace permanentní terapie

- Věk pacienta (> 65 let)
- Diabetes mellitus s orgánovými komplikacemi
- Multietážová ateroskleroza
- Těžká obezita
- Excesivní imunosensitizace
- Interval vyléčené malignity < 5 let

Miniaturizace a technologické inovace

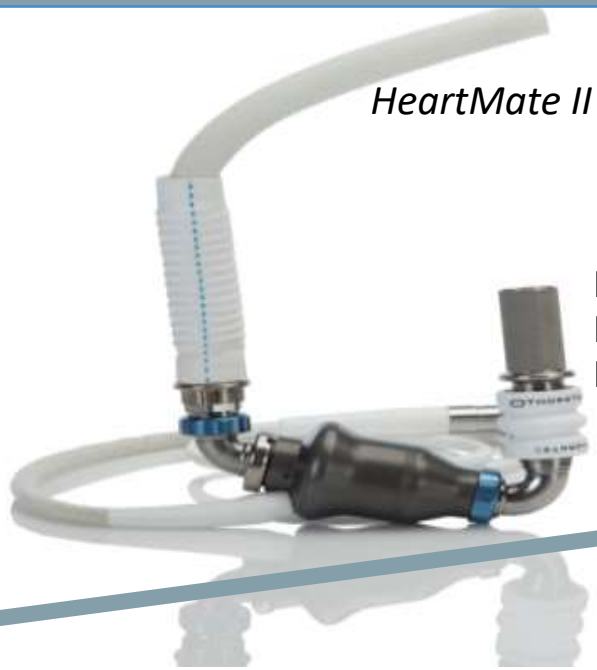
Pulsatile Technology

HeartMate XVE

FDA Approved
BTT 1998
DT 2002

Continuous Flow Technology: Axial Design

HeartMate II



FDA Approved
BTT 2008
DT 2010

Continuous Flow Technology: Centrifugal Design

HeartMate 3

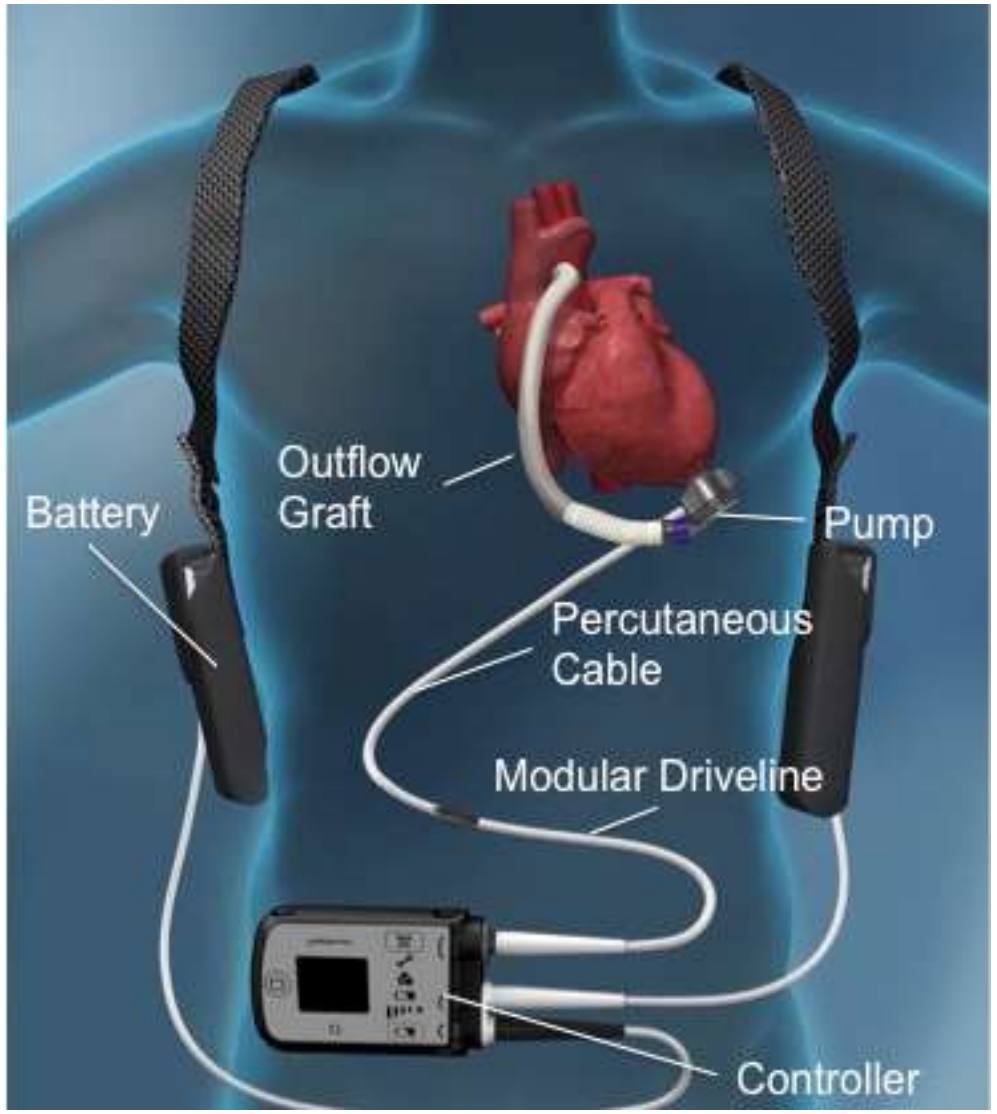
Heartware HVAD

Bearingless rotor with
Magnetic Levitation

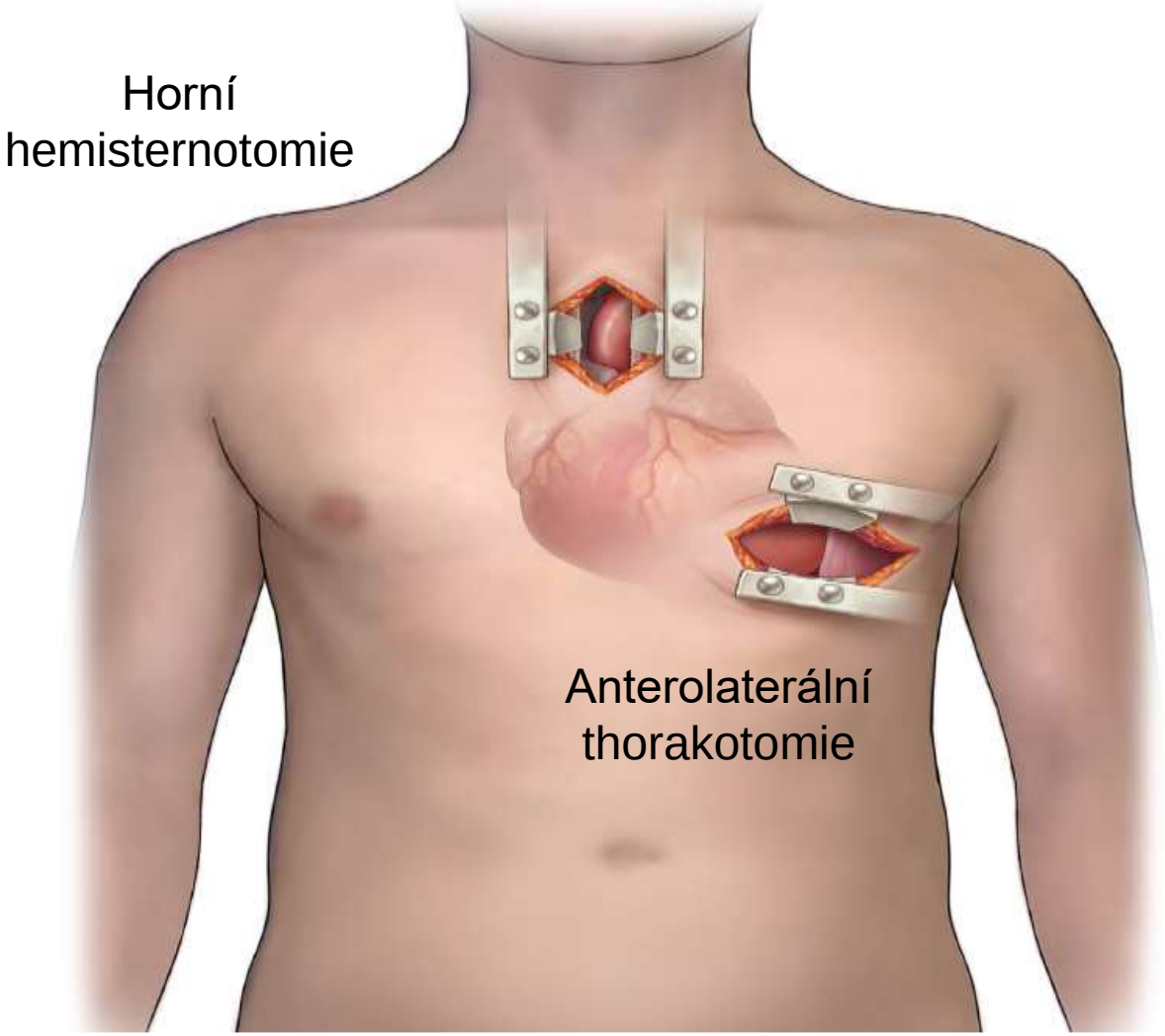
Rotor with bearings

Pusher plate &
Inflow and outflow valve

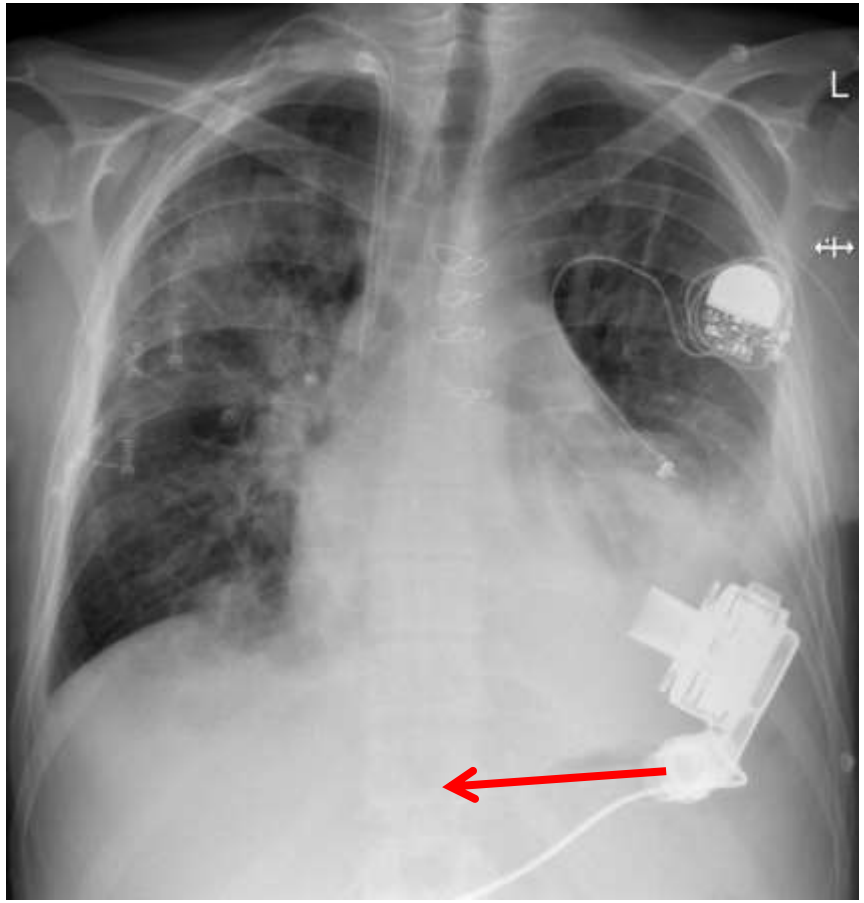
HeartMate 3

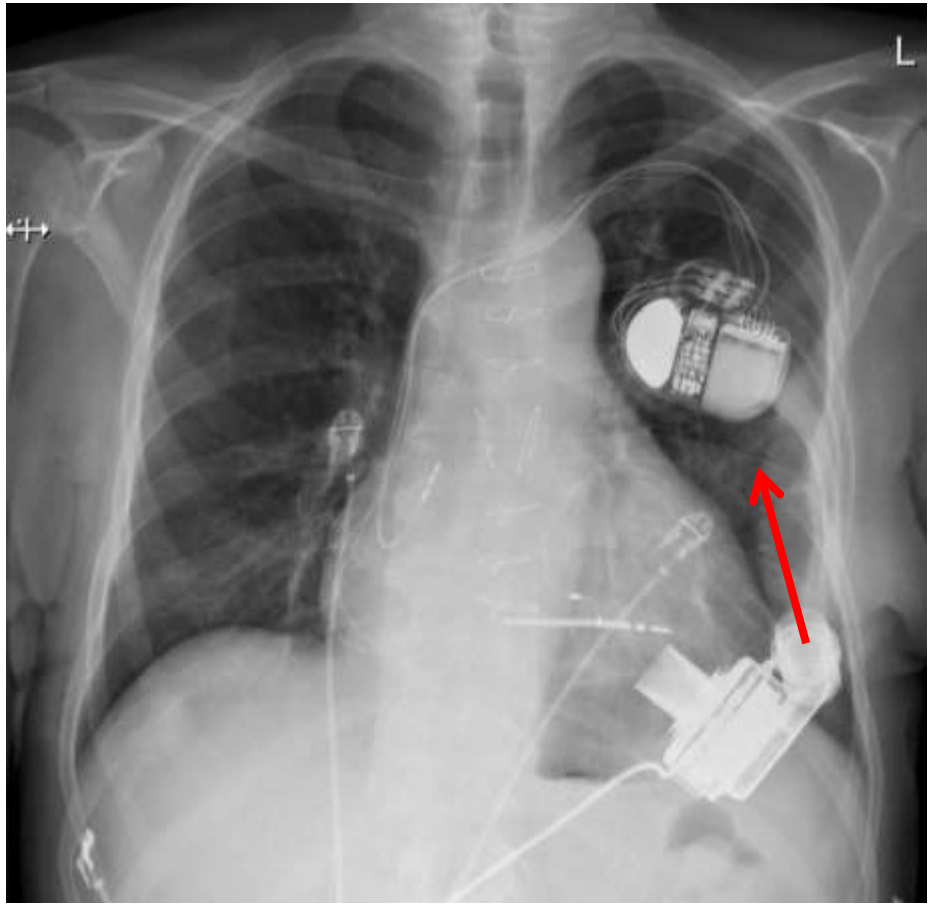

Outflow
Graft
Battery
Pump
Percutaneous
Cable
Modular Driveline
Controller

Mini-invazivní implantace



Mini-invazivní implantace



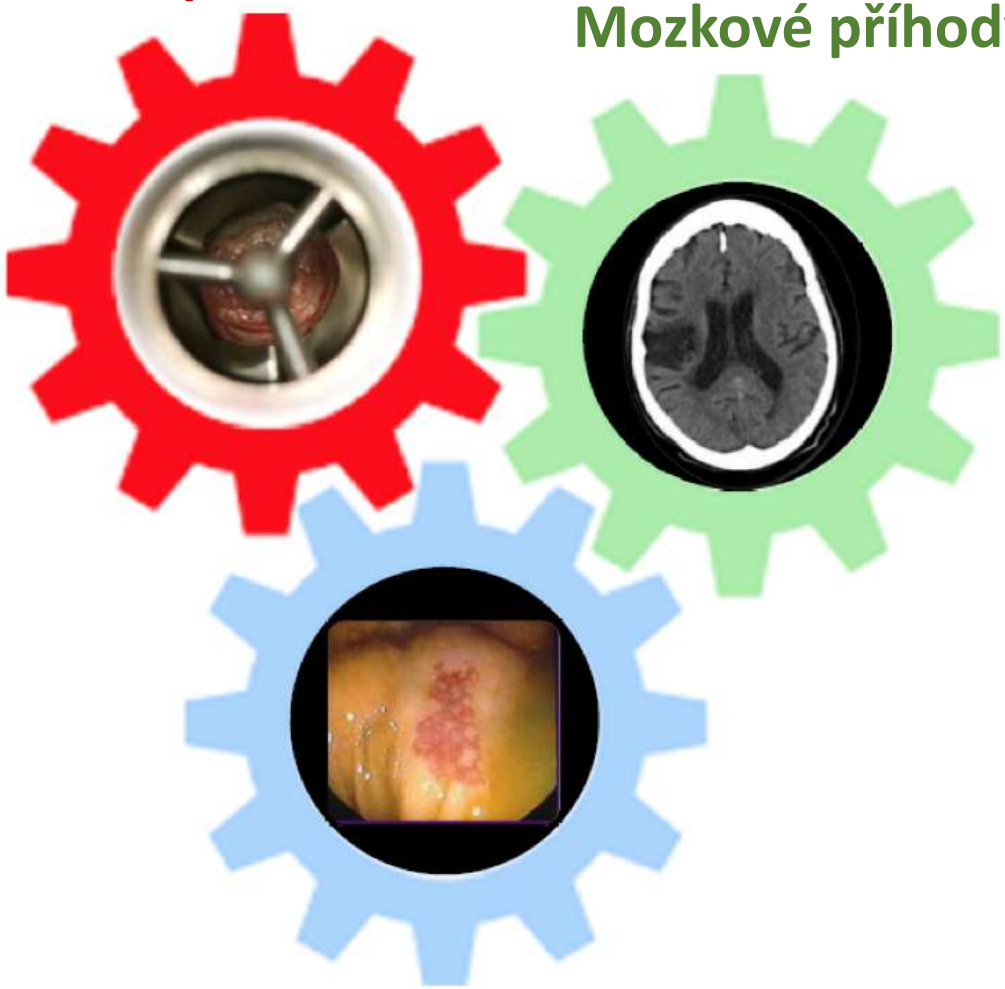


Mini-invazivní implantace

Limitovaná hemokompatibilita LVAD

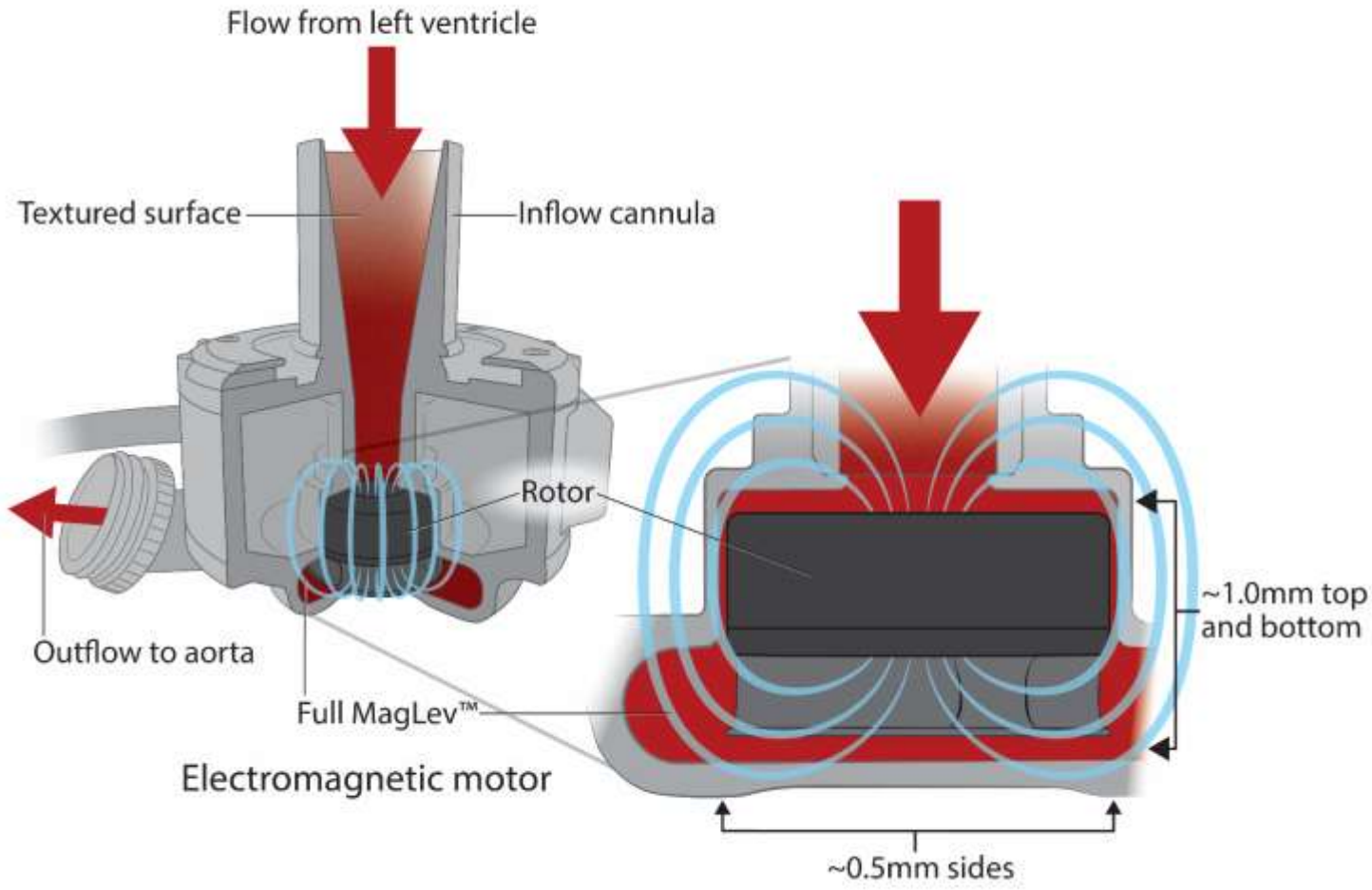
Trombóza čerpadla

Mozkové příhody



Krvácení do GIT

Magnetická levitace rotoru - HeartMate 3



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ORIGINAL INVESTIGATIONS

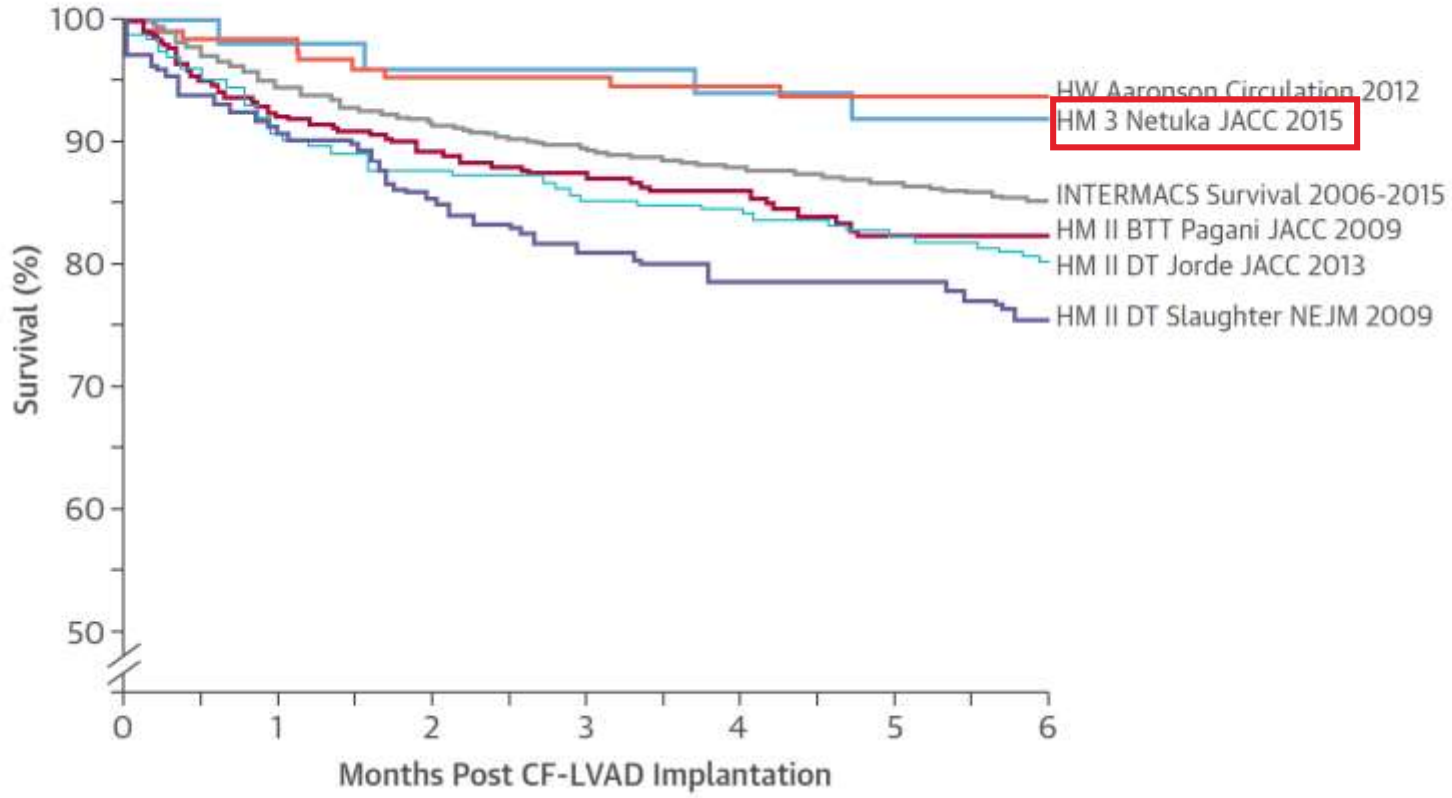
Fully Magnetically Levitated Left Ventricular Assist System for Treating Advanced HF

A Multicenter Study

Ivan Netuka, MD, PhD,*† Poornima Sood, MD, MBA,‡ Yuriy Pya, MD,§ Daniel Zimpfer, MD,‖ Thomas Krabatsch, MD, PhD,¶ Jens Garbade, MD, PhD,# Vivek Rao, MD, PhD,** Michiel Morshuis, MD,†† Silvana Marasco, MBBS,‡‡ Friedhelm Beyersdorf, MD,§§ Laura Damme, RN, MPH,‡ Jan D. Schmitto, MD, PhD‖‖

HeartMate 3 CE Mark Trial

FIGURE 1 Progressive Improvement in Outcomes of Patients Supported With CF-LVADs for Advanced Heart Failure



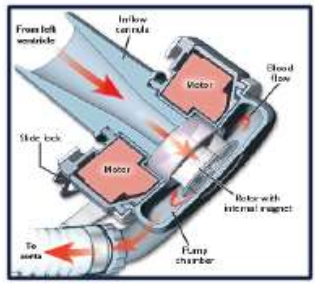
The NEW ENGLAND JOURNAL of MEDICINE

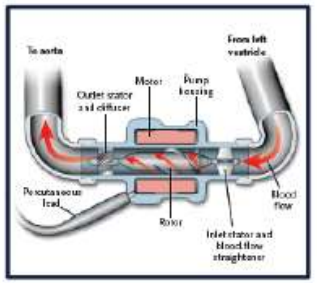
ORIGINAL ARTICLE

A Fully Magnetically Levitated Left Ventricular Assist Device — Final Report

