

Kde LVAD nestačí: Jak na biventrikulární srdeční selhání?

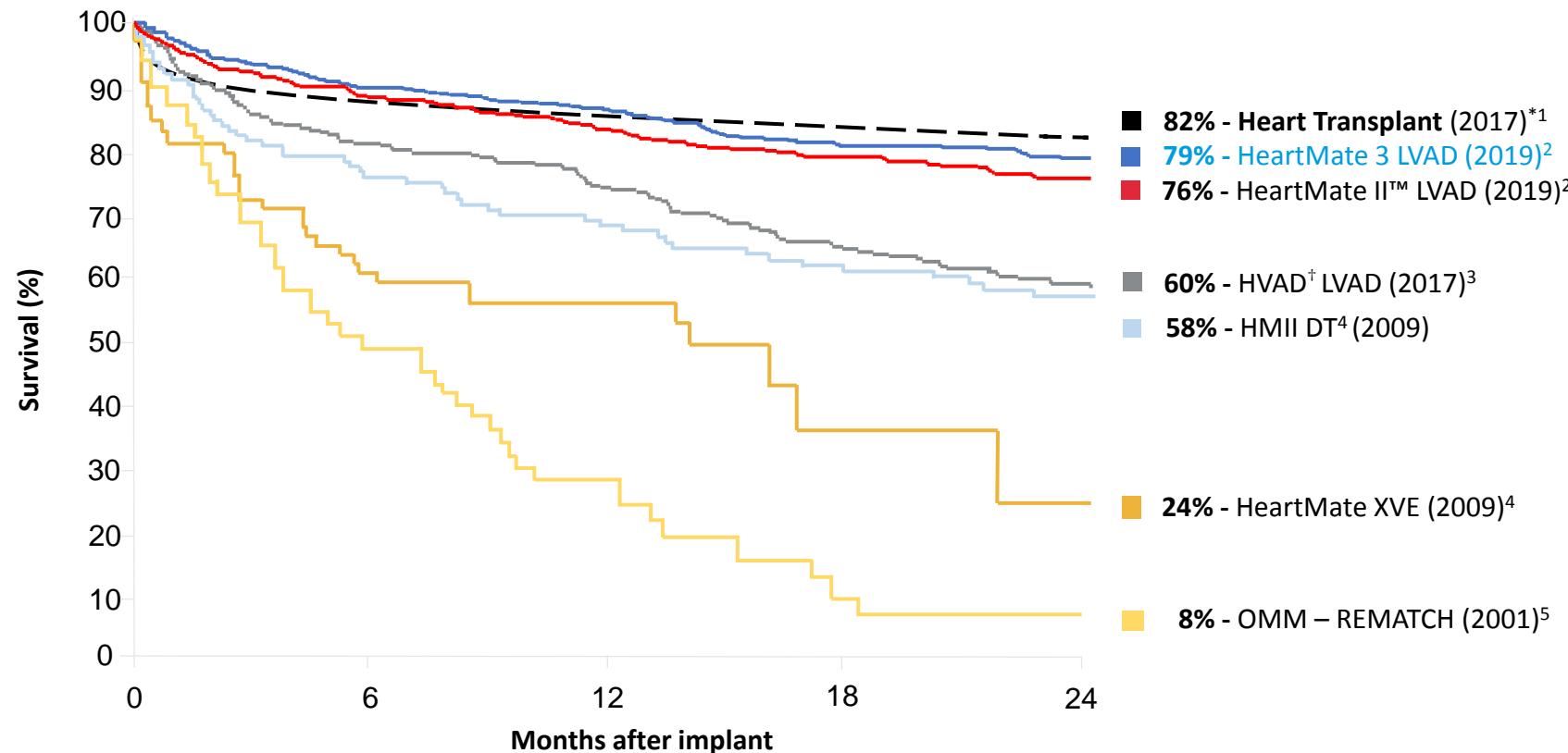
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Impact of advancing technology and the best practice



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 2015¹

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. Intraperitoneal 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.