M.R. Mehra, N. Uriel, Y. Naka, J.C. Cleveland, Jr., M. Yuzefpolskaya, C.T. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, S.W. Hutchins, J. Ransom, G.A. Ewald, A. Itoh, N.Y. Raval, S.C. Silvestry, R. Cogswell, R. John, A. Bhimaraj, B.A. Bruckner, B.D. Lowes, J.Y. Um, V. Jeevanandam, G. Sayer, A.A. Mangi, E.J. Molina, F. Sheikh, K. Aaronson, F.D. Pagani, W.G. Cotts, A.J. Tatooles, A. Babu, D. Chomsky, J.N. Katz, P.B. Tessmann, D. Dean, A. Krishnamoorthy, J. Chuang, I. Topuria, P. Sood, and D.J. Goldstein, for the MOMENTUM 3 Investigators*

Full Cohort





Full Cohort
N=1028
24-month follow-up

HeartMate 3
N=516

HeartMate II
N=512

Intent-to-Treat (ITT) Population
N=1028

Withdrawn before implant
N = 1
Death: 1

Withdrawn before implant
N = 7
Death: 2
No LVAD implant: 2
Withdrawal of consent: 1
Transplant: 1
Implanted with non-study LVAD: 1

As-Treated Population
N=1020

Implanted with HeartMate 3
N=515

Implanted with HeartMate II
N=505

Withdrawn after implant
N = 6
Implanted with non-study device: 2
Withdrawal of consent: 1
Non-compliance: 1
Other reason: 2

Withdrawn after implant
N = 15
Implanted with non-study device: 5
Withdrawal of consent: 1
Implanted with HM3: 6
Other reason: 3

Completed study follow-up
N=509

Completed study follow-up
N=490

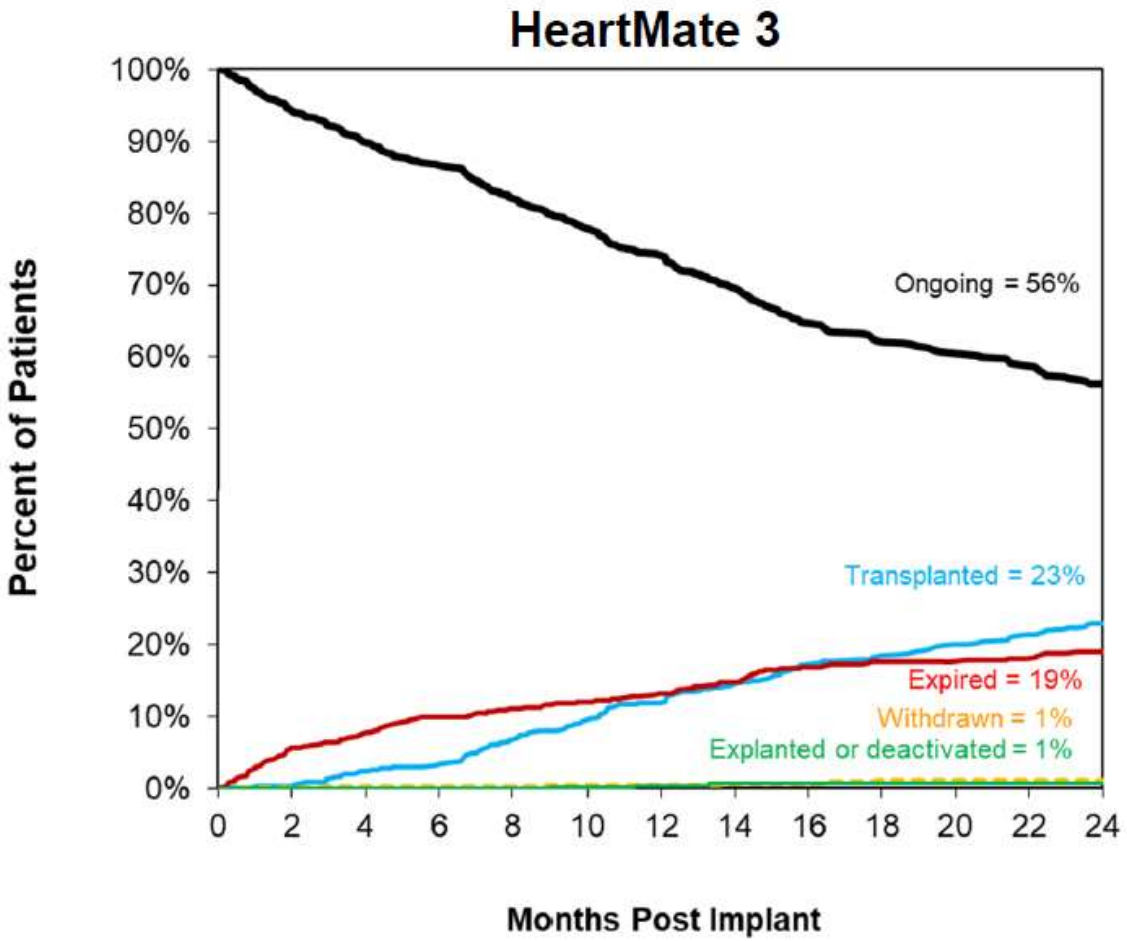
MOMENTUM 3

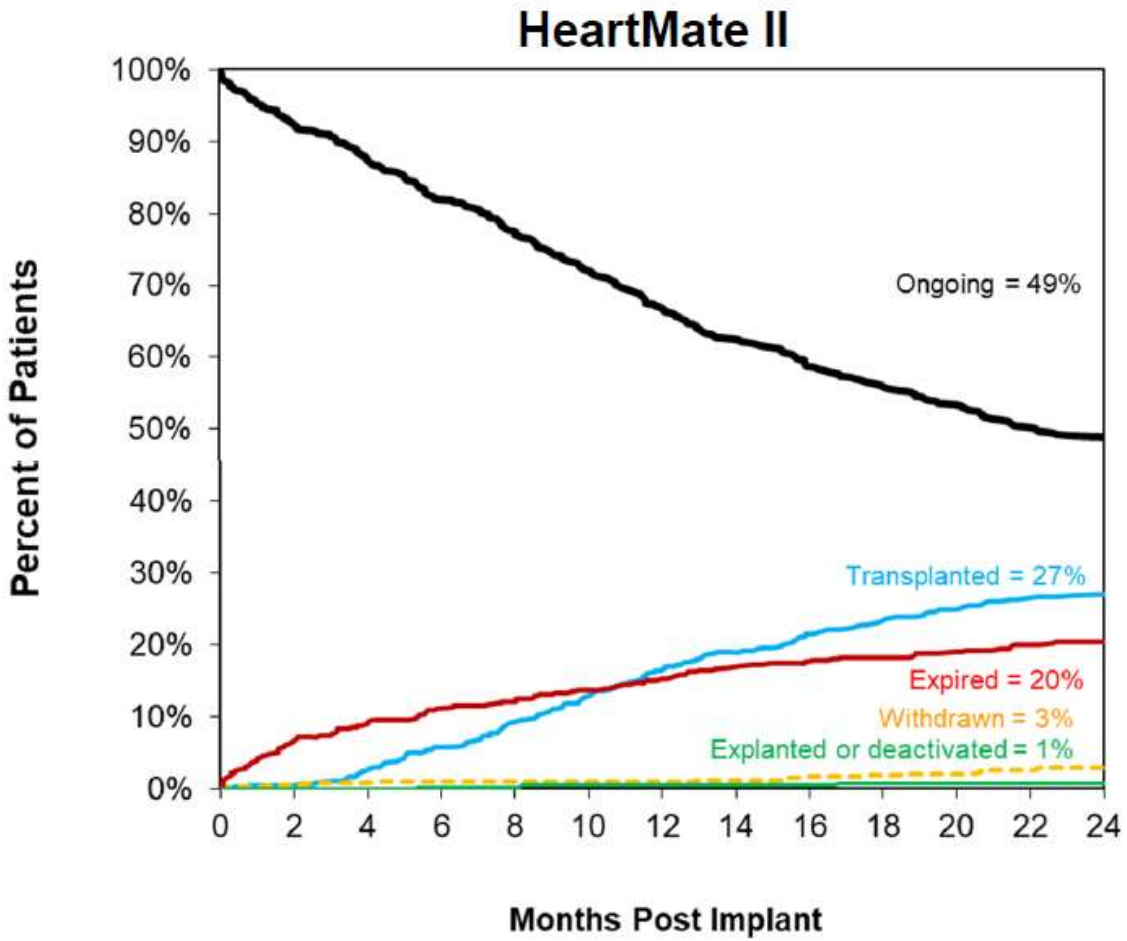
Baseline Characteristics

Characteristic	HeartMate 3 (n=516)	HeartMate II (n=512)
Mean age - years	59 ± 12	60 ± 12
Male - no. (%)	411 (79.7)	419 (81.8)
Race - no. (%)		
White	342 (66.3)	367 (71.7)
Black or African American	145 (28.1)	120 (23.4)
Asian	8 (1.6)	3 (0.6)
Native Hawaiian or Pacific islander	0 (0)	4 (0.8)
Other	21 (4.1)	18 (3.5)
Ischemic cause of heart failure - no. (%)	216 (41.9)	240 (46.9)
Intravenous inotropic agents - no. (%)	445 (86.2)	423 (82.6)
Intra aortic balloon pump - no. (%)	64 (12.4)	79 (15.4)
Serum creatinine - mg/dl	1.4 ± 0.4	1.4 ± 0.4
Serum sodium – mmol/liter	135.4 ± 4.1	135.5 ± 4.2
Mean arterial pressure - mmHg	79.2 ± 10.4	79.2 ± 10.1
INTERMACS profile - no. (%)		
1	11 (2.1)	18 (3.5)
2	156 (30.2)	146 (28.5)
3	272 (52.7)	251 (49.0)
4	67 (13.0)	82 (16.0)
5-7 or not provided*	10 (1.9)	15 (2.9)
Intended goal of pump support - no. (%)		
Bridge to transplantation (BTT)	113 (21.9)	121 (23.6)
Bridge to candidacy for transplantation	86 (16.7)	81 (15.8)
Destination therapy (DT)	317 (61.4)	310 (60.5)

There were significant differences between groups for race (P=0.04). *Assessments were not performed in 2 HeartMate 3 patients and 5 HeartMate II patients.