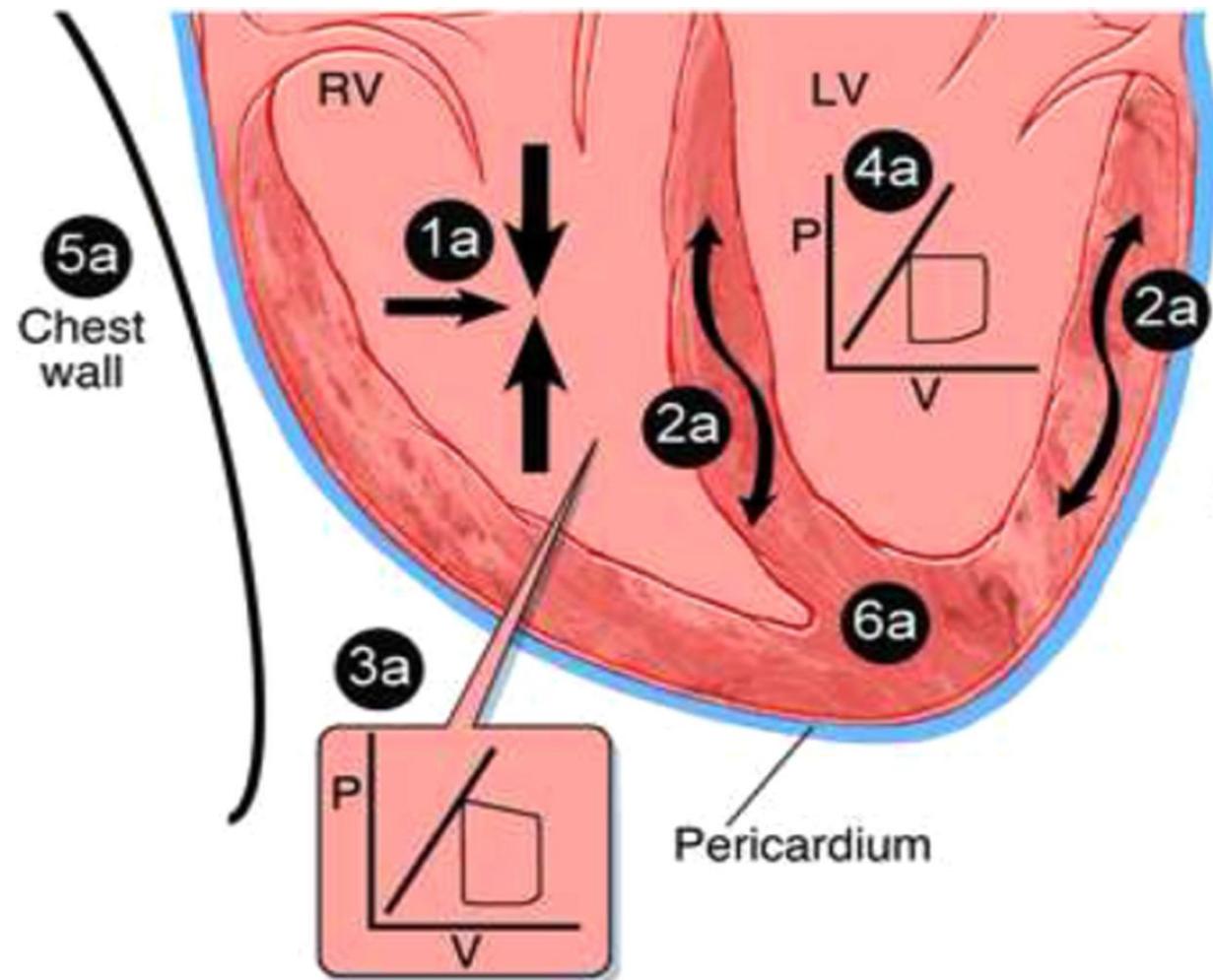


Two-Year Outcomes with a Magnetically Levitated Cardiac Pump in Heart Failure

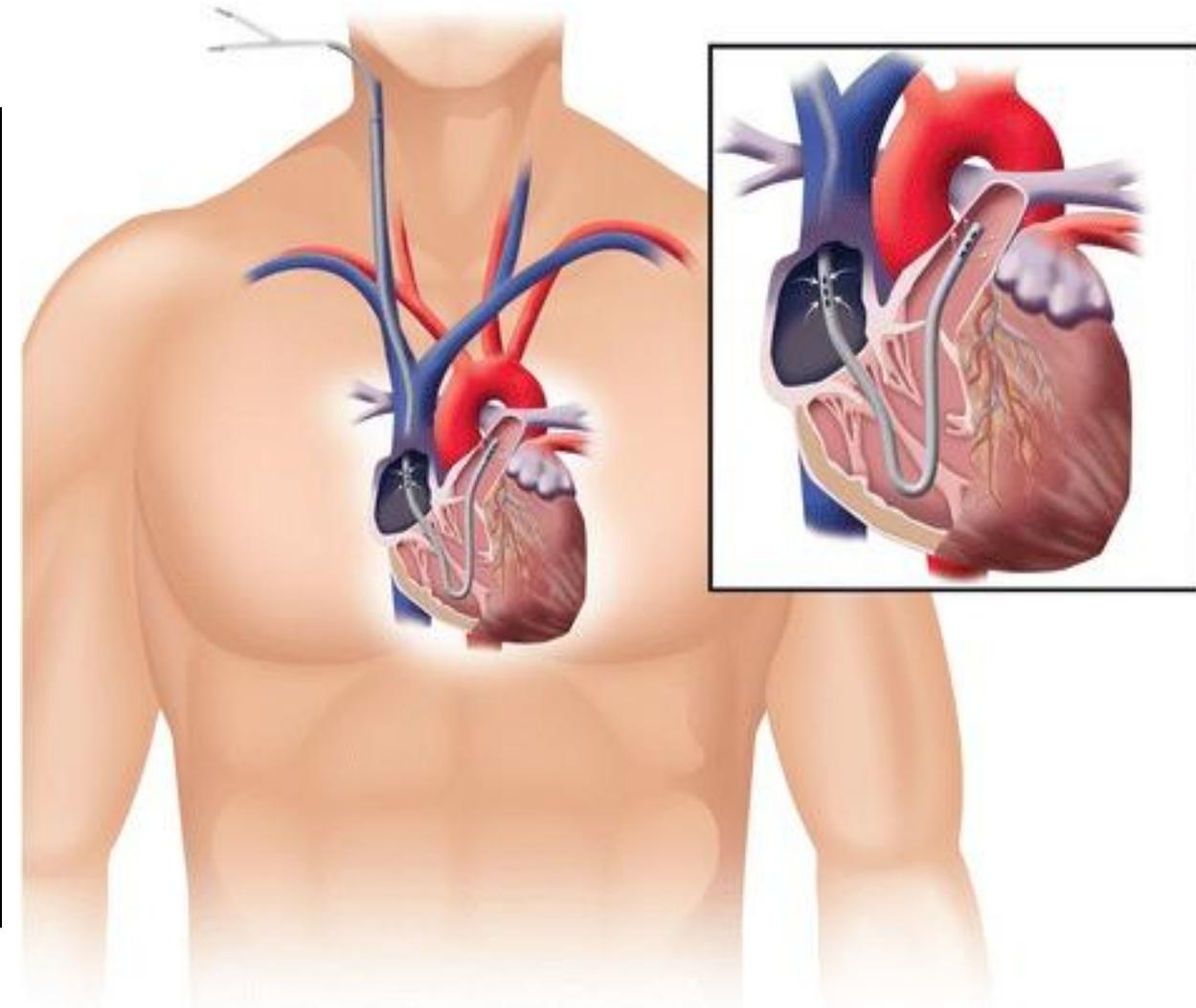
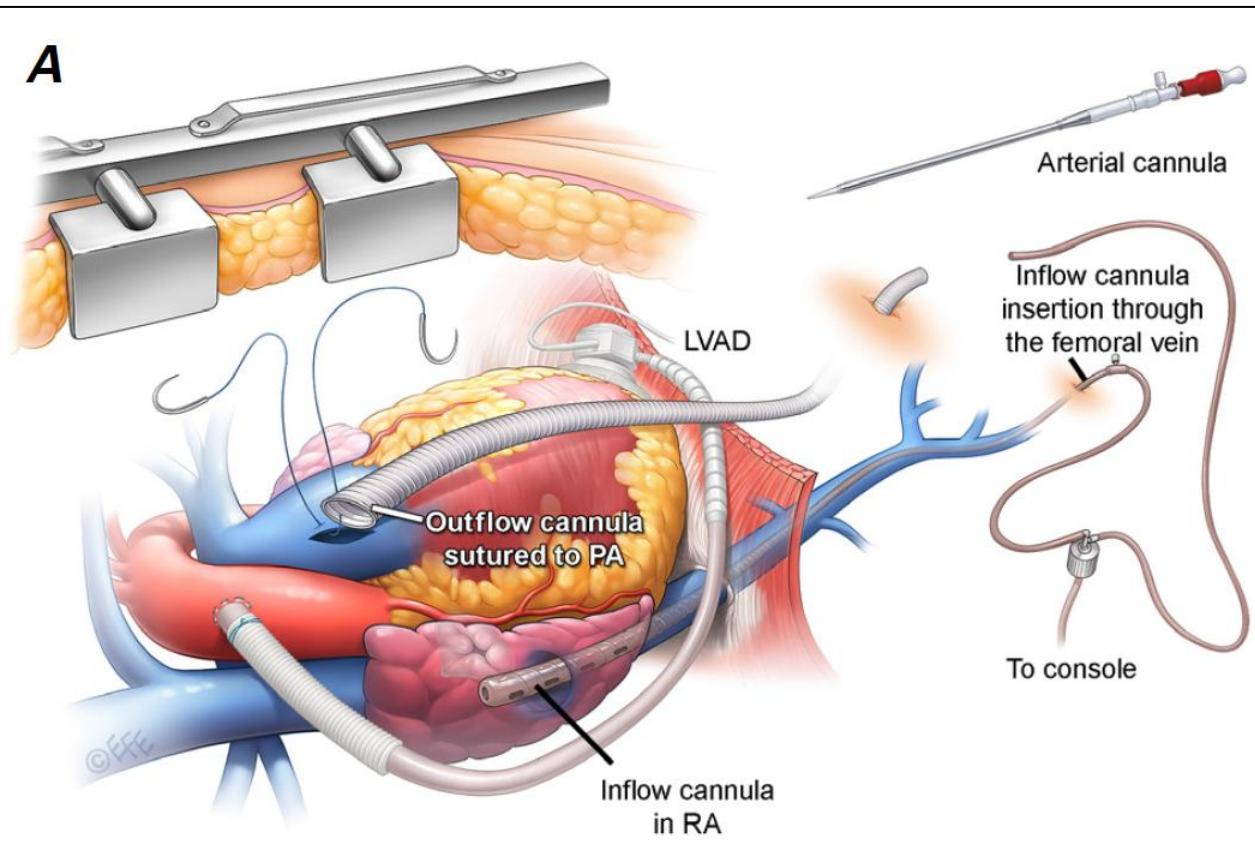
M.R. Mehra, D.J. Goldstein, N. Uriel, J.C. Cleveland, Jr., M. Yuzefpolskaya,