Competing Outcomes





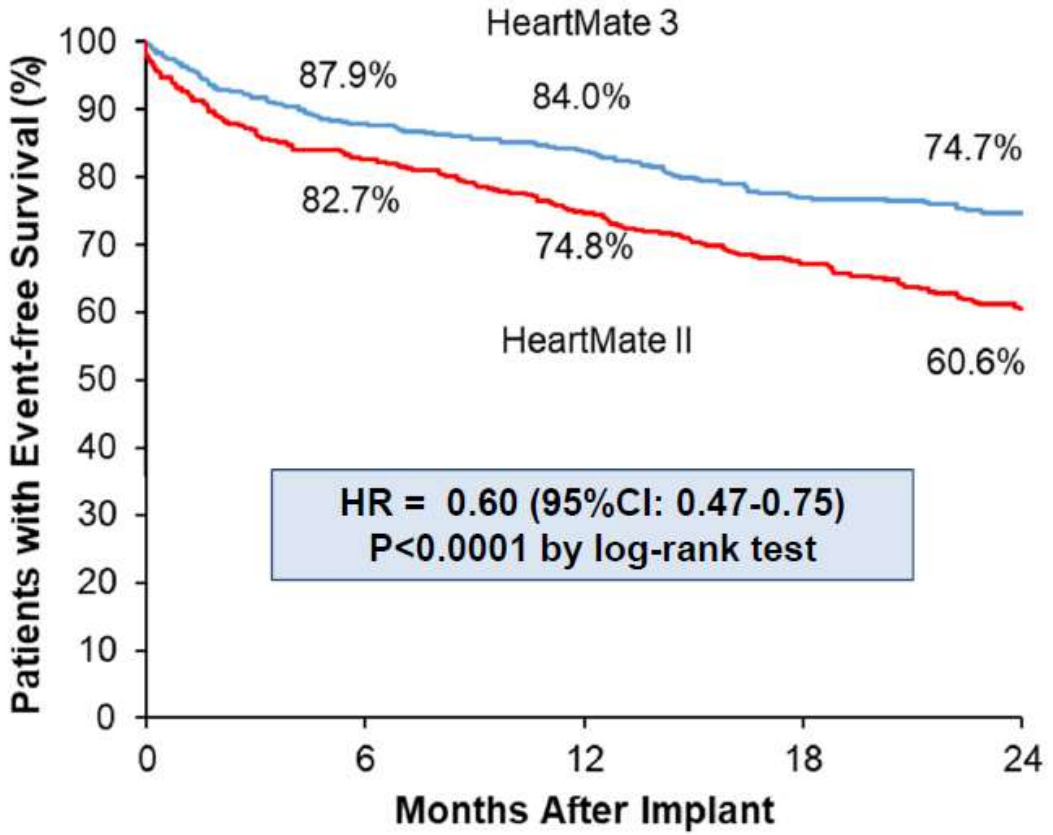
81.0% survival for HeartMate 3 at 2-years

Overall survival at 2-years was not significantly different between the groups

MOMENTUM 3

Primary End Point (ITT)

Survival at 2 years free of disabling stroke (>3 mRS) or reoperation to replace or remove a malfunctioning device



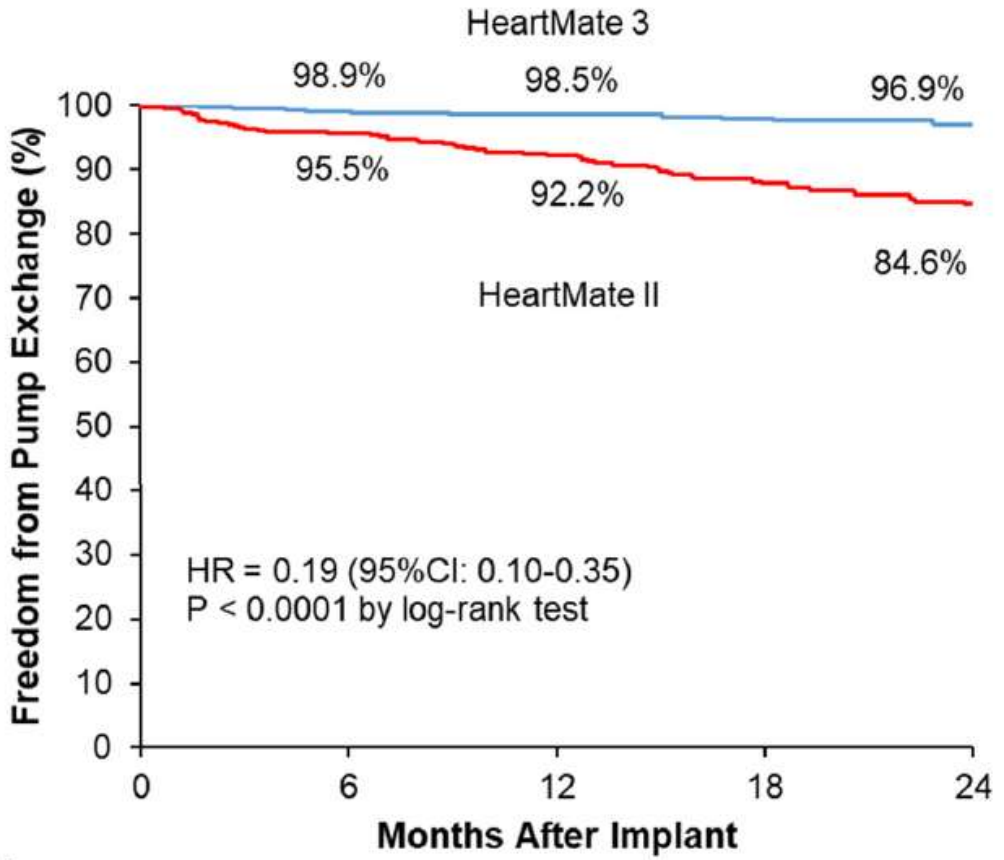
No. at Risk:					
HeartMate 3	516	438	373	313	280
HeartMate II	512	401	321	264	223

MOMENTUM 3

mRS denotes modified Rankin Score; HR, hazard ratio; CI, confidence interval

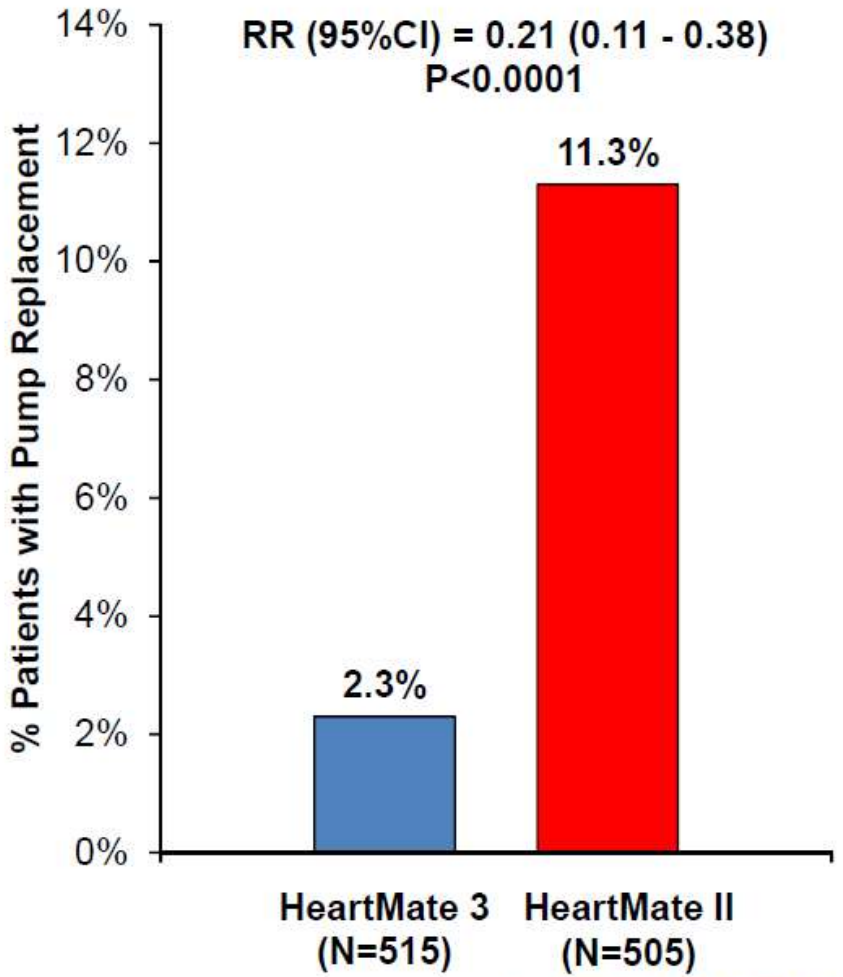
Principal Secondary End Point

Pump replacement at 2 years



No. at Risk:

HeartMate 3	515	444	379	317	283
HeartMate II	505	403	322	264	226

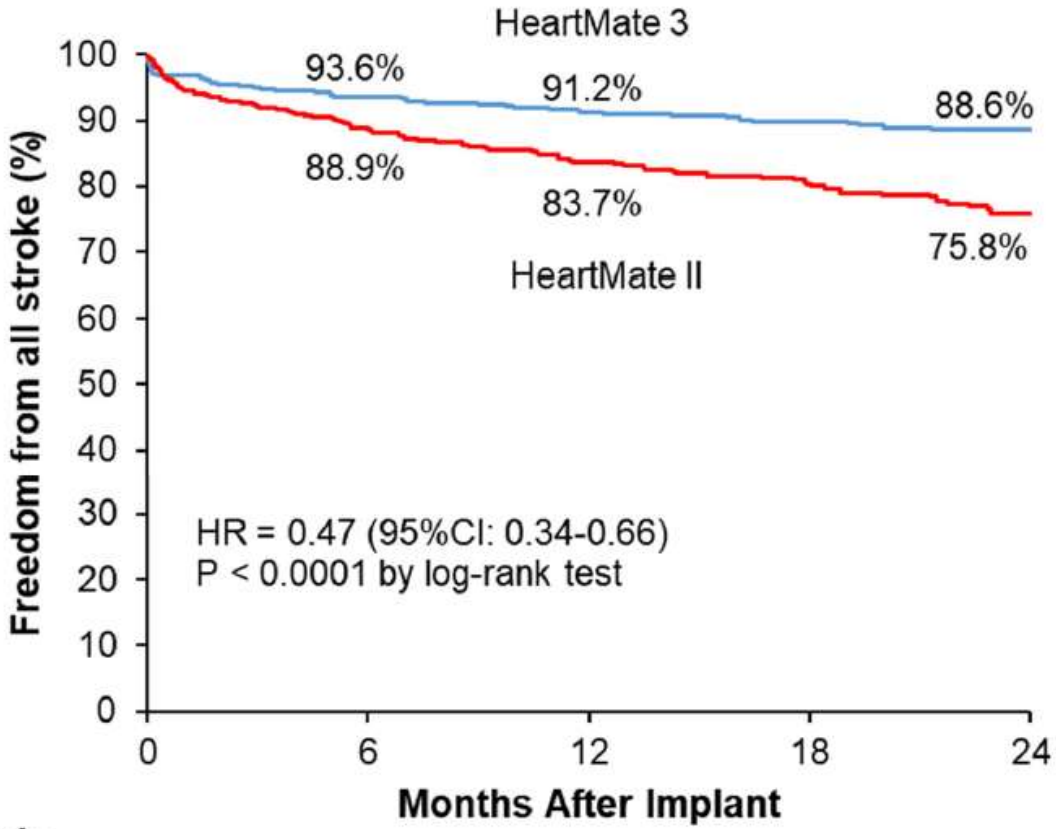


MOMENTUM 3

RR denotes relative risk; CI, confidence interval; HR, hazard ratio

Stroke

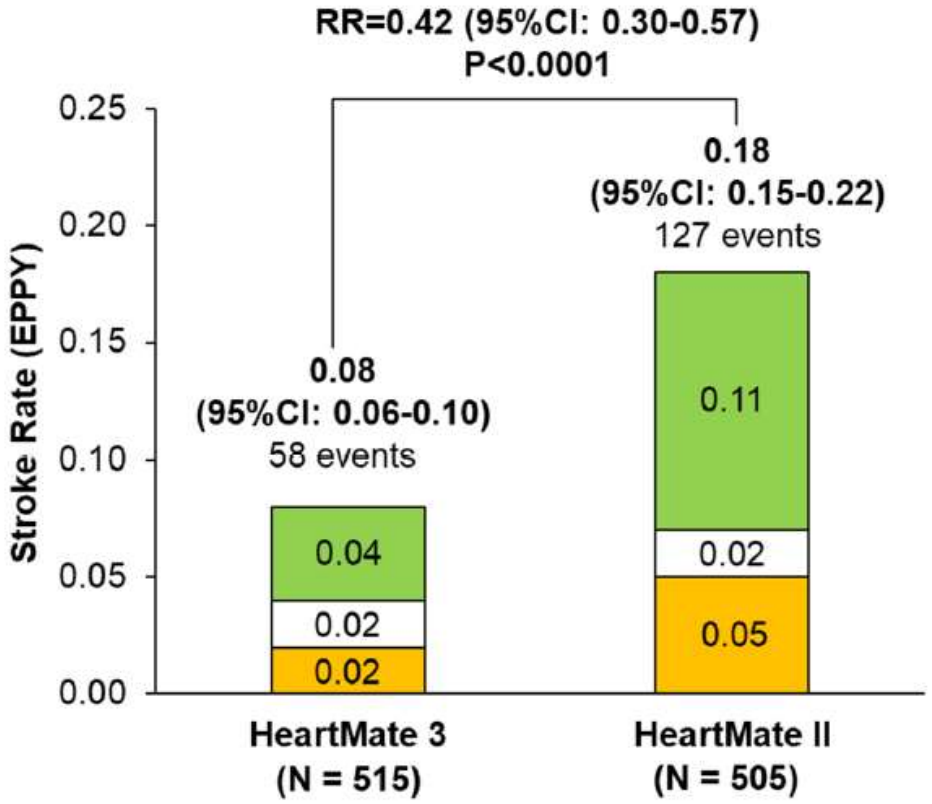
Freedom from All Stroke



No. at Risk:

HeartMate 3	515	429	361	304	270
HeartMate II	505	384	299	252	210

Stroke Severity

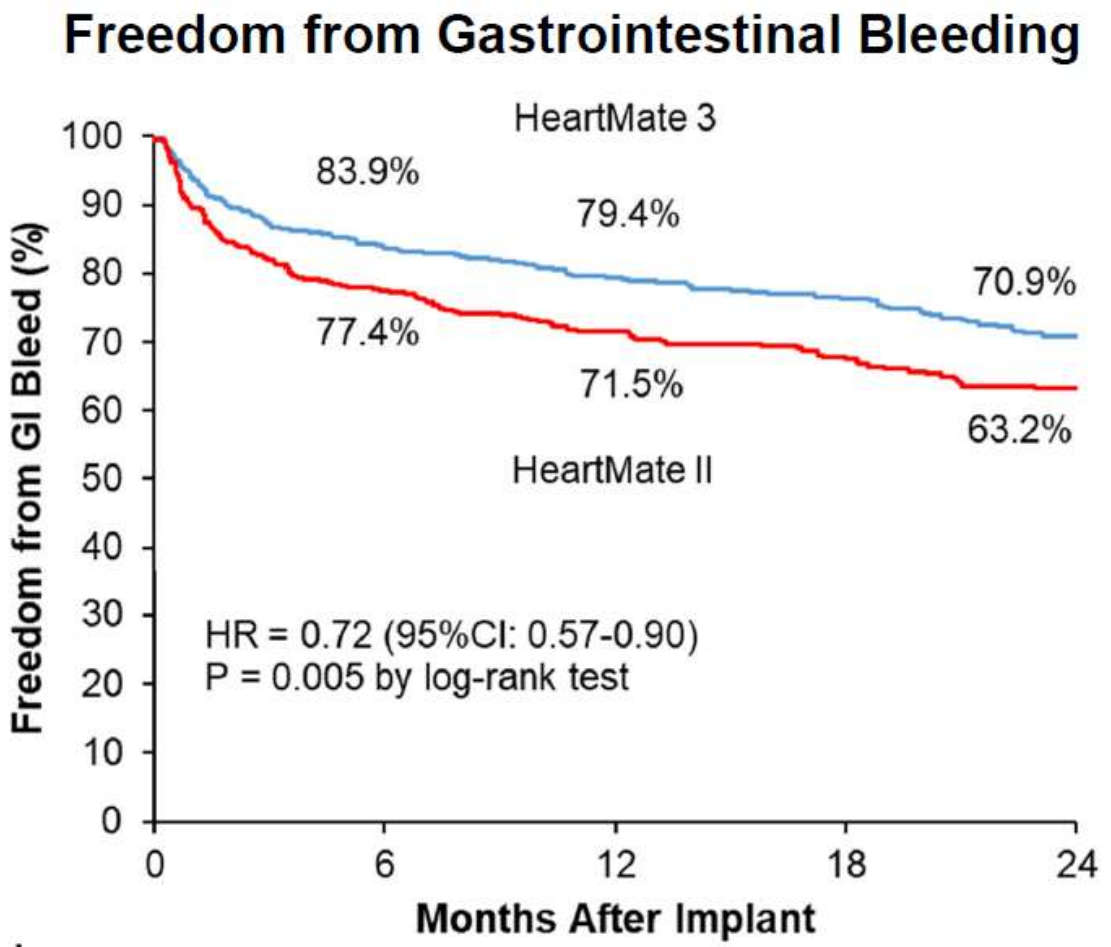


Non-Disabling Stroke (Modified Rankin Score 0-3)
Disabling Stroke (Modified Rankin Score 4-5)
Death (Modified Rankin Score 6)

MOMENTUM 3

HR denotes hazard ratio; CI, confidence interval; RR, relative risk; EPPY, events per patient year