LVAS drive-line infection	45 (23.8)	68	34 (19.8)	59	1.15 (0.73–1.79)	0.37
Local infection not associated with LVAS	70 (37.0)	108	60 (34.9)	114	1.00 (0.71–1.42)	0.74
Right heart failure						
Any right heart failure	60 (31.7)	73	48 (27.9)	53	1.12 (0.77–1.64)	0.49
Right heart failure managed with RVAS	6 (3.2)	6	8 (4.7)	8	0.67 (0.23–1.94)	0.59
Cardiac arrhythmia						
Any cardiac arrhythmia	71 (37.6)	108	70 (40.7)	105	0.88 (0.63–1.23)	0.59
Ventricular arrhythmia	45 (23.8)	67	39 (22.7)	64	1.04 (0.67–1.59)	0.80
Supraventricular arrhythmia	33 (17.5)	40	36 (20.9)	37	0.79 (0.49–1.26)	0.42

Right Ventricle and LVAD Interplay



RVAD CentriMag & Protek Duo



BIVAD and TAH Target Population

Patients with end-stage heart failure, OMM refractory, requiring mechanical circulatory support in whom LVAD is considered inefficient or contraindicated:

- **RVEF ≤ 30%**
- **TAPSE ≤ 14mm**
- **RV-to-LV end-diastolic diameter ratio > 0.72**
- **CVP > 15 mmHg**
- **CVP-to-PCWP ratio > 0.63**
- **PAPi ≤ 2.0 (PAs - PAd/CVP)**
- **Tricuspid insufficiency grade 4**

In patients with severe chronic biventricular failure, a BiVAD or a TAH should be considered.

IIa

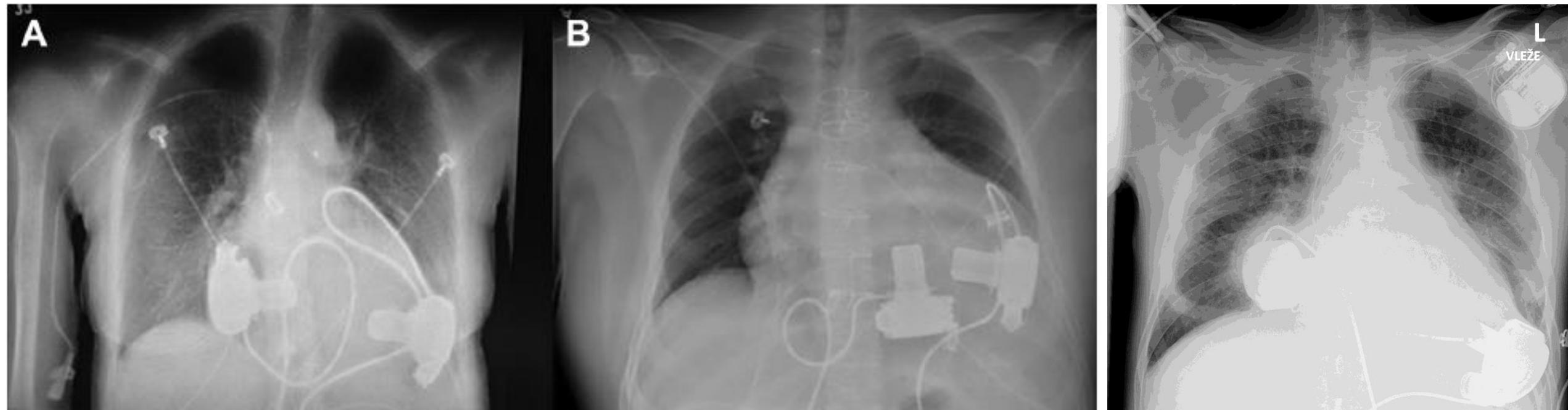
B

[81, 147,
162–178,
187–191,
200,
203–208,
212]