Gastrointestinal Bleeding



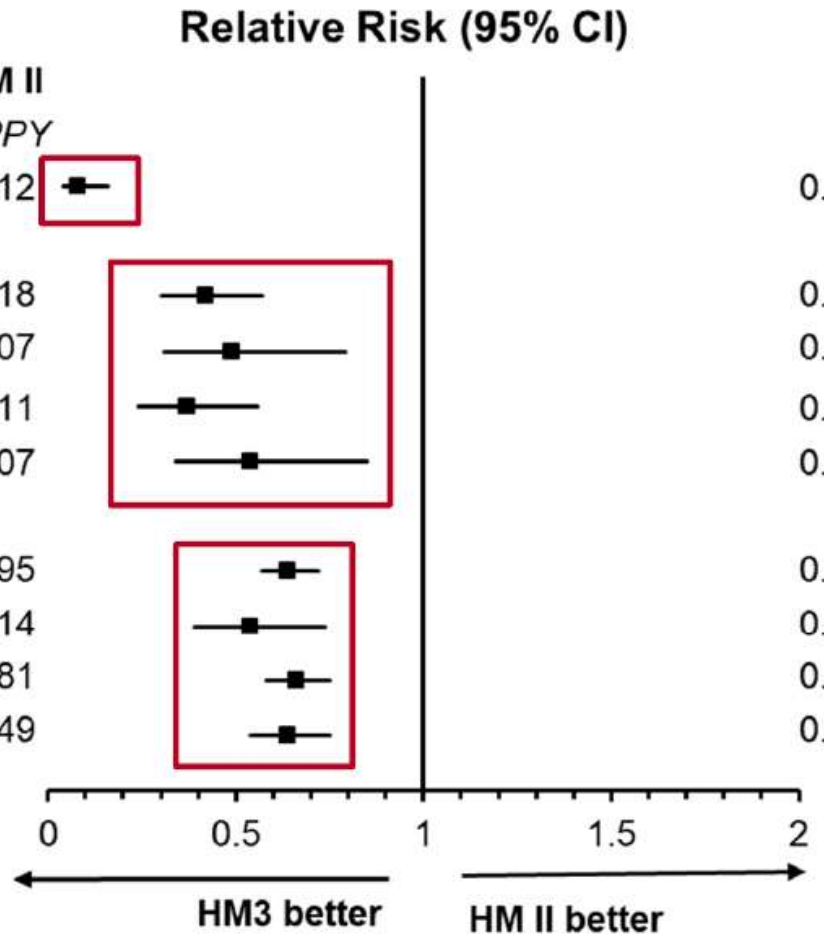
No. at Risk:					
HeartMate 3	515	381	308	251	204
HeartMate II	505	325	248	202	167

MOMENTUM 3

GI denotes gastrointestinal; HR hazard ratio; CI, confidence interval

Principal Hemocompatibility-Related Adverse Events

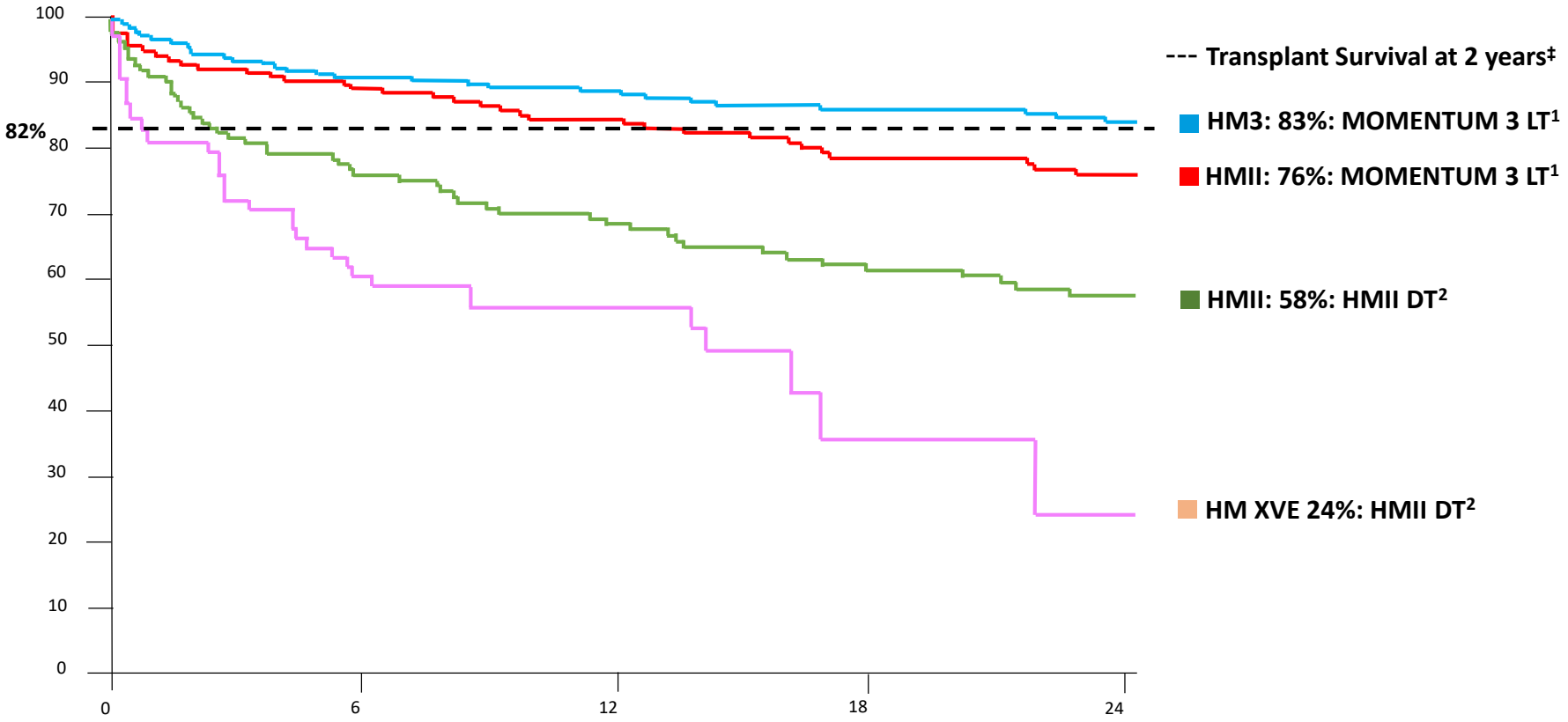
Adverse Event	HM3 n (%)	HM II n (%)	HM3 EPPY	HM II EPPY	Relative Risk (95% CI)	P-Value*
Suspected pump thrombosis	7 (1.4)	70 (13.9)	0.01	0.12	0.08 (0.04 - 0.16)	<0.0001
Any stroke	51 (9.9)	98 (19.4)	0.08	0.18	0.42 (0.30 - 0.57)	<0.0001
Hemorrhagic stroke	25 (4.9)	43 (8.5)	0.03	0.07	0.49 (0.31 - 0.79)	0.004
Ischemic stroke	29 (5.6)	65 (12.9)	0.04	0.11	0.37 (0.24 - 0.56)	<0.0001
Disabling stroke	26 (5.0)	38 (7.5)	0.04	0.07	0.54 (0.34 - 0.85)	0.008
Any bleeding	225 (43.7)	278 (55.0)	0.61	0.95	0.64 (0.57 - 0.72)	<0.0001
Requiring surgery	50 (9.7)	89 (17.6)	0.08	0.14	0.54 (0.39 - 0.74)	<0.001
Not requiring surgery	197 (38.3)	251 (49.7)	0.53	0.81	0.66 (0.58 - 0.75)	<0.0001
Gastrointestinal bleeding	126 (24.5)	156 (30.9)	0.31	0.49	0.64 (0.54 - 0.75)	<0.0001



MOMENTUM 3

HM3 denotes HeartMate 3; HMII HeartMate II; EPPY events per patient year; CI, confidence interval. *P values were calculated with Poisson regression.

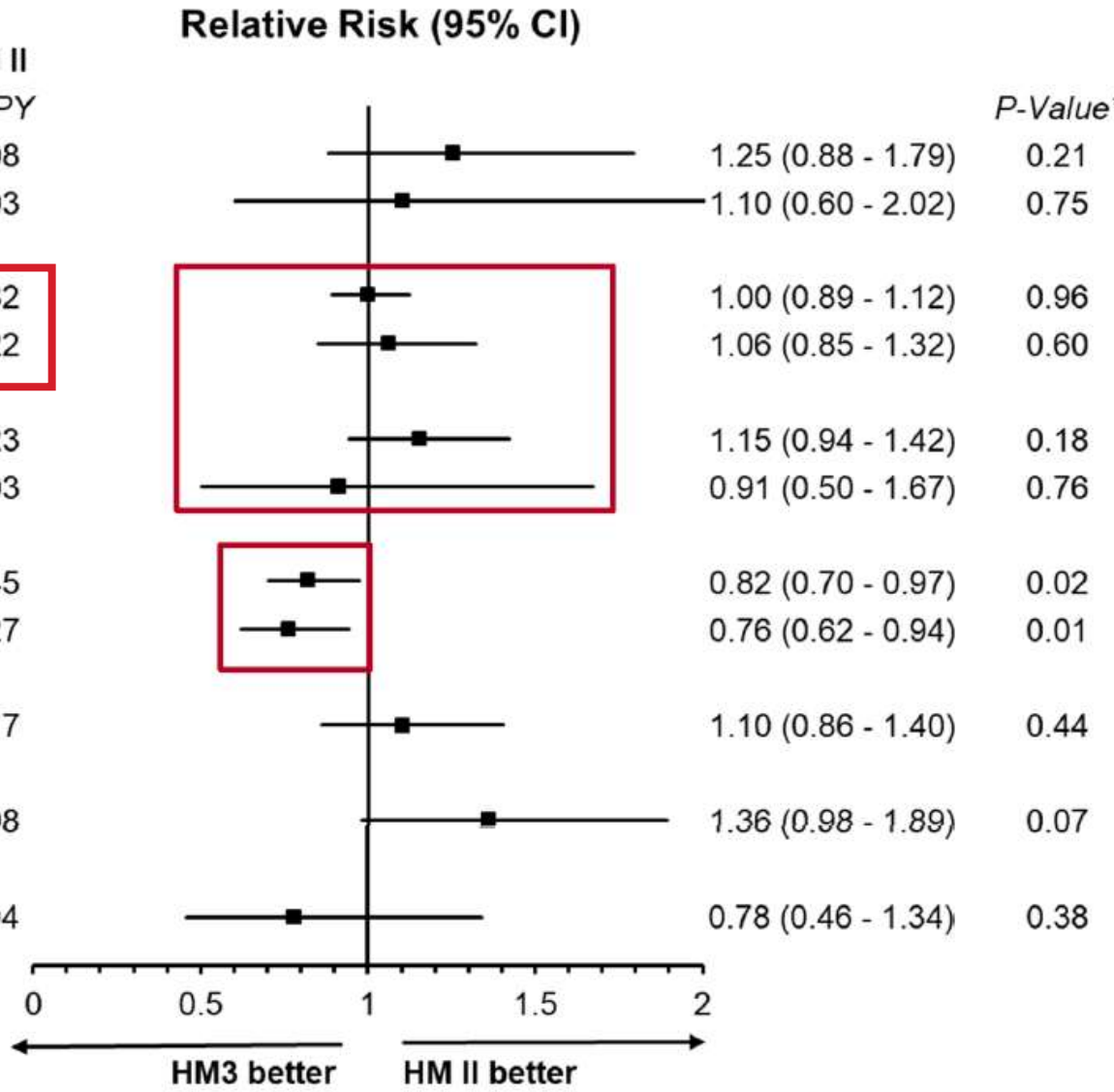
Pokroky v přežití pacientů na LVAD



1. Mehra MR, et al., for the MOMENTUM 3 investigators. N Engl J Med. 2018. **2.** Slaughter, et al. NEJM
‡ The International Society for Heart & Lung Transplantation. http://www.ishlt.org/registries/slides.asp?slides=heartLungRegistry.

Other Adverse Events

Adverse Event	HM3 *n (%)*	HM II *n (%)*	HM3 *EPPY*	HM II *EPPY*	*P-Value**
Other neurologic event+	59 (11.5)	47 (9.3)	0.09	0.08	1.25 (0.88 - 1.79) 0.21
TIA	16 (3.1)	19 (3.8)	0.03	0.03	1.10 (0.60 - 2.02) 0.75
Any major infection	300 (58.3)	285 (56.4)	0.82	0.82	1.00 (0.89 - 1.12) 0.96
LVAS driveline infection	120 (23.3)	98 (19.4)	0.23	0.22	1.06 (0.85 - 1.32) 0.60
Any right heart failure	176 (34.2)	143 (28.3)	0.27	0.23	1.15 (0.94 - 1.42) 0.18
Managed with RVAS	21 (4.1)	21 (4.2)	0.03	0.03	0.91 (0.50 - 1.67) 0.76
Cardiac arrhythmia	185 (35.9)	207 (41.0)	0.37	0.45	0.82 (0.70 - 0.97) 0.02
Ventricular arrhythmia	107 (20.8)	128 (25.3)	0.20	0.27	0.76 (0.62 - 0.94) 0.01
Respiratory failure	111 (21.6)	98 (19.4)	0.19	0.17	1.10 (0.86 - 1.40) 0.44
Renal dysfunction	73 (14.2)	56 (11.1)	0.11	0.08	1.36 (0.98 - 1.89) 0.07
Hepatic dysfunction	25 (4.9)	27 (5.3)	0.03	0.04	0.78 (0.46 - 1.34) 0.38



HM3 denotes HeartMate 3; HMII HeartMate II; EPPY events per patient year; CI, confidence interval; TIA transient ischemic attack; RVAS right ventricular assist system.
*P values were calculated with Poisson regression. +Includes TIA, encephalopathy, seizure and neurologic events other than stroke

MOMENTUM 3

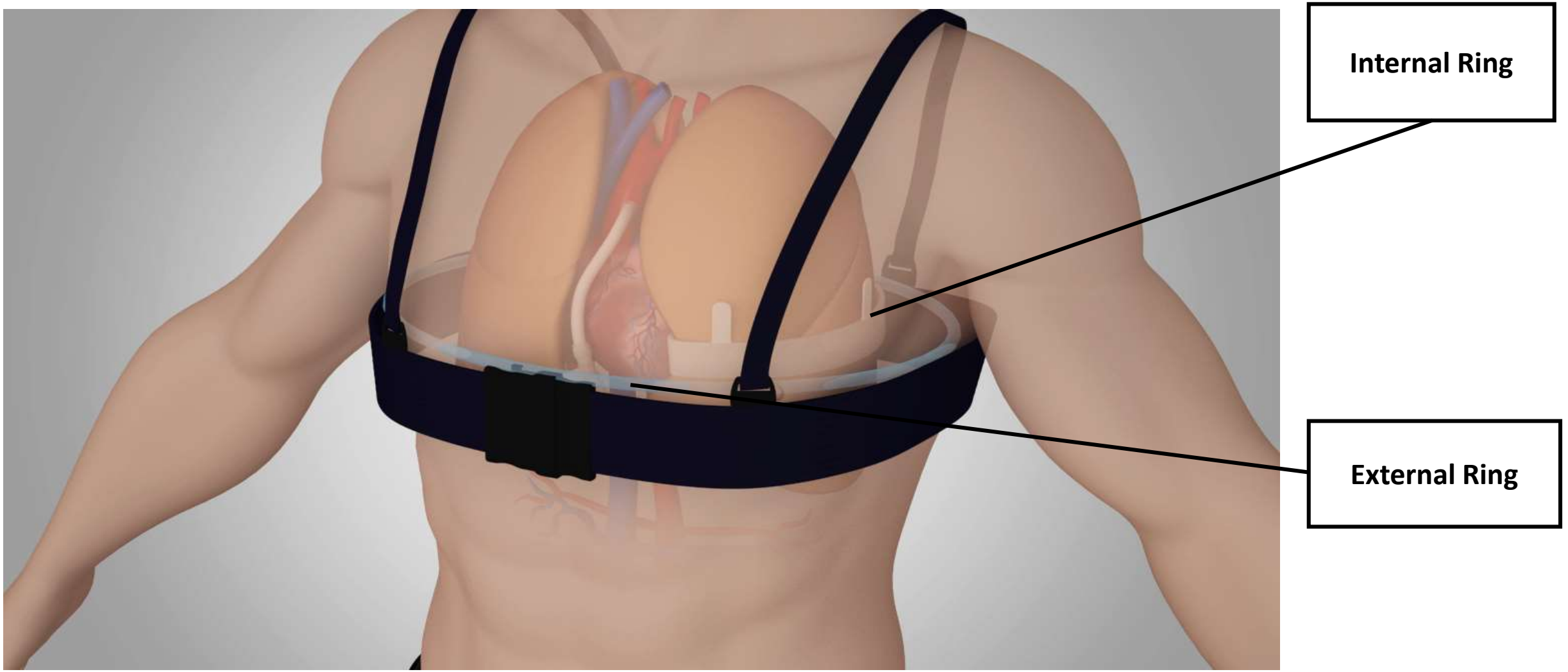
LeviticusCardio FiVAD™

First human use of a wireless coplanar energy transfer coupled with a continuous-flow left ventricular assist device

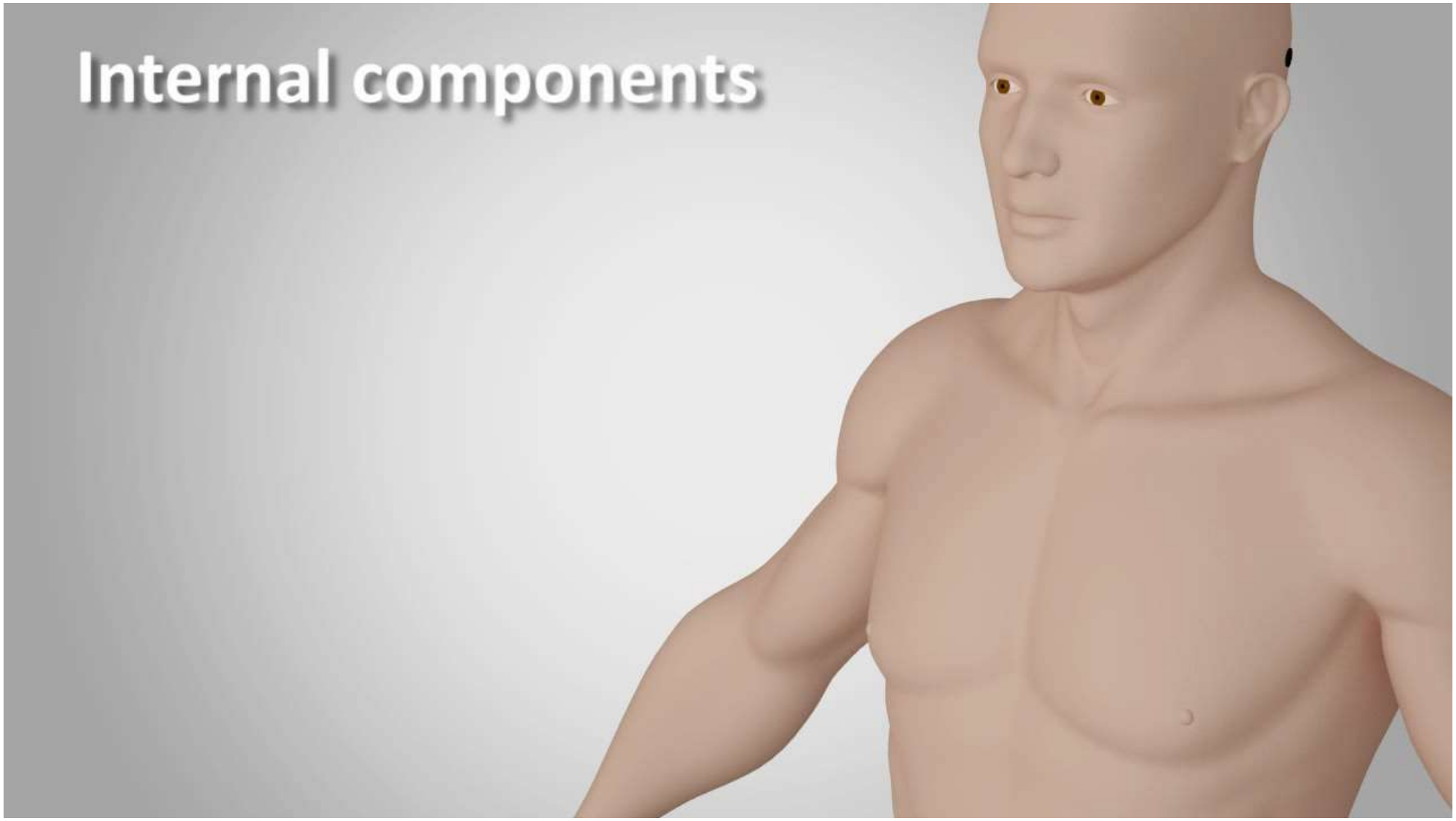
Yuryi Pya, MD,[a] Jiri Maly, MD, PhD,[b] Mahabbat Bekbossynova, MD,[a] Roman Salov, MBA,[a] Stephan Schueler, MD, PhD, FRCS,[c] Bart Meyns, MD, PhD,[d] Yigal Kassif, MD,[e] Massimo Massetti, MD, PhD,[f] Michael Zilbershlag, BSc,[g] and Ivan Netuka, MD, PhD[b]

J Heart Lung Transplant. 2019;38(4):339-343.

CET - Coplanar Energy Transfer



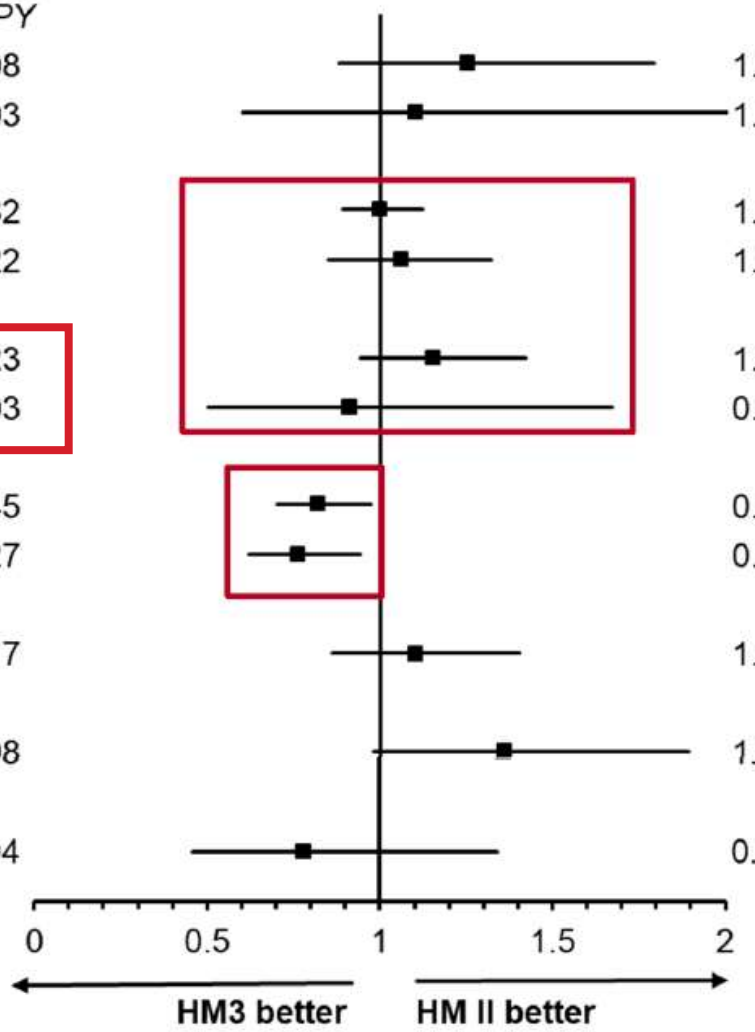
CET - System Overview



CET - System Overview

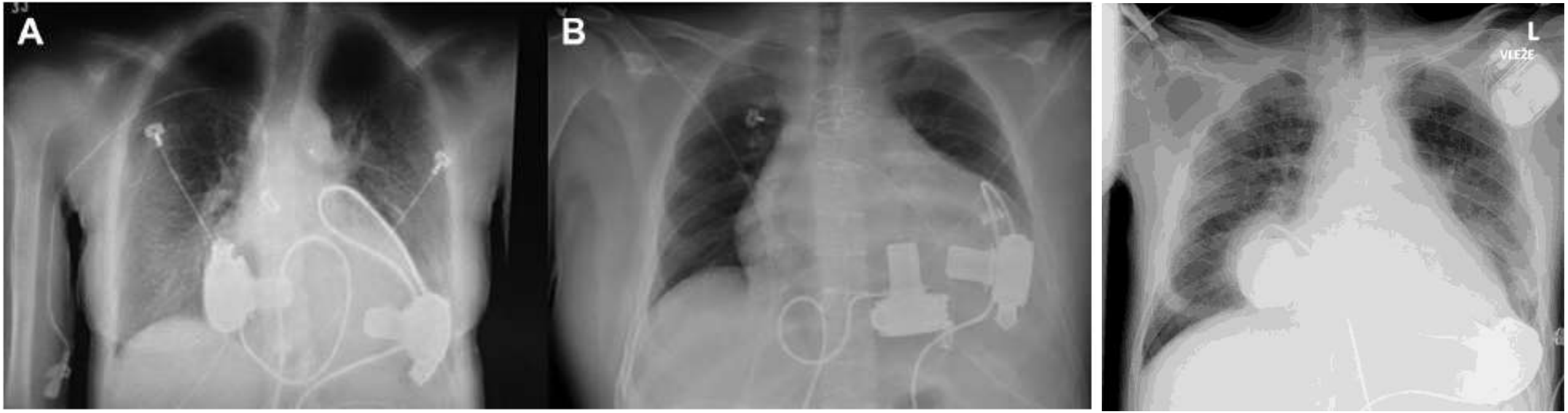
Other Adverse Events

Adverse Event	HM3 *n (%)*	HM II *n (%)*	HM3 *EPPY*	HM II *EPPY*	Relative Risk (95% CI)	*P-Value**
Other neurologic event+	59 (11.5)	47 (9.3)	0.09	0.08	1.25 (0.88 - 1.79)	0.21
TIA	16 (3.1)	19 (3.8)	0.03	0.03	1.10 (0.60 - 2.02)	0.75
Any major infection	300 (58.3)	285 (56.4)	0.82	0.82	1.00 (0.89 - 1.12)	0.96
LVAS driveline infection	120 (23.3)	98 (19.4)	0.23	0.22	1.06 (0.85 - 1.32)	0.60
Any right heart failure	176 (34.2)	143 (28.3)	0.27	0.23	1.15 (0.94 - 1.42)	0.18
Managed with RVAS	21 (4.1)	21 (4.2)	0.03	0.03	0.91 (0.50 - 1.67)	0.76
Cardiac arrhythmia	185 (35.9)	207 (41.0)	0.37	0.45	0.82 (0.70 - 0.97)	0.02
Ventricular arrhythmia	107 (20.8)	128 (25.3)	0.20	0.27	0.76 (0.62 - 0.94)	0.01
Respiratory failure	111 (21.6)	98 (19.4)	0.19	0.17	1.10 (0.86 - 1.40)	0.44
Renal dysfunction	73 (14.2)	56 (11.1)	0.11	0.08	1.36 (0.98 - 1.89)	0.07
Hepatic dysfunction	25 (4.9)	27 (5.3)	0.03	0.04	0.78 (0.46 - 1.34)	0.38



HM3 denotes HeartMate 3; HMII HeartMate II; EPPY events per patient year; CI, confidence interval; TIA transient ischemic attack; RVAS right ventricular assist system.
*P values were calculated with Poisson regression. +Includes TIA, encephalopathy, seizure and neurologic events other than stroke

LVAD - biventrikulárního konfiguraci (BIVAD)



HeartMate 3 BIVAD

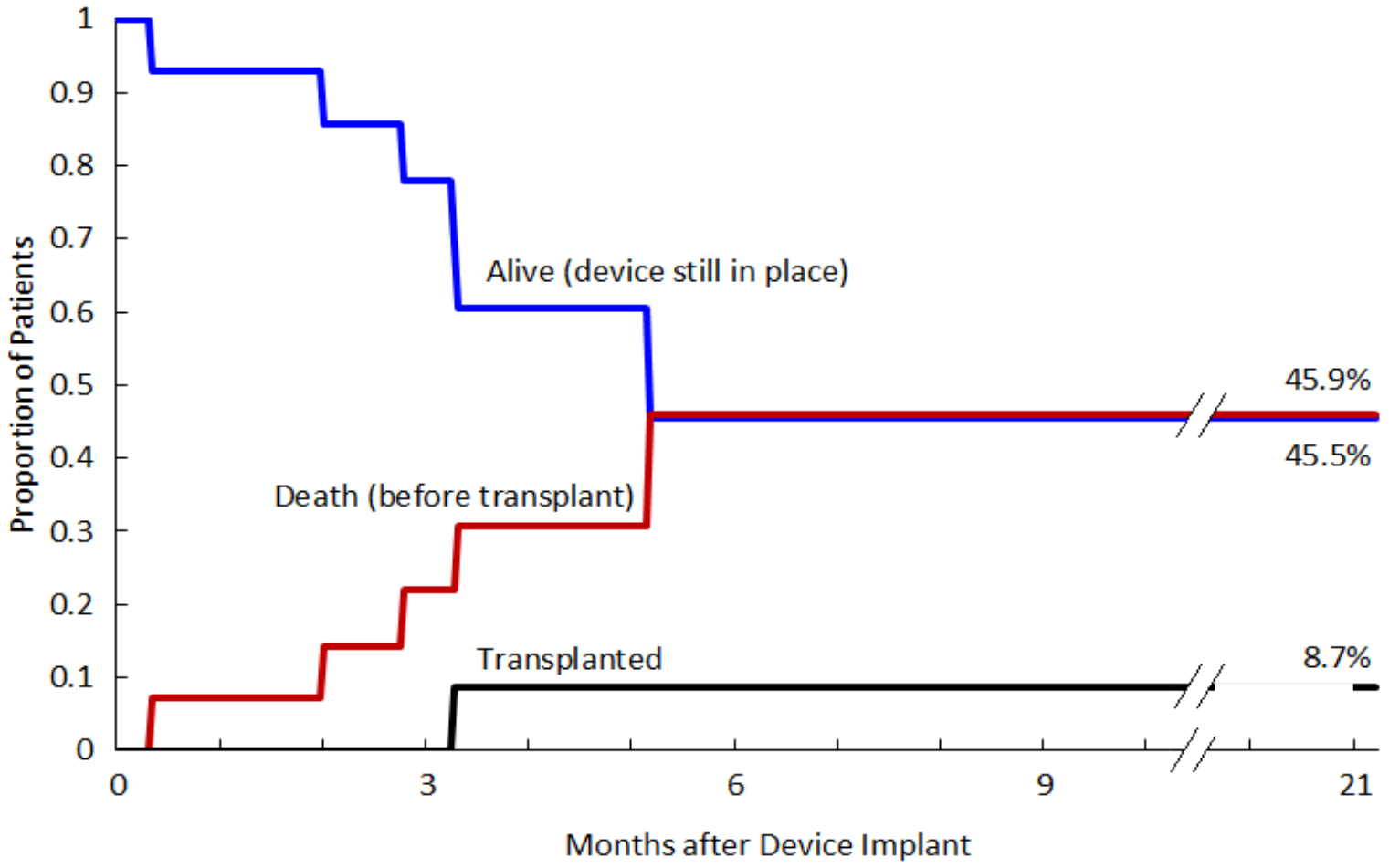


Figure 1: Competing outcomes depiction for two HeartMate 3 ventricular assist devices (BioVAD)

Fyziologická náhrada srdce

Fyziologická náhrada srdce Carmat

Pulsatilita

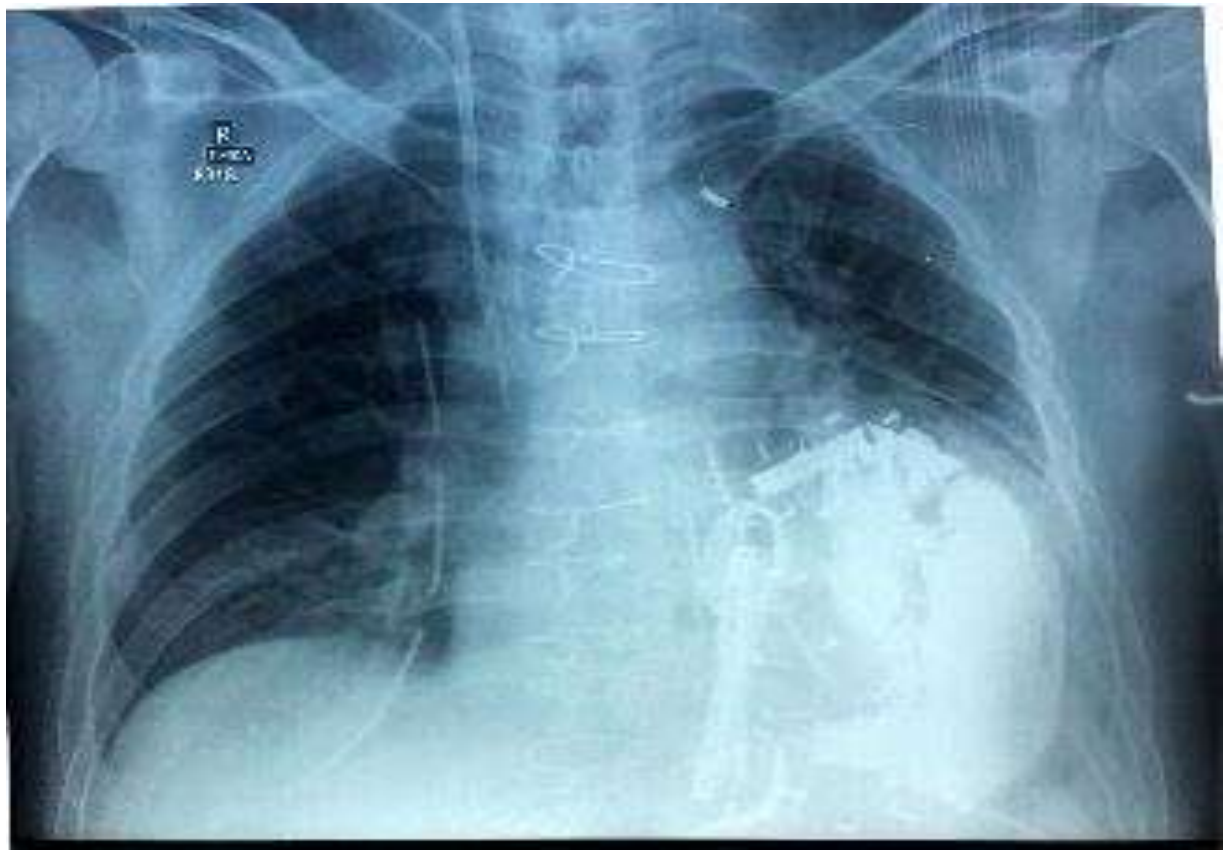
Biventrikulární řešení

Hemokompatibilita

Autoregulace

Elektrohydraulický pohon

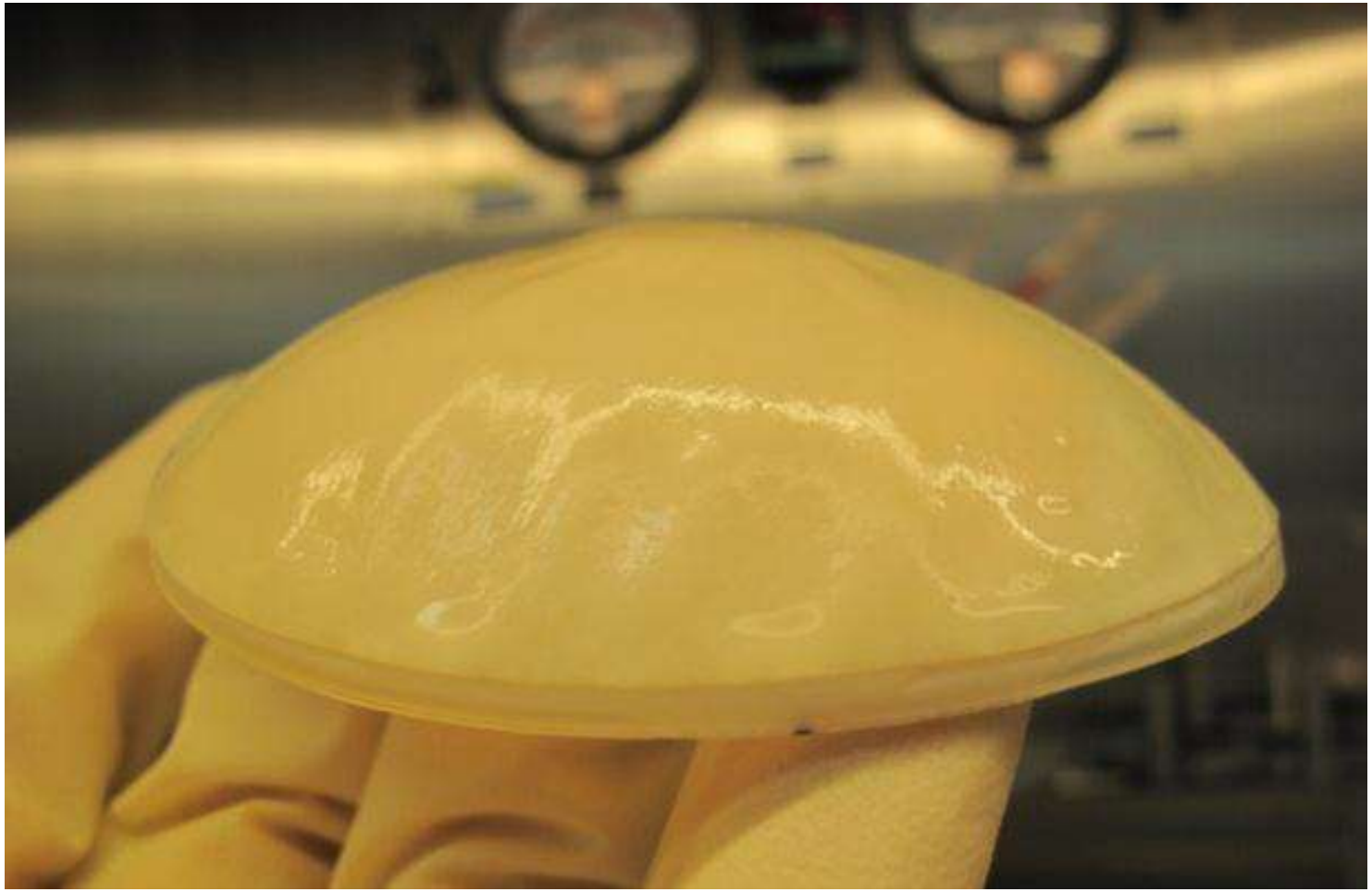
Princip funkce a charakteristiky systému Carmat