Potapov et al. EJCVS, 2019



Biventricular LVAD implant (BIVAD)

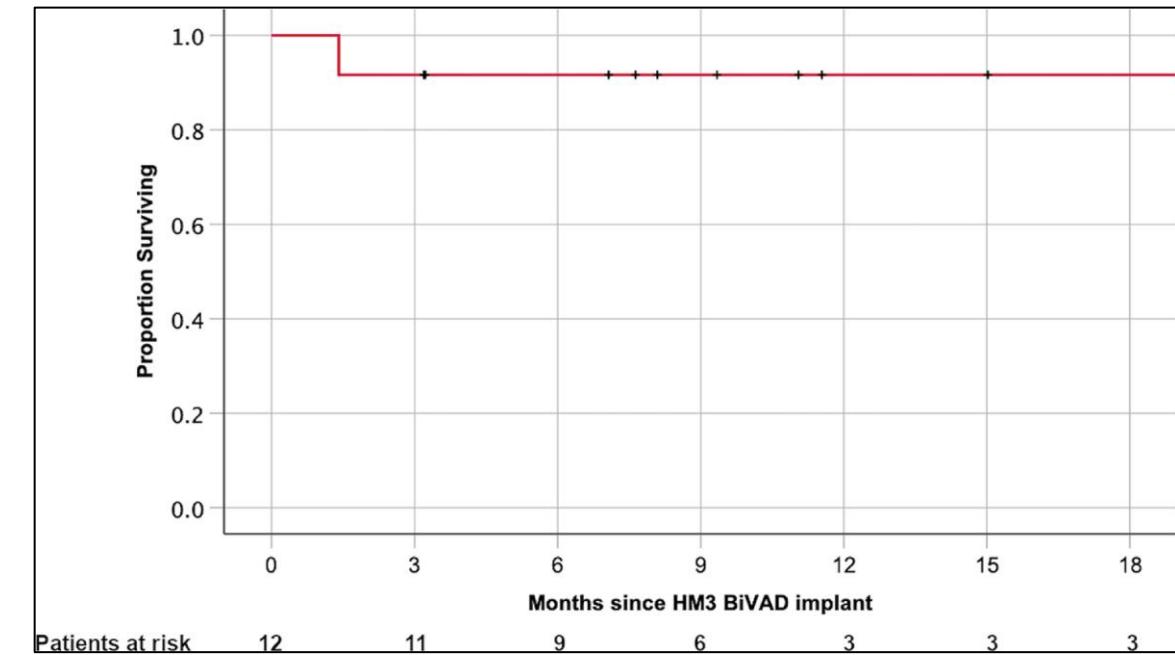
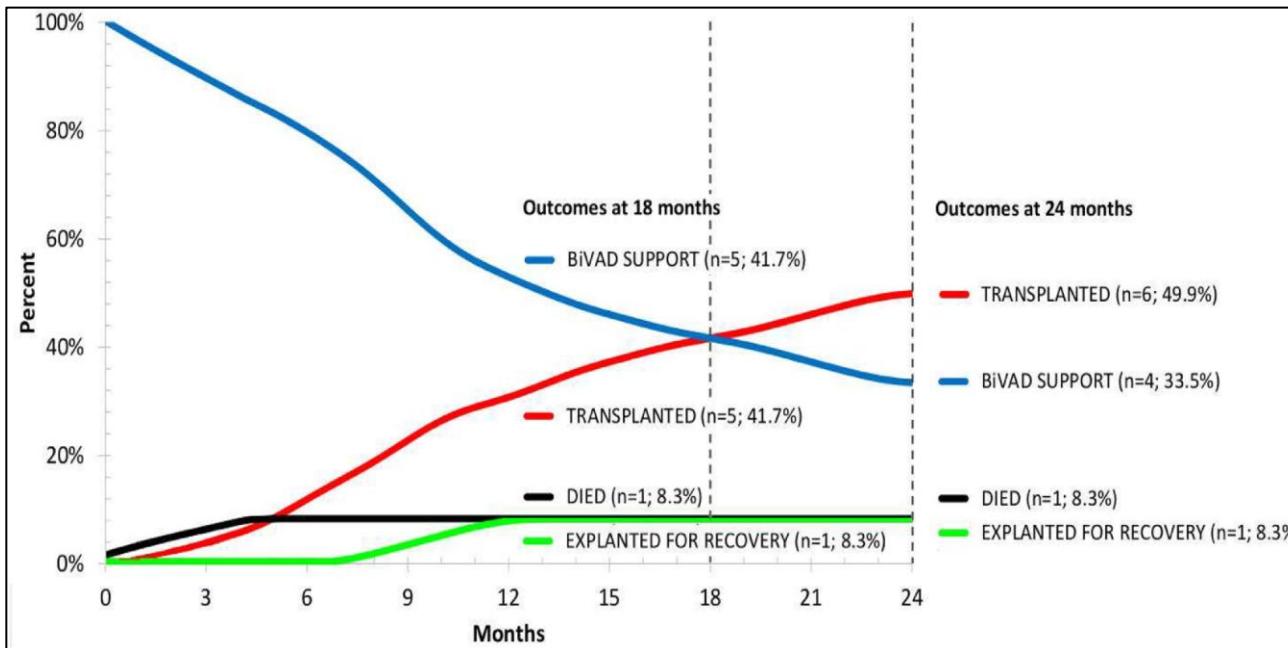