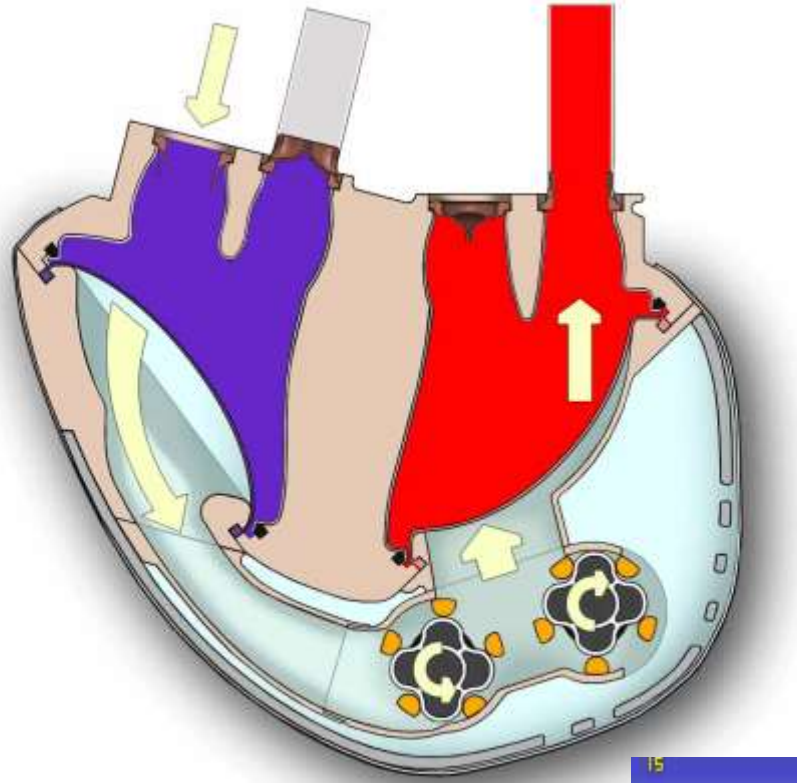
Biologické povrchy krevní cesty

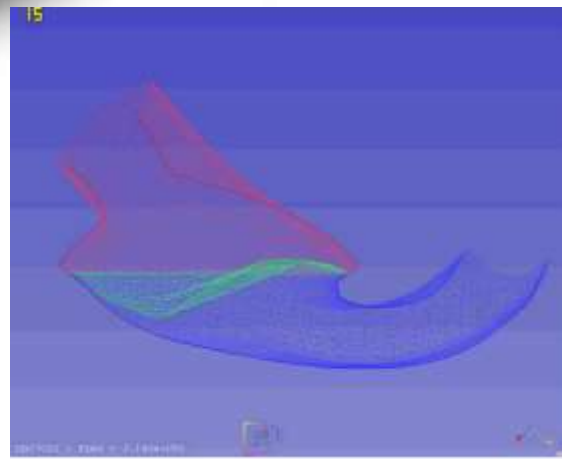
Plná pulsatilita ⟷ Autoregulace

Biologické povrchy krevní cesty



Princip funkce a charakteristiky systému Carmat

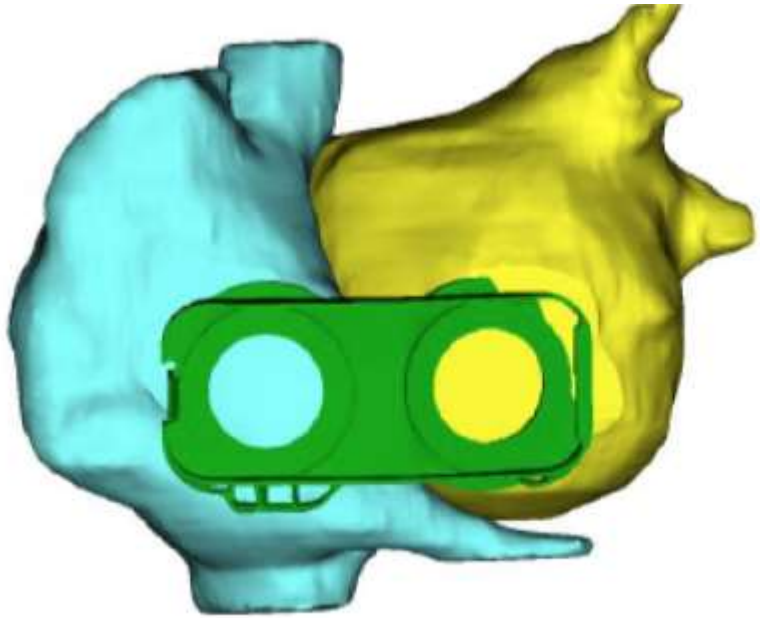




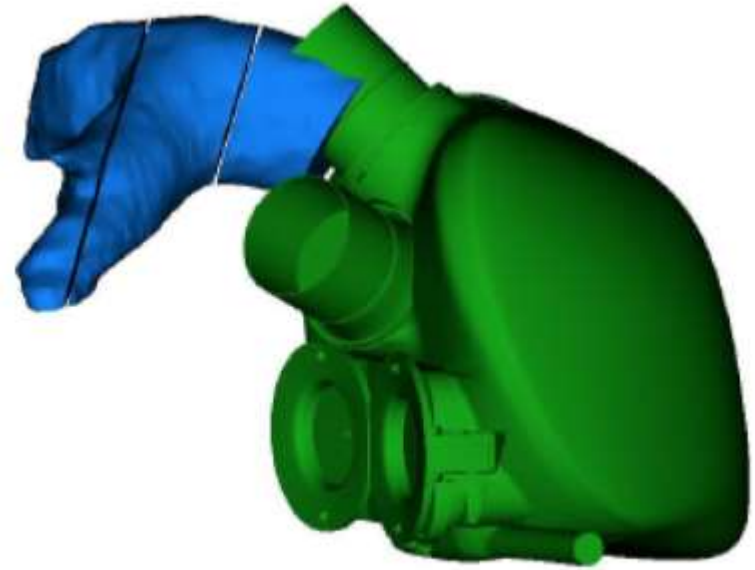
Měření oběhových a tlakových veličin pomocí sensorů v reálném čase

Adaptivní autoregulace volumetrických pump ultrazvukovými sensory polohy membrány

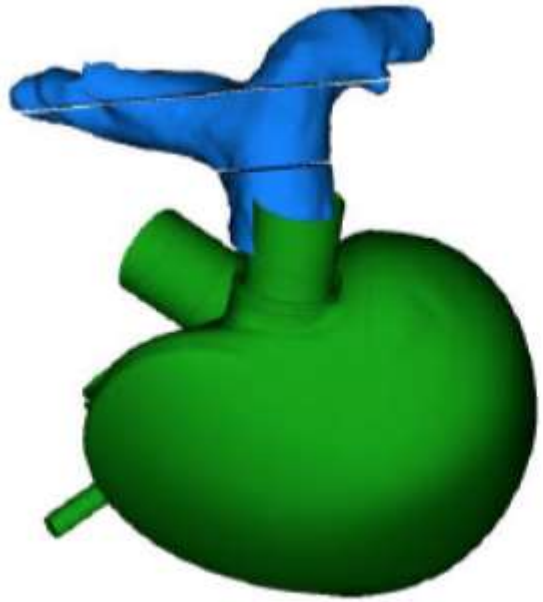
Modulace srdečního výdeje na základě aktuálního srdečního návratu a potřeb organizmu



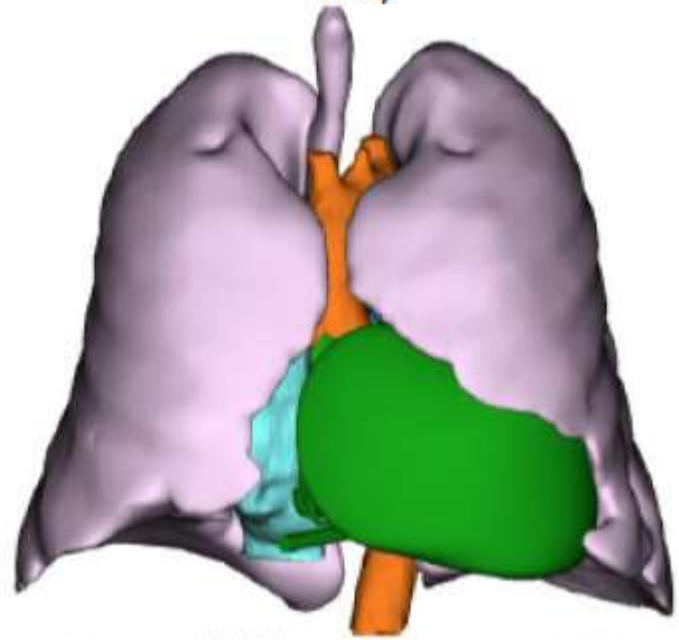
3D view: Atrial connections



3D view: Orientation and distance between prosthesis and pulmonary artery

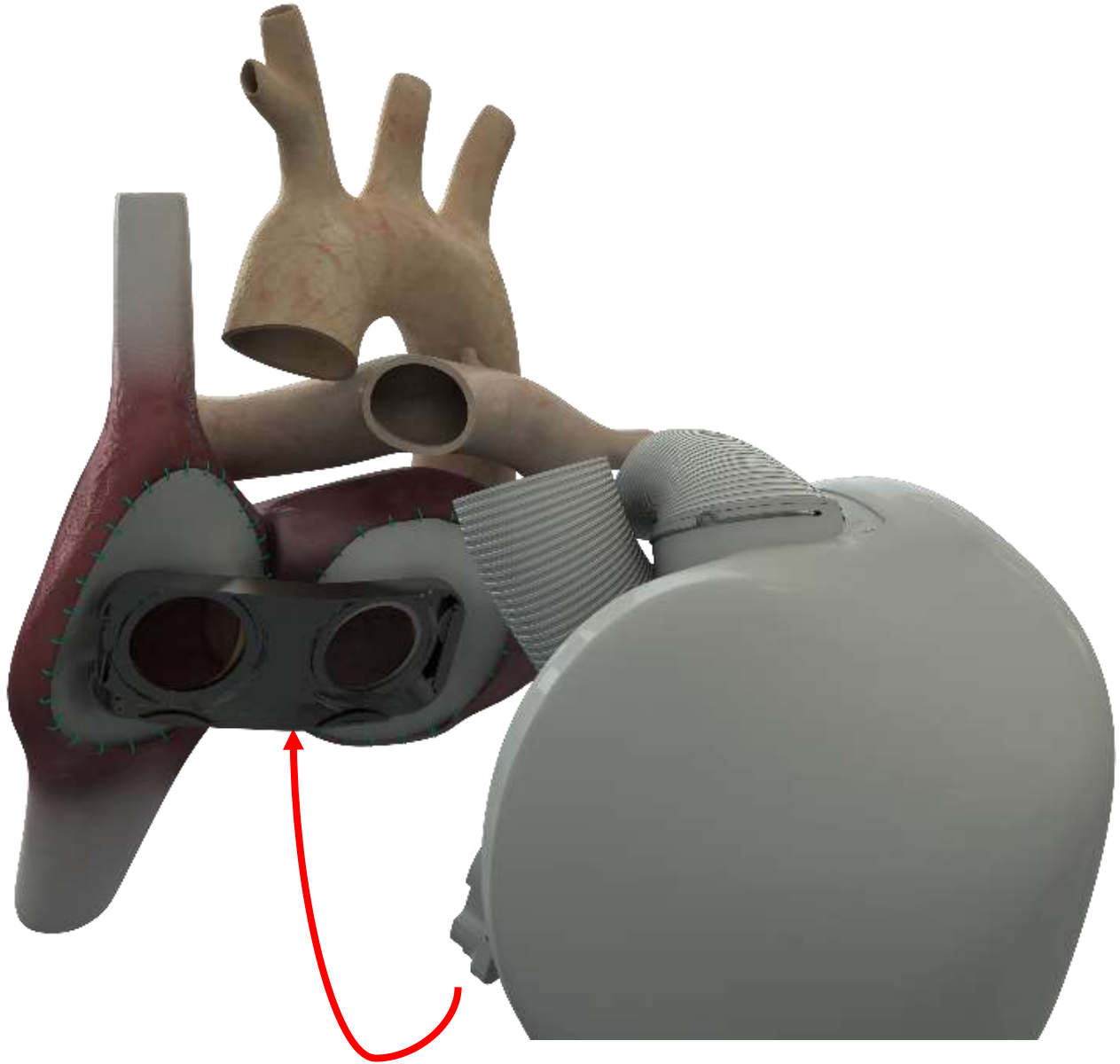


3D view: Orientation of the pulmonary artery

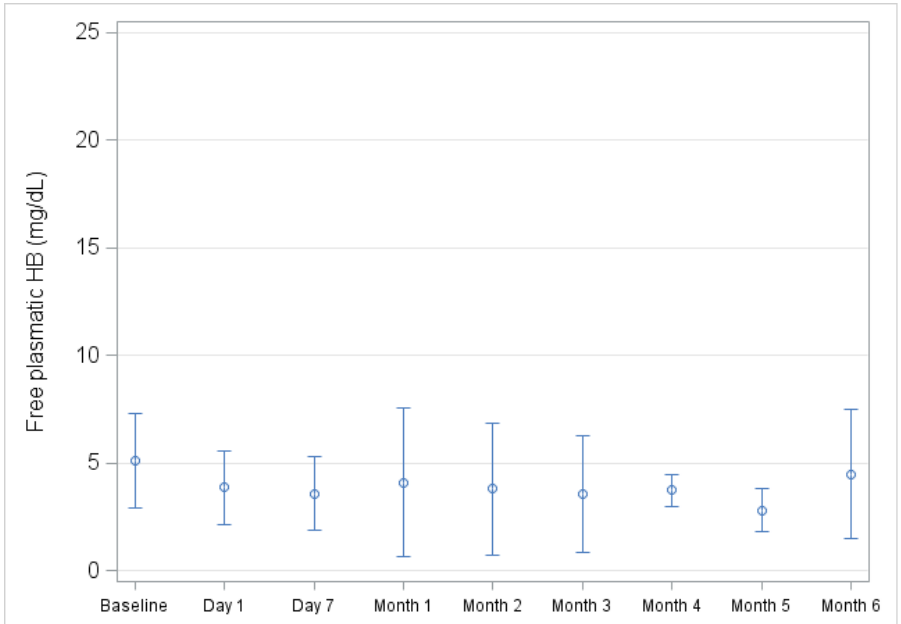


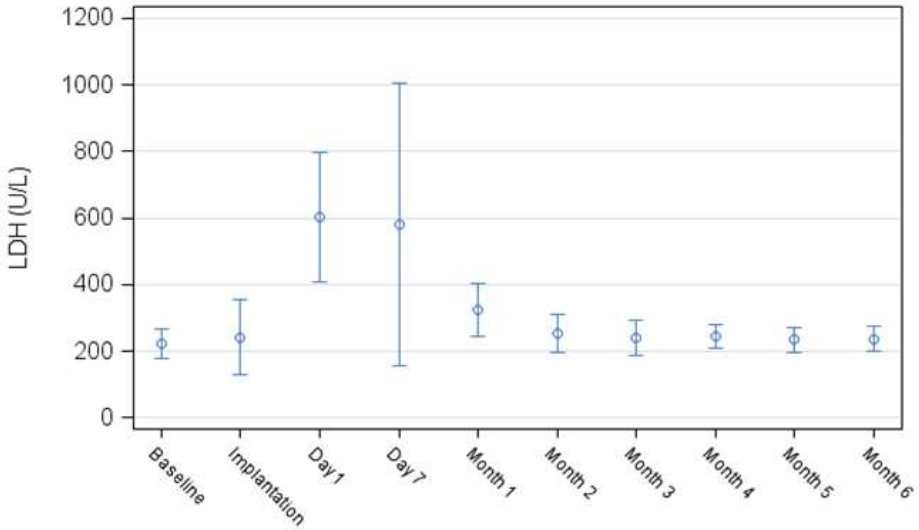
Estimated left lung compression: 3,87%
Estimated total lung compression: 1,81%