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ČESKÉ KARDIOLOGICKÉ
SPOLEČNOSTI



The results of a single-center experience with HeartMate 3 in a biventricular configuration

David McGiffin, MD,^a Christina Kure, PhD,^a Janelle McLean, RN,^b
Silvana Marasco, MD, PhD,^a Peter Bergin, MD,^b James L. Hare, MD, PhD,^b
Angeline Leet, MD,^b Hitesh Patel, MD, PhD,^b Adam Zimmet, MD,^a
Julia Rix, RN,^b Andrew Taylor, MD, PhD,^b and David Kaye, MD, PhD^b



TAH Target Population

Patients with end-stage heart failure, OMM refractory, requiring mechanical circulatory support in whom LVAD is considered inefficient or contraindicated:

- **Ventricular thrombosis**
- **Ventricular septal defect**
- **Restrictive/constrictive etiologies**
- **Cardiac tumors**
- **Refractory arrhythmias**
- **Fulminant rejection after HTx**

A TAH may be indicated in patients with biventricular failure, restrictive cardiomyopathy, cardiac tumours or large ventricular septal defects.	IIb	C	[187, 193, 197-201]
In patients with anatomical or other clinical conditions that are not well served with an LVAD or BiVAD, implantation of a TAH may be considered.	IIb	C	[203-208]

Potapov et al. EJCVTS, 2019



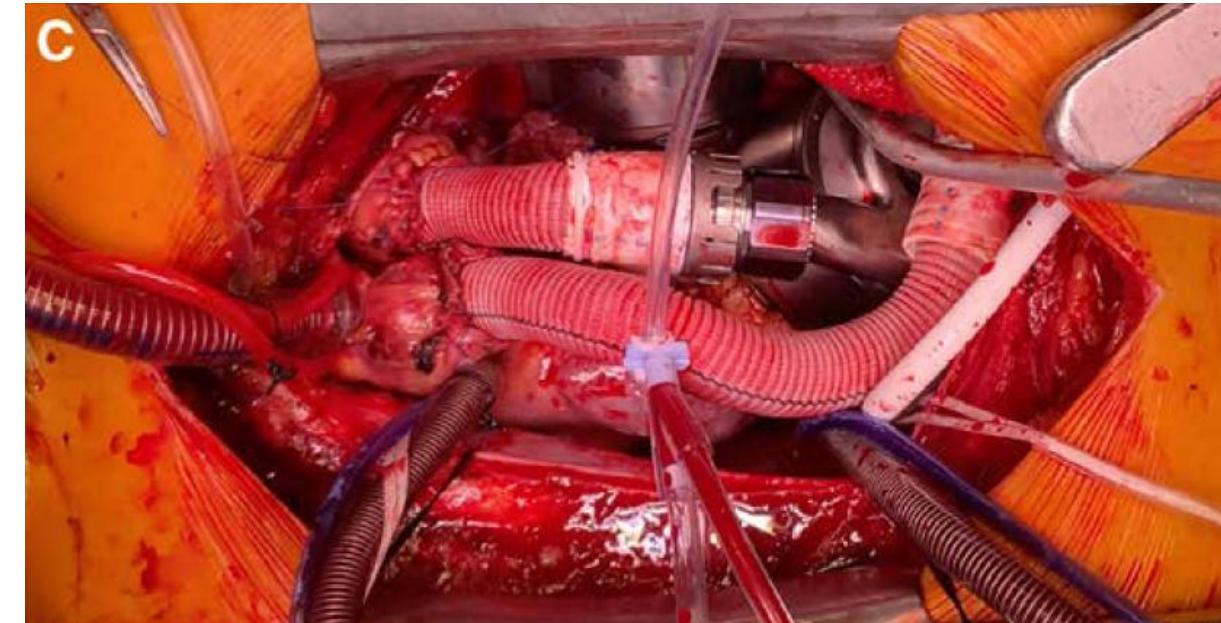
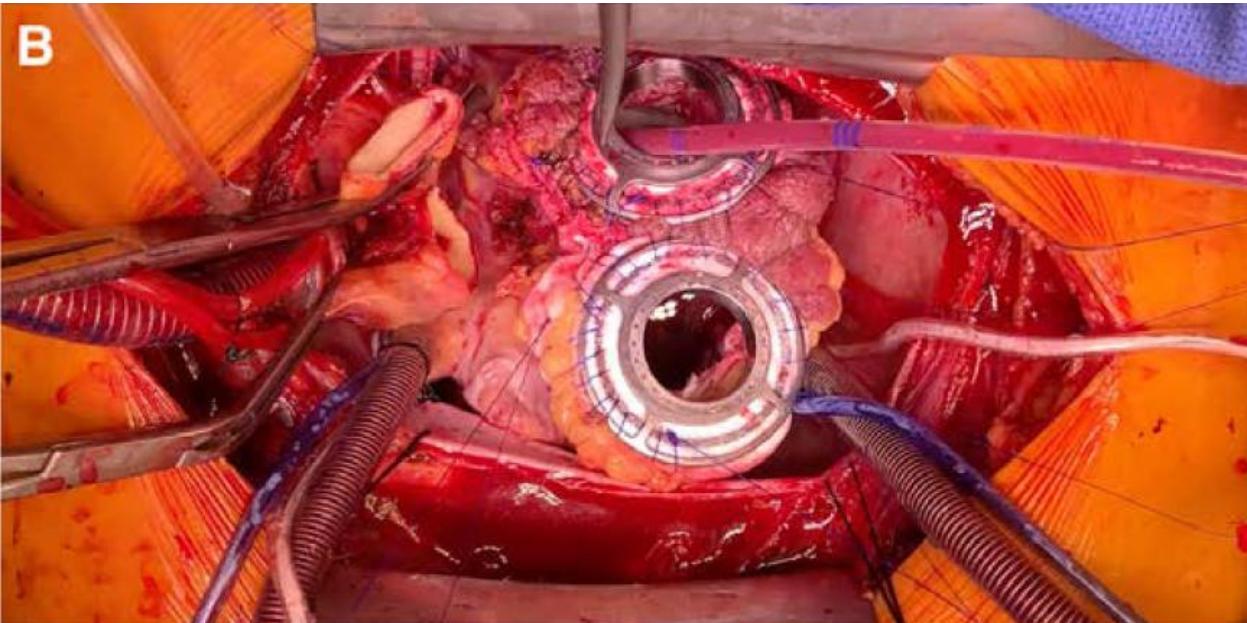
HeartMate 6 – TAH Alternative

Adult

Operative Techniques in
Thoracic and
Cardiovascular Surgery

Implantation of two HeartMate 3s in the setting of a Total Artificial Heart

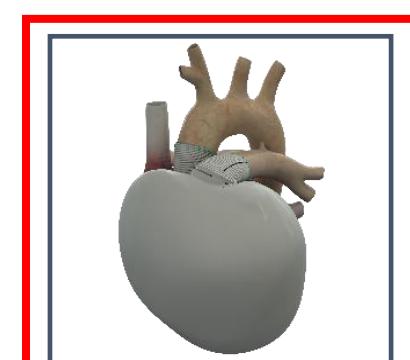
Jasmin S. Hanke, MD, Günes Dogan, MD, Axel Haverich, MD, PhD and
Jan D. Schmitto, MD, PhD



Novel Total Artificial Hearts

TOTAL ARTIFICIAL HEART

PULSATILE FLOW



ReinHeart

RealHeart

CARMAT

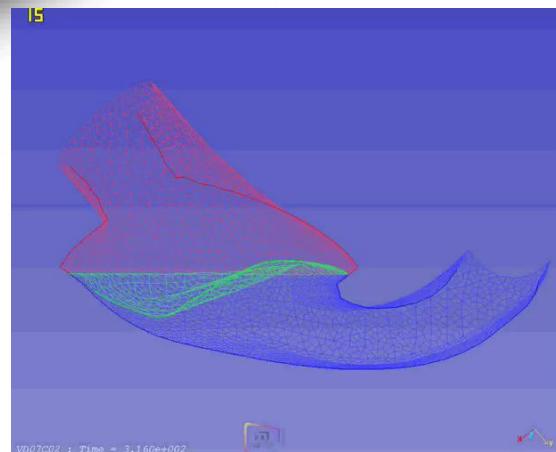
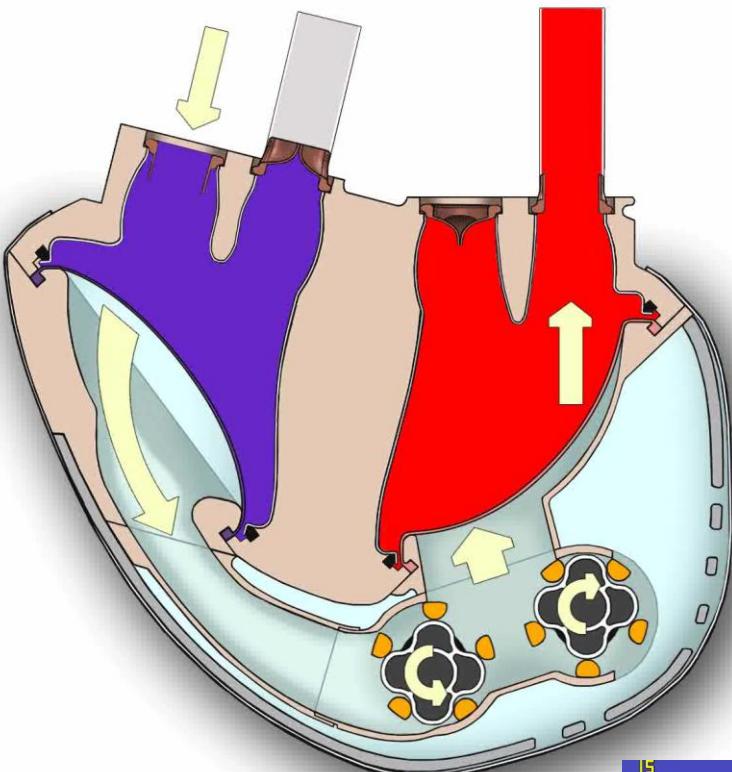
Carmat TAH CE-Mark Target Population

Patients with end-stage heart failure, OMM refractory, requiring mechanical circulatory support in whom LVAD is considered inefficient or contraindicated:

- Biventricular failure necessitating RVAD support in addition to LVAD
- Treatment-refractory recurrent ventricular tachycardia or fibrillation
- Restrictive or constrictive physiology (hypertrophic cardiomyopathy, cardiac amyloidosis or other infiltrative heart disease)



Principle of Carmat TAH – Sensors based autoregulation



1 – Blood flow assessment

Inflow pressure measured by sensors every millisecond to calculate flow required

2 – Flow auto-regulation

Speed and direction of rotation of volumetric pumps adapted every 2 milliseconds to deliver the necessary pulsatile flow

3 – Flow Control

Position of the membranes checked by 2 ultrasound sensors every 2 milliseconds to ensure full ejection at every beat, to avoid stasis in blood compartment



Initial bridge to transplant experience with a bioprosthetic autoregulated artificial heart