Chirurgická technika implantace Carmat

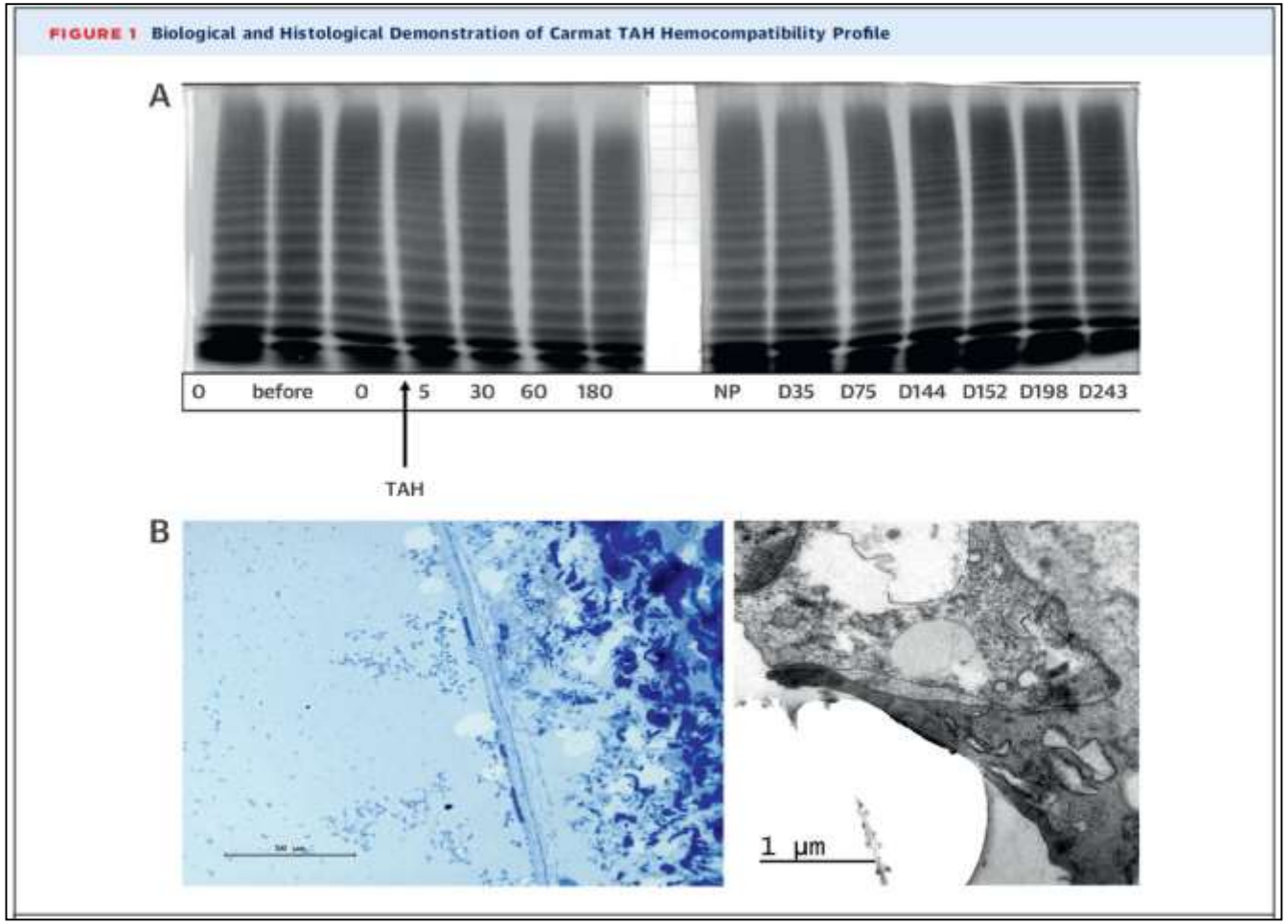


Hemokompatibilita systému Carmat





- **Absence získaného von Willebrandova syndromu**
- **Časná neo-endotelizace povrchu membrán**



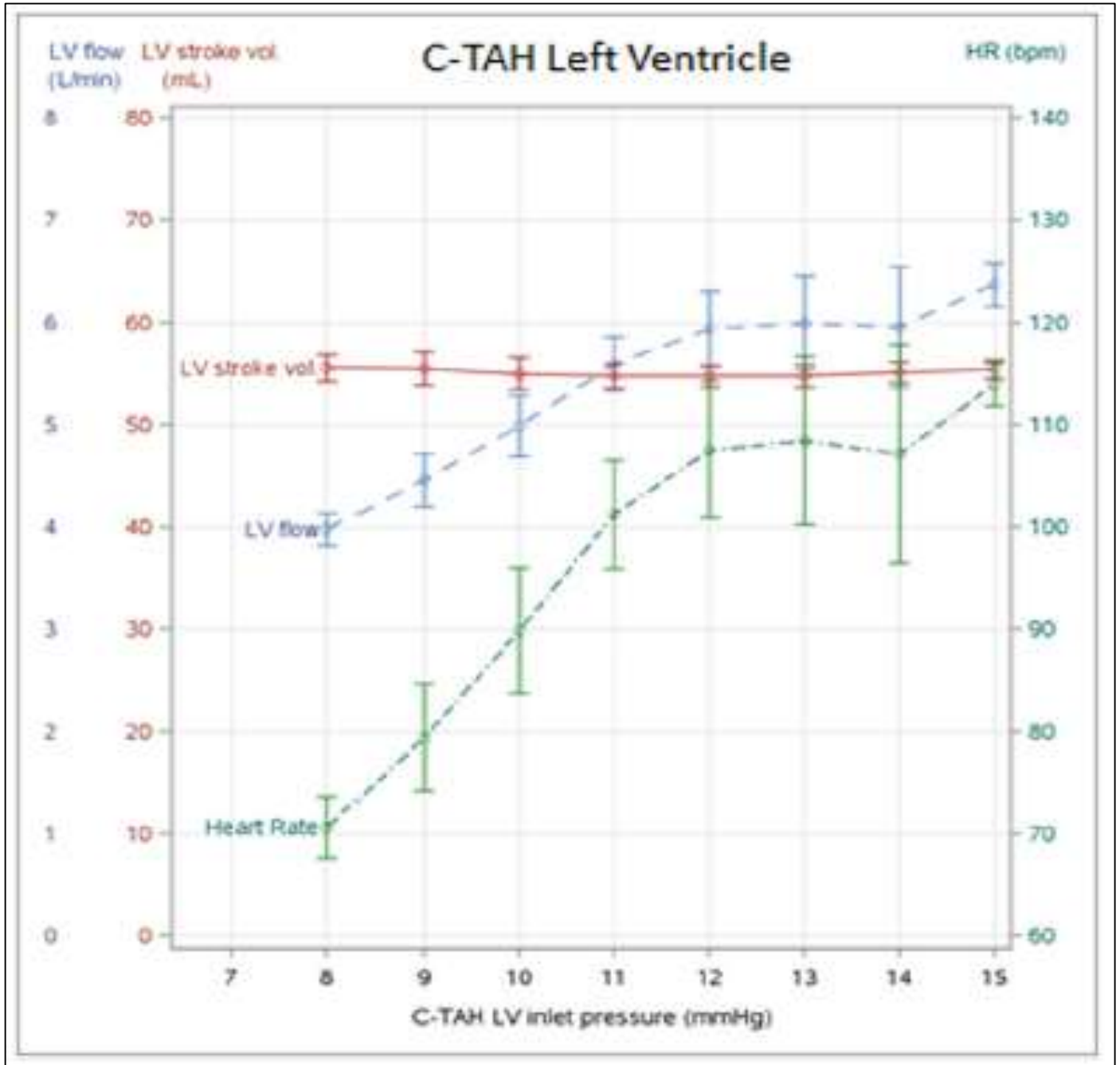
Smadja DM et al. JACC 2017;70:404-6.

ELSEVIER

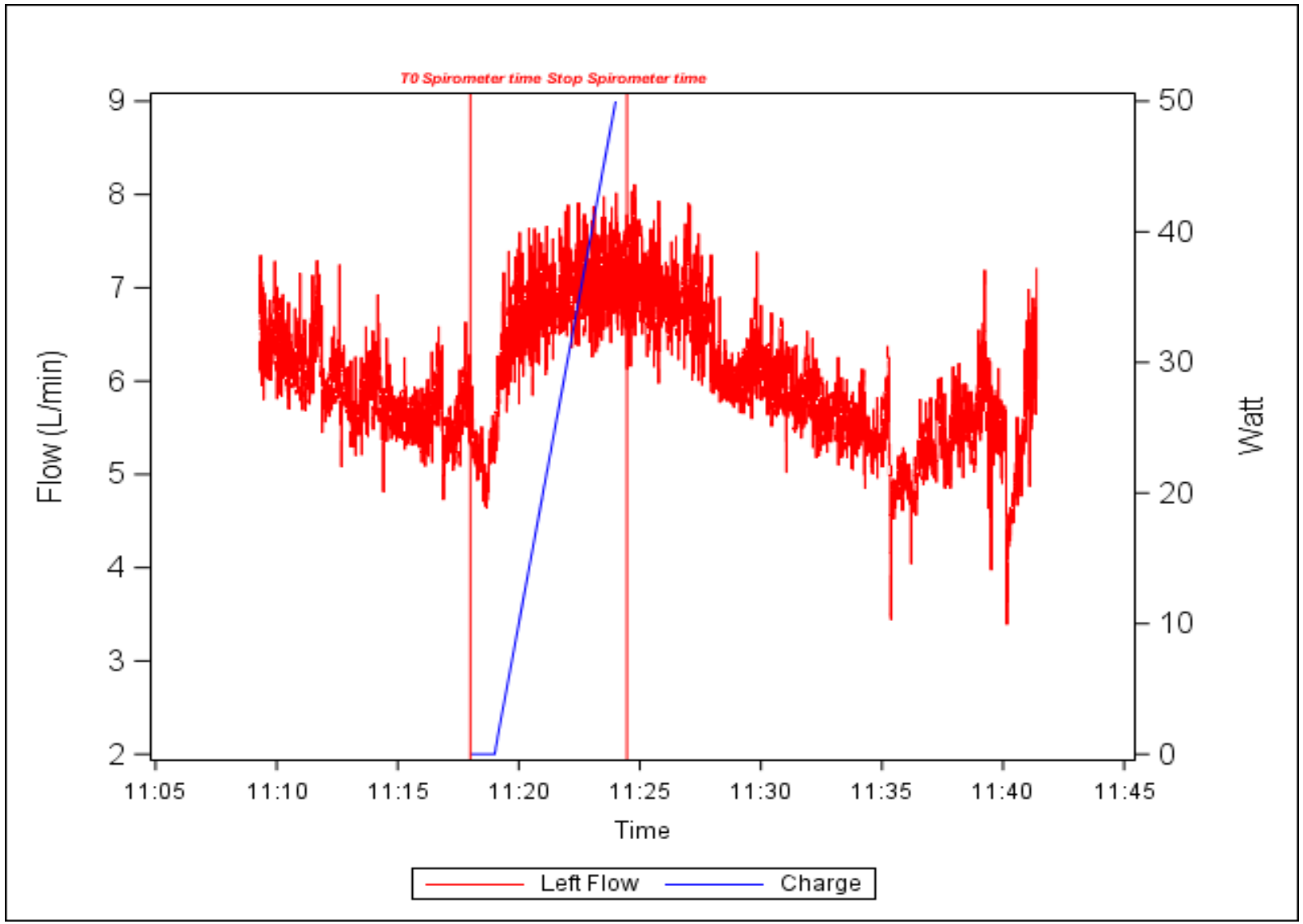
RESEARCH CORRESPONDENCE

Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period

Philippe Bizouarn, MD, PhD,[a]
Jean-Christian Roussel, MD, PhD,[b]
Jean-Noël Trochu, MD, PhD,[b]
Jean-Christophe Perlès, MSc,[c] and
Christian Latrémouille, MD, PhD[d]



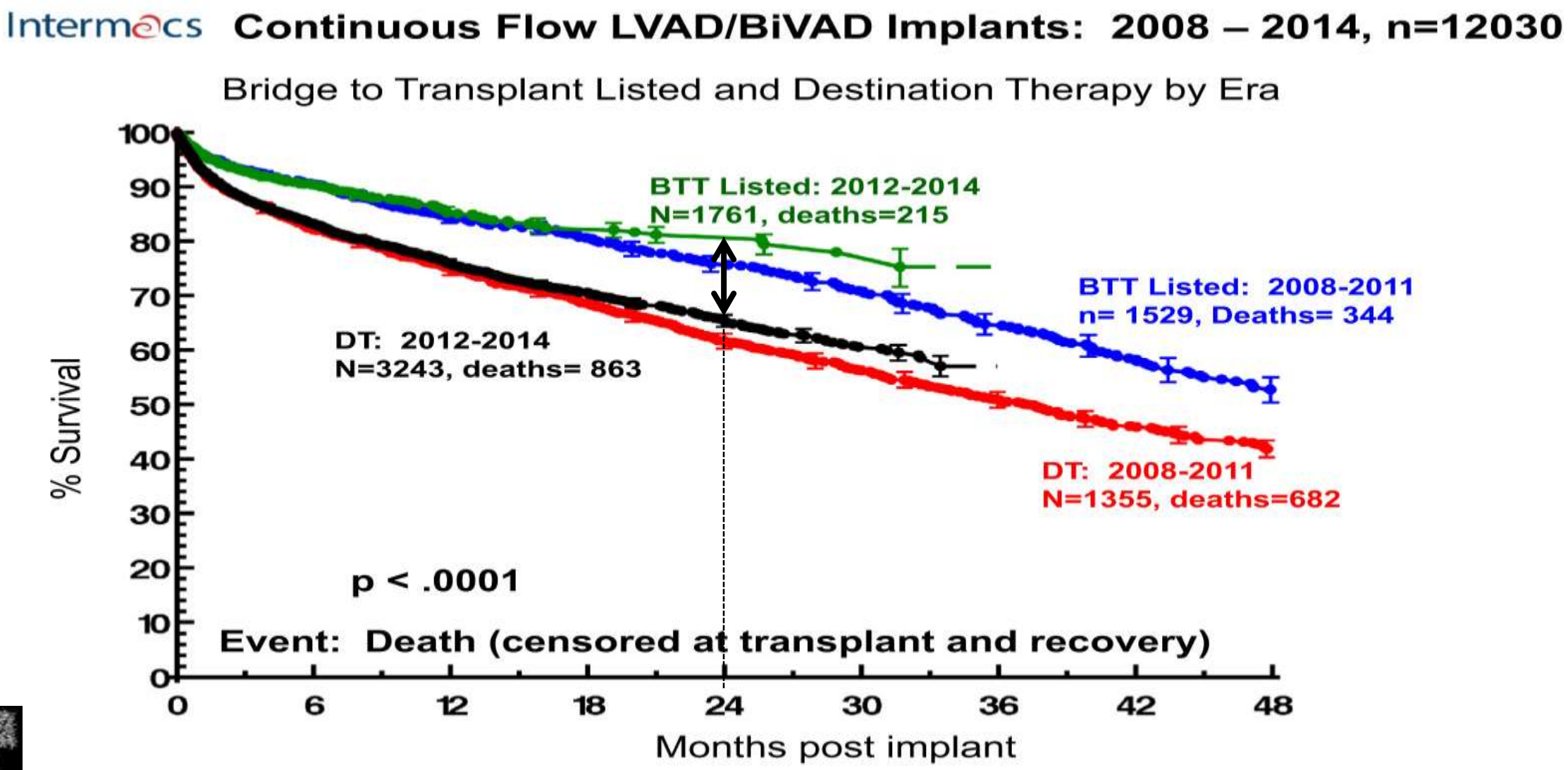
Adaptace srdečního výdeje při zátěžovém testu



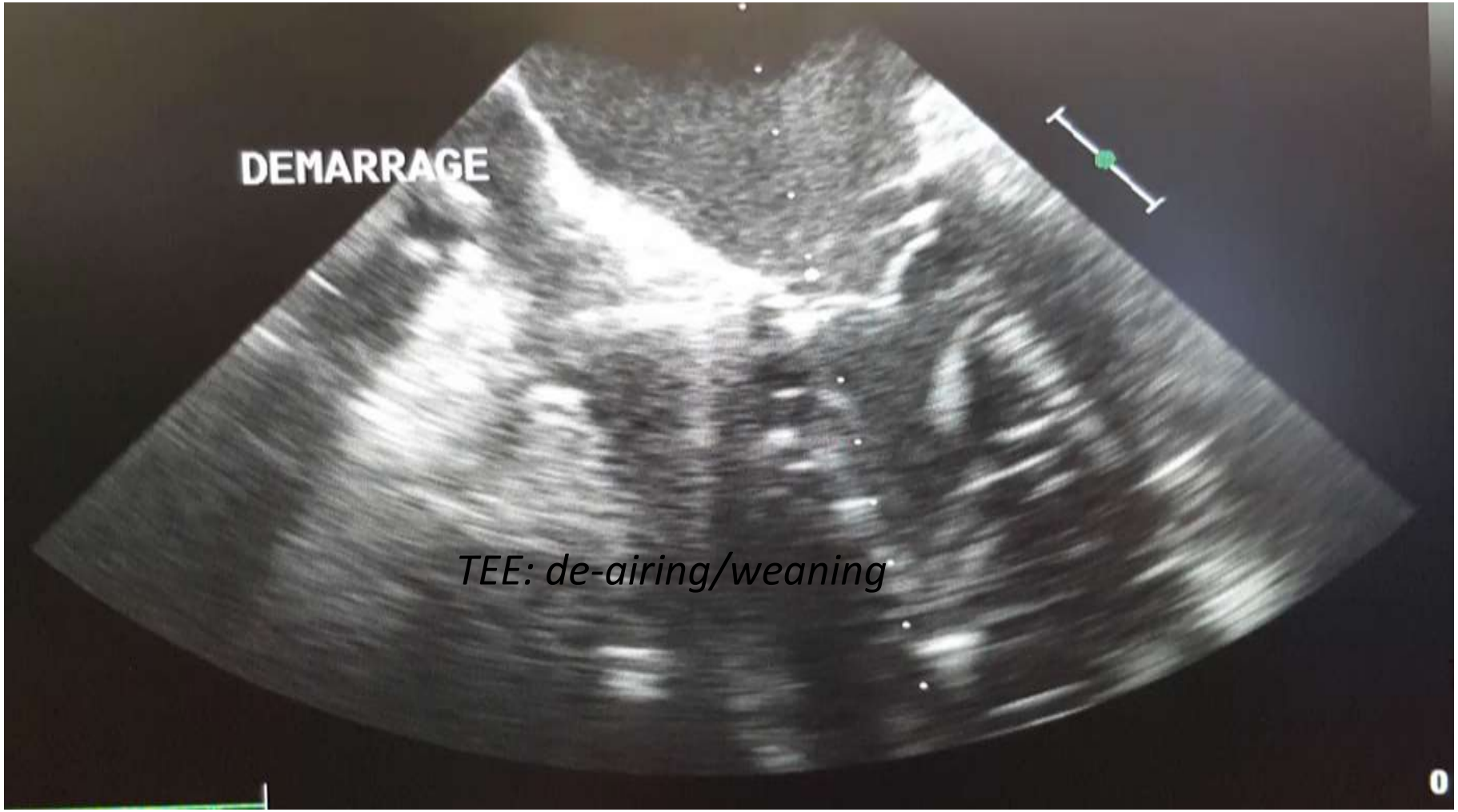
Souhrn

- Mini-invazivní implantační technika
- Přežití prakticky srovnatelné s transplantací srdce
- Eliminace trombózy čerpadla
- Snížení komplikací v doméně hemokompatibility
- Reálný horizont uvedení plně implantabilních LVAD
- Klinické testování fyziologické biventrikulární náhrady srdce