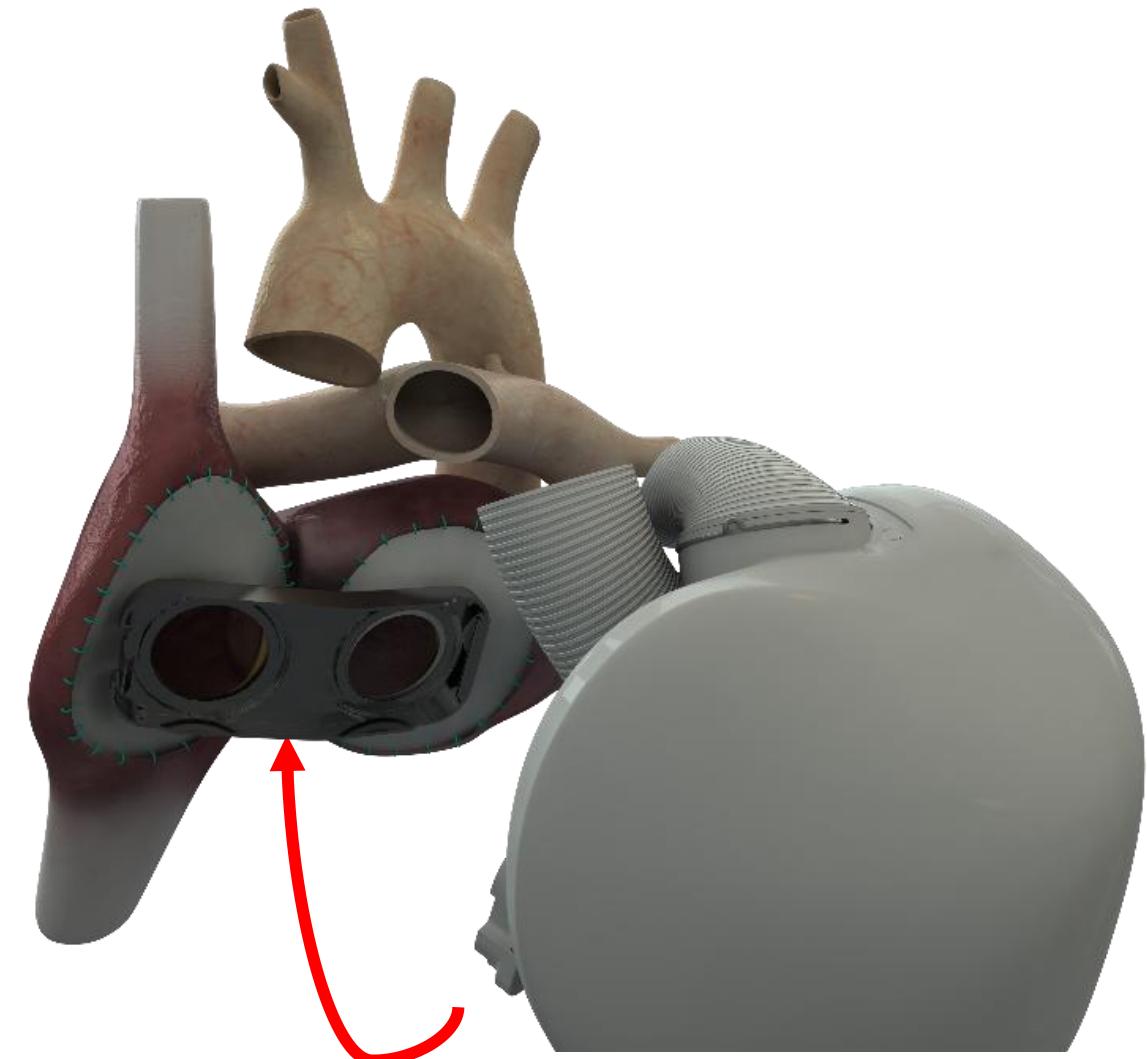


CrossMark

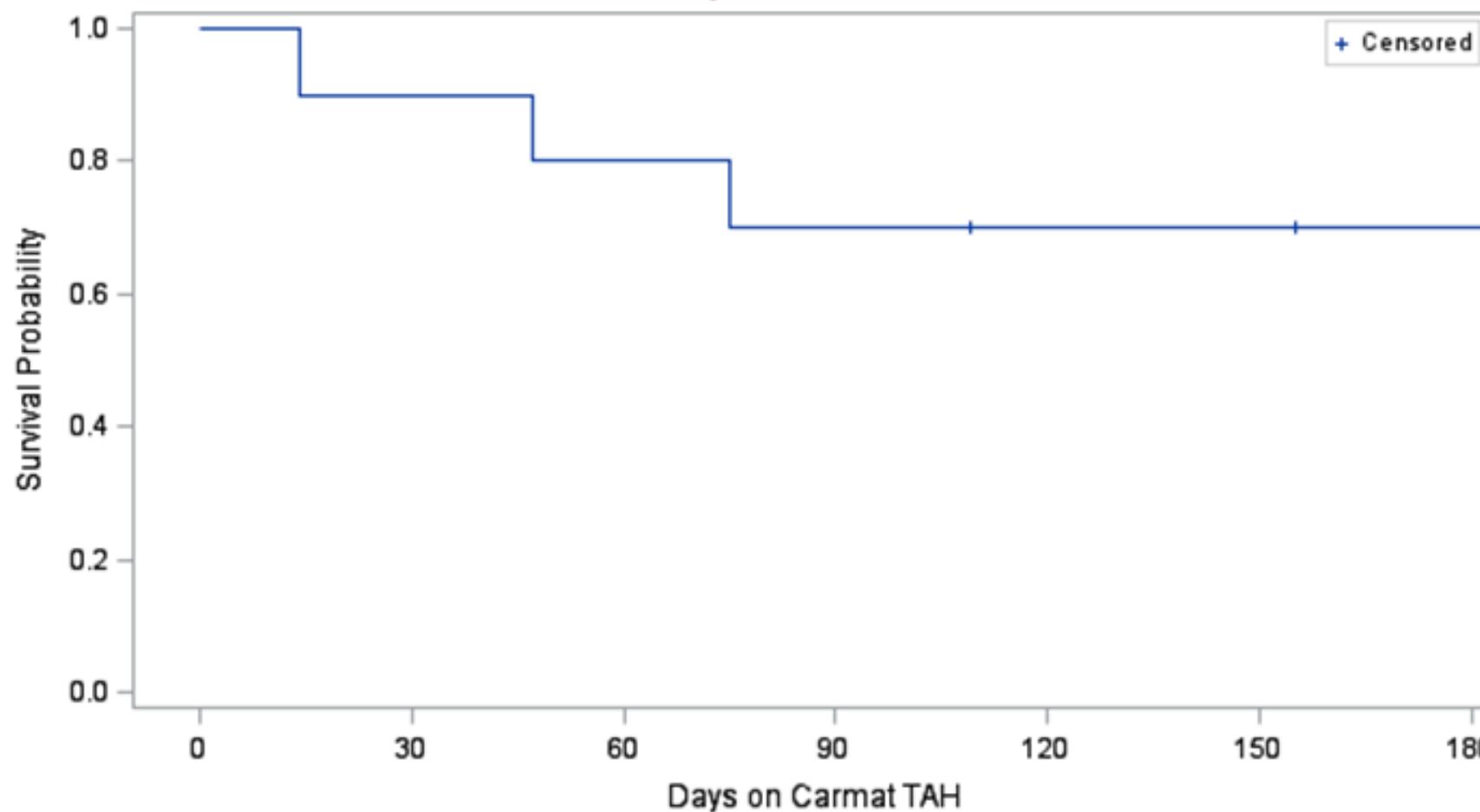
Ivan Netuka, MD, PhD,^a Yuriy Pya, MD,^b
Makhabbat Bekbossynova, MD,^b Peter Ivak, MD, PhD,^a
Miroslav Konarik, MD,^a Finn Gustafsson, MD, PhD,^c
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Christian Latrémouille, MD, PhD^d

J Heart Lung Transplant 2021

Carmat Total Artificial Heart



6-Month Survival in CE Mark Study



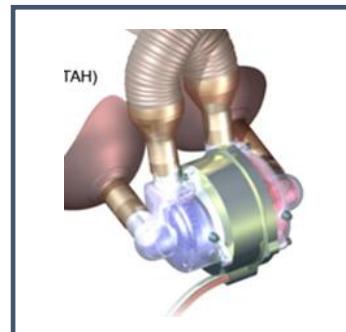
Novel Total Artificial Hearts

TOTAL ARTIFICIAL HEART

CONTINUOUS FLOW



BiVACOR



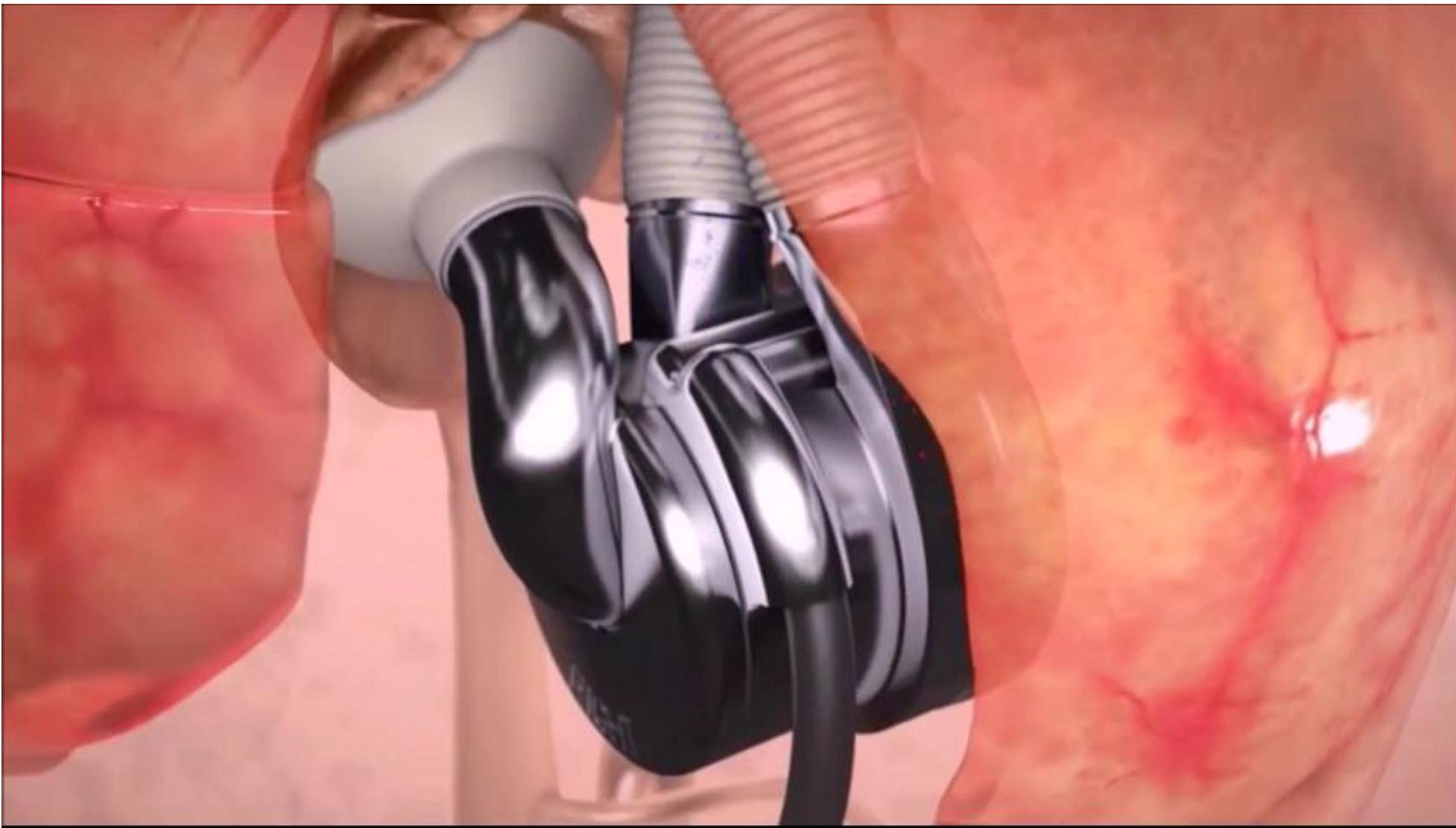
SmartHeart



OregonHeart



Continuous-flow TAHs



BiVACOR device operation

Conclusions

- Complex interaction between RV and implanted LVAD
- Lower threshold for a less invasive temporary RVAD
- Dual LVADs in a BIVAD configuration outcomes encouraging
- Dual HeartMate 3 TAH - complex challenge
- Dedicated pulsatile Carmat TAH promising, yet long-term durability to be determined
- Continuous-flow rotary TAHs clinical testing warranted



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