Registr INTERMACS

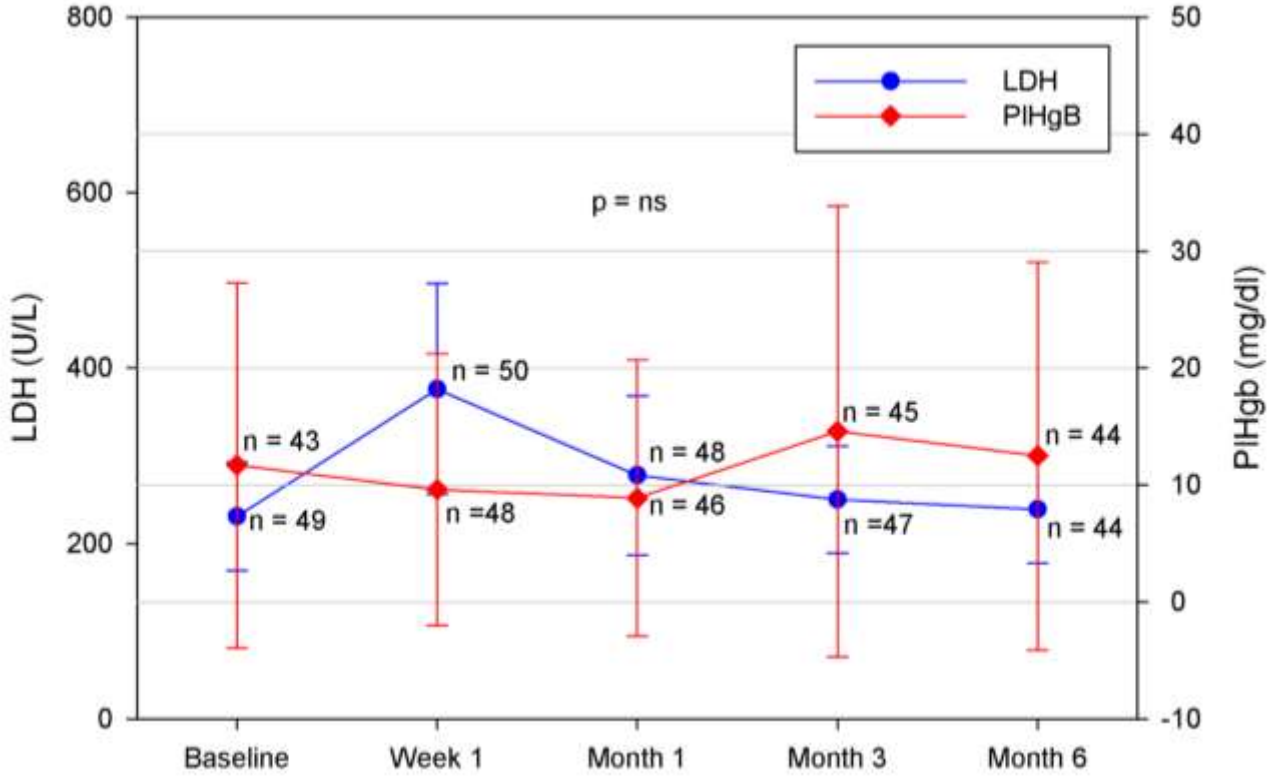


TEE monitorace

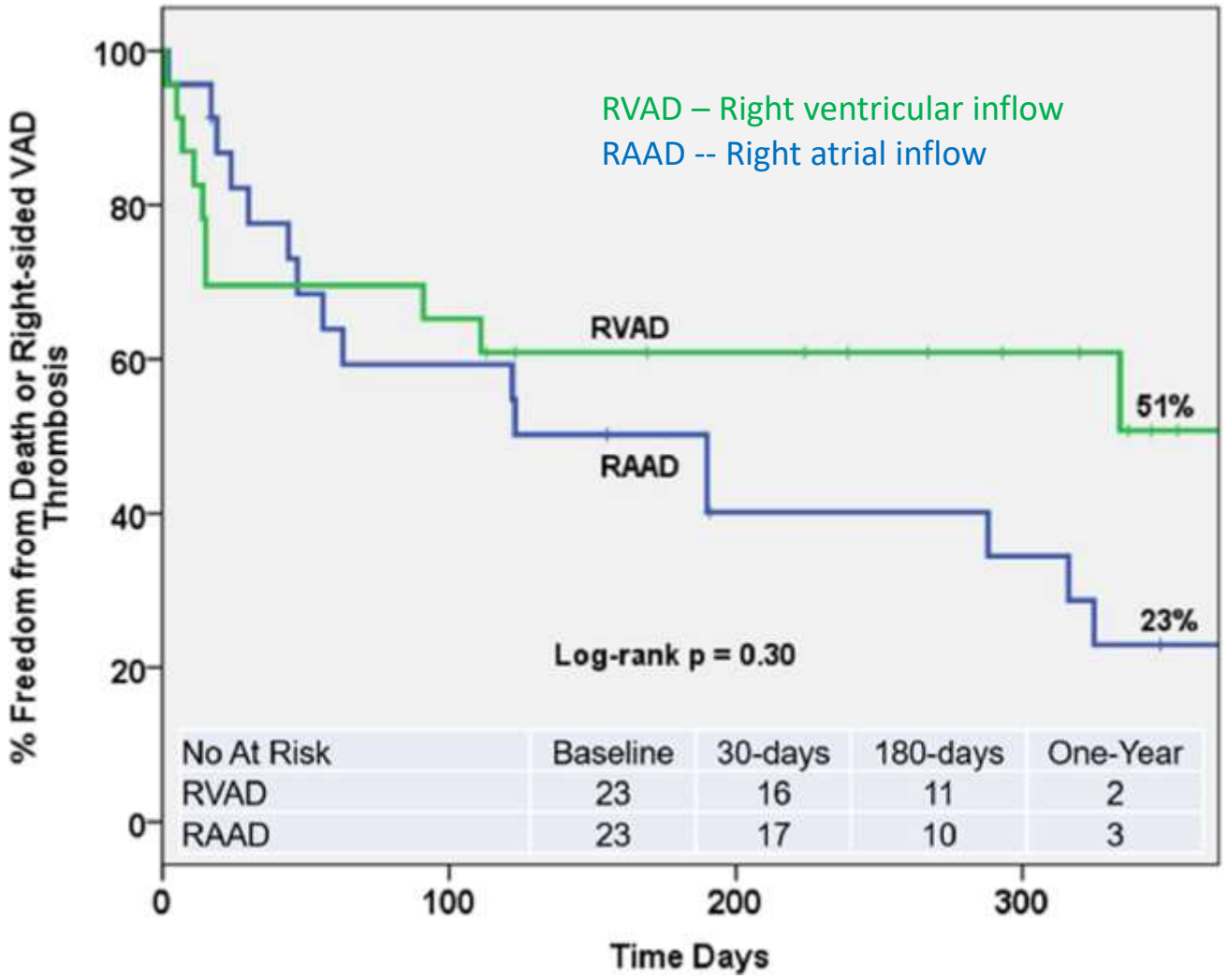


Iniciální pozorování hemokompatibility LVAD HeartMate 3

	Days 0 – 30 (n=50)			Days 0 – 180 (n=50)		
Event	# Pts	% Pts	# Events	# Pts	% Pts	# Events
Pump Malfunction	0	0%	0	0	0%	0
Pump Thrombosis	0	0%	0	0	0%	0
Hemolysis	0	0%	0	0	0%	0



HeartWare BIVAD



J Heart Lung Transplant. 2018;37:1093-1101

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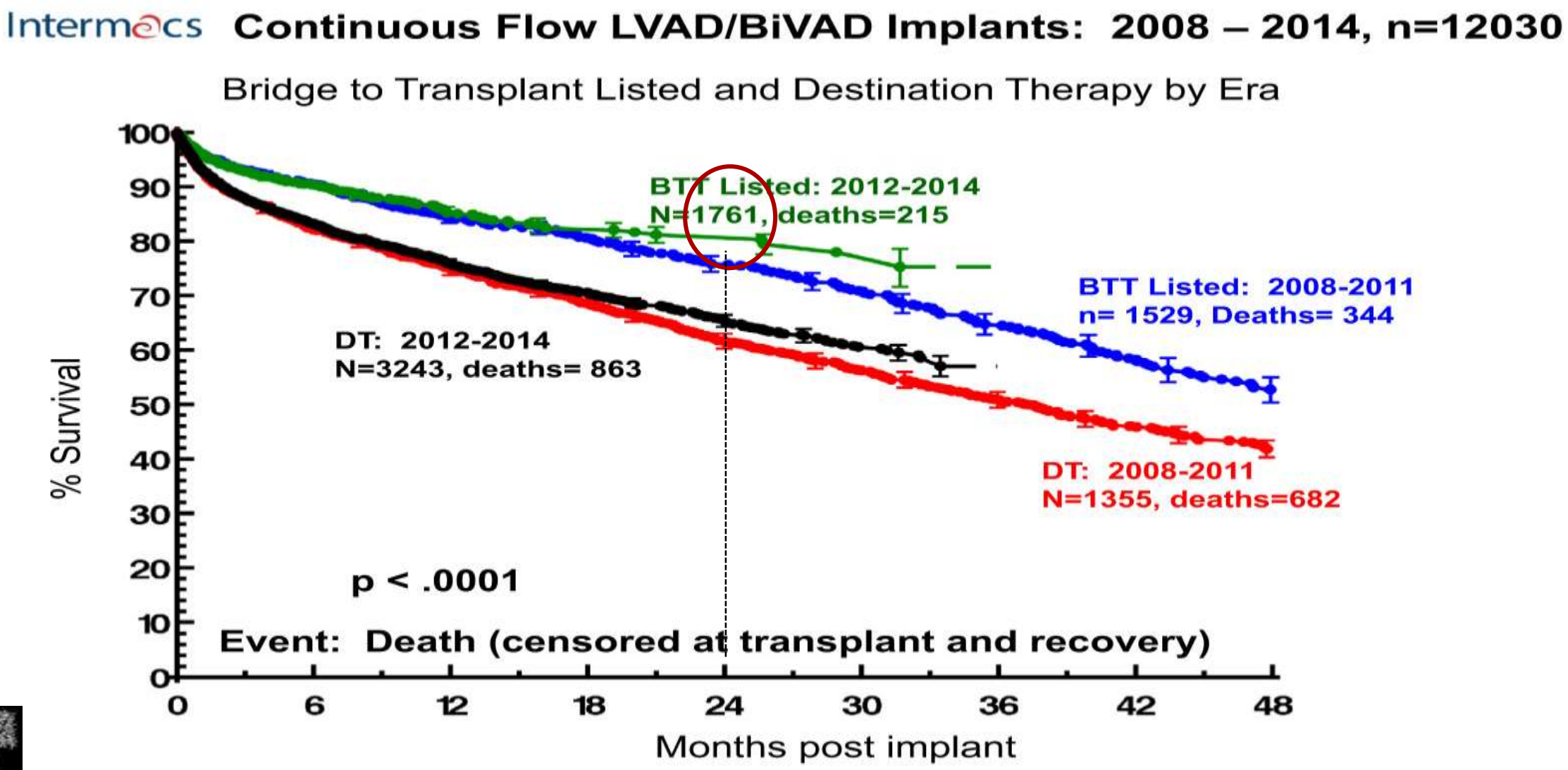
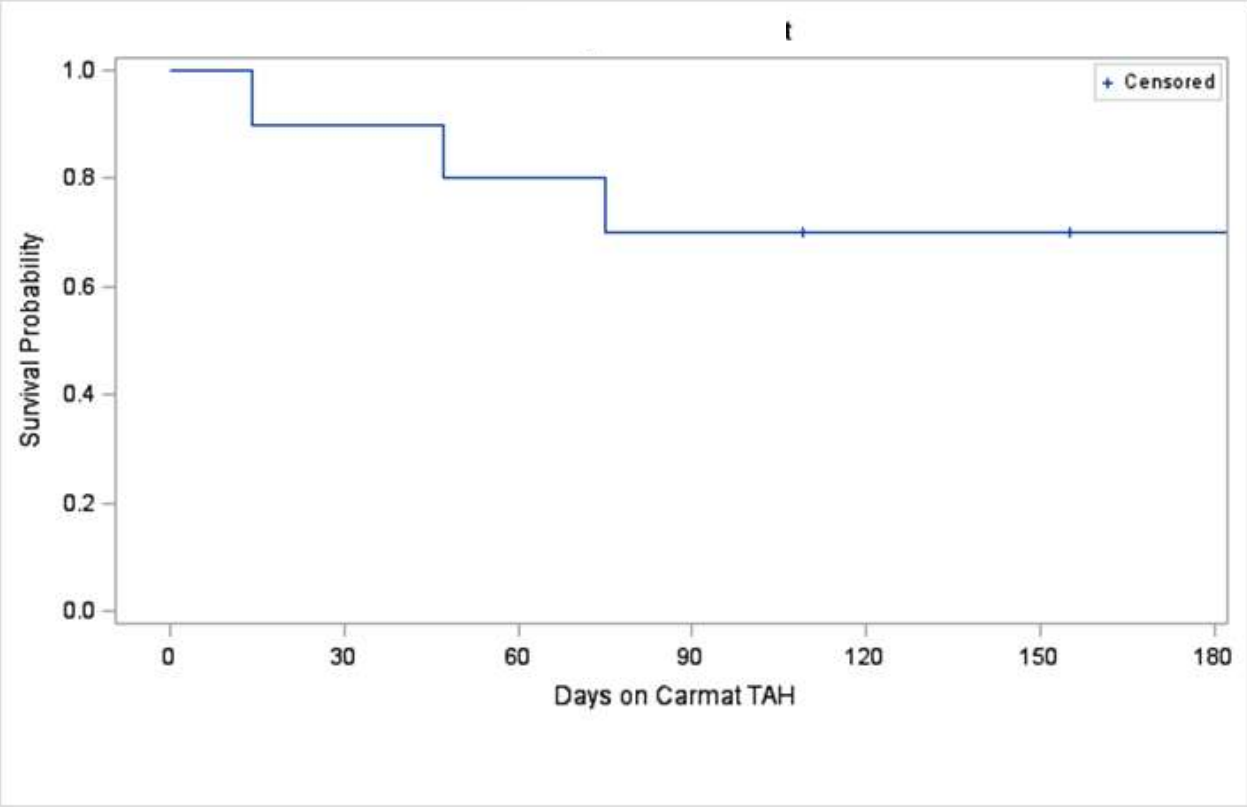


Carmat CE Mark Trial - 1. kohorta (n=10)

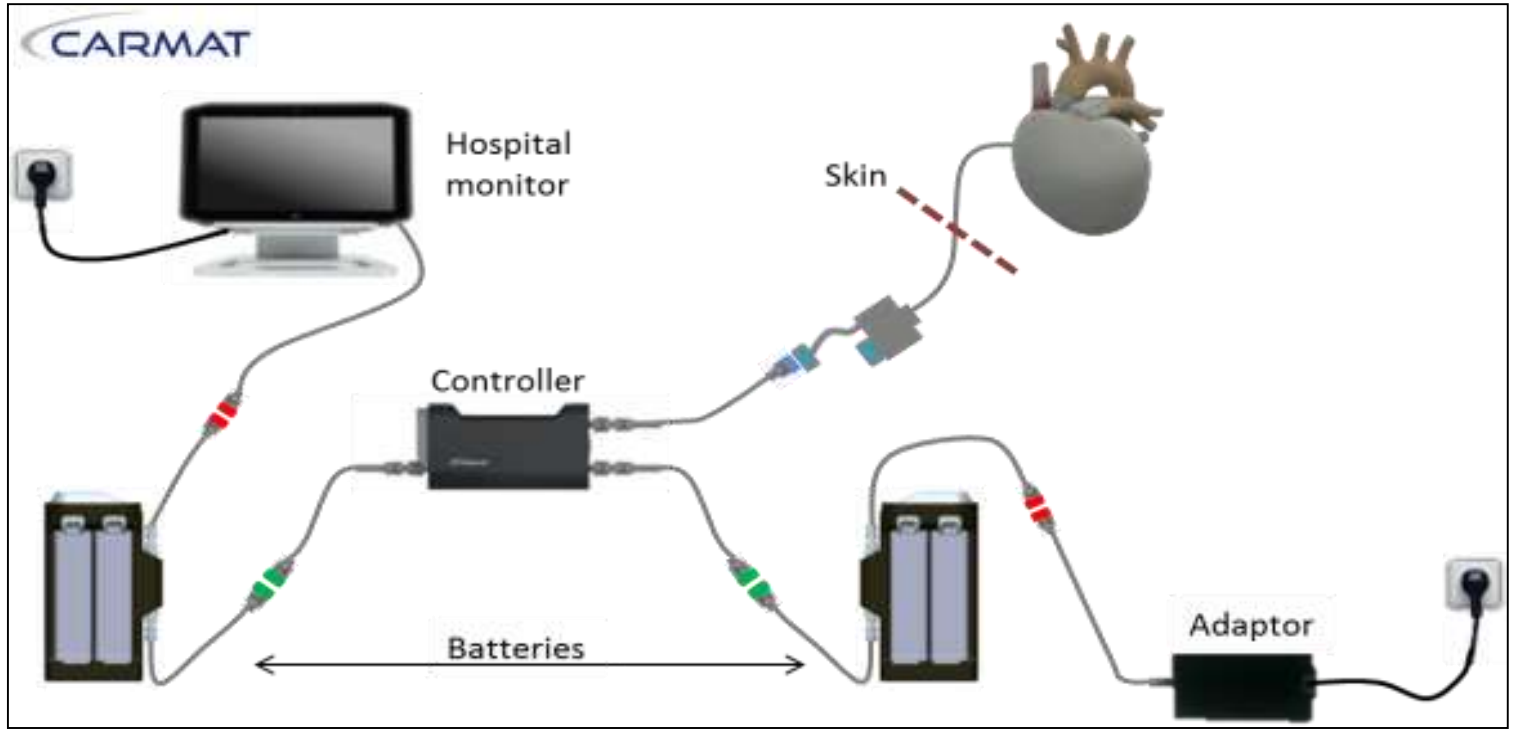
Přežití 6 měsíců = 70%



	Přežití 6 měsíců
CARMAT FIM	50%
CARMAT CE Mark Trial	**70%**
SynCardia*	54% - 62%
BIVAD**	46% - 68%
LVAD***	90% - 92%

* Kirklin JK *et al.*, J Heart Lung Transplant 2018;37:685-691. Arabia F *et al.*, J Heart Lung Transplant, 2018;37:1304–1312.
** Lavee J *et al.*, J Heart Lung Transplant 2018;37:1399–1402. Arabia F *et al.*, Ann Thorac Surg 2018;105:548–56.
*** Strueber M *et al.* J Am Coll Cardiol 2011;57:1375–82. Netuka I *et al.*, J Am Coll Cardiol 2015;66:2579–89.

Konfigurace systému Carmat



Wearable System

- Controller/monitor + 2x2 batteries
- Total weight 3 kg
- Autonomy at least 4 hours at 6 l/min