

CARDIOLOGY
2023

STRATEGIES FOR MCS: WHAT'S AVAILABLE? CHOOSING THE RIGHT TECHNOLOGY FOR THE RIGHT CONDITION

Constantine D. Mavroudis, MD, MSc, MTR
Children's Hospital of Philadelphia

Feb 24, 2023



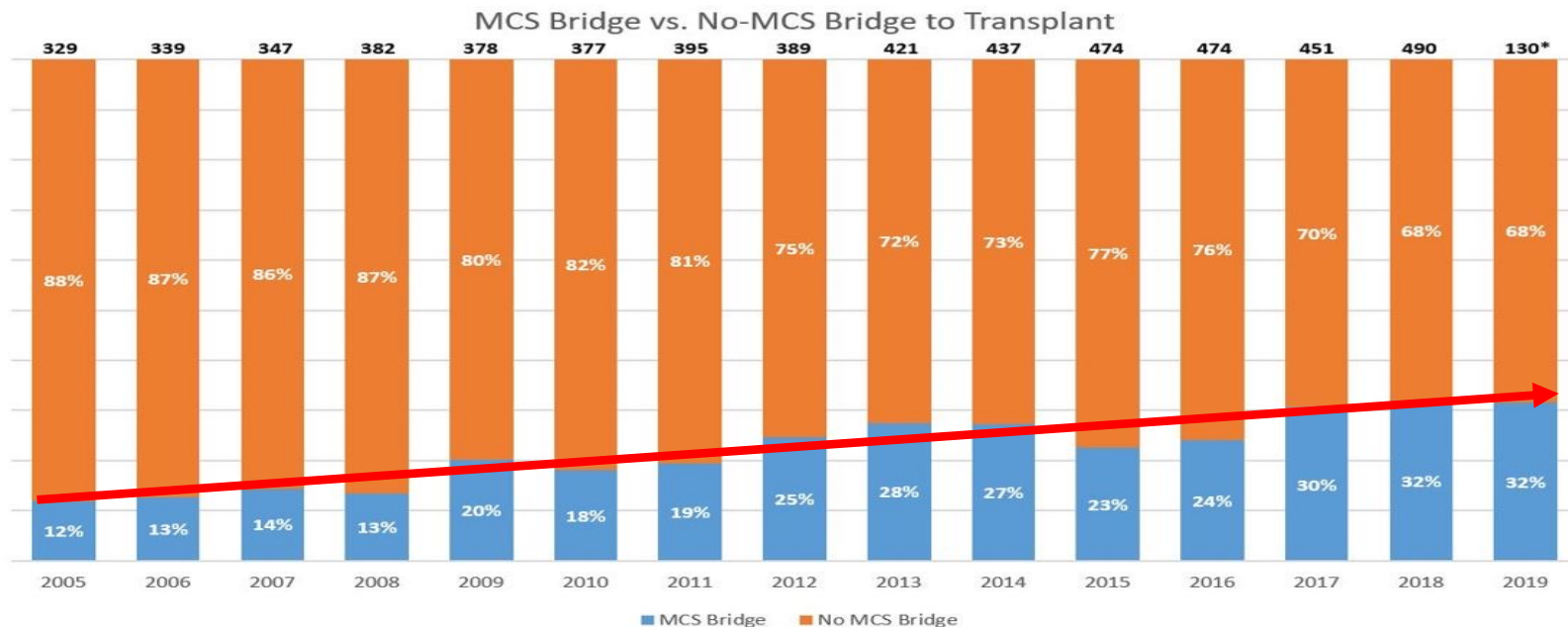
NO DISCLOSURES

**** Will be discussing off label
use of devices****

OUTLINE

- Trends in MCS usage in pediatric patients
- Specific devices and their indications
- Specific pediatric indications and strategies
 - BiVAD support
 - Single ventricle VAD support
 - Hybrid VAD

WHY DISCUSS MCS?



WHAT ARE PEOPLE USING?

	2005-2009 (n=282)	2010-2014 (n=496)	2015-2019 (n=511)	Overall (n=1289)	P-Value
LVAD (%)	62%	74%	85%	76%	<0.001
RVAD (%)	3%	2%	3%	2%	0.992
BiVAD (%)	37%	25%	13%	23%	<0.001
TAH (%)	1%	2%	1%	1%	0.820

WHAT ARE PEOPLE USING?

	2005-2009 (n=280)	2010-2014 (n=493)	2015-2019 (n=493)	P-value
Paracorporeal Continuous-flow (n, %)	14 (5%)	38 (8%)	67 (14%)	<0.001
Paracorporeal Pulsatile-flow (n, %)	206 (74%)	298 (60%)	179 (36%)	<0.001
Intracorporeal Continuous-flow (n, %)	36 (13%)	145 (29%)	243 (49%)	<0.001
Intracorporeal Pulsatile-flow (n, %)	24 (9%)	12 (2%)	4 (1%)	<0.001

WHY ARE THEY USING THEM?

Risk Factor	Time of Listing	Time of Transplant	P-value
Inotrope Use (%)	48% → 33%		<0.001
Ventilator Dependence (%)	24% → 17%		<0.001
Renal Dysfunction (%)	15% → 12%		0.007
Functional Status >50% (%)	36% → 50%		<0.001

WHAT ABOUT ECMO?

- Gold standard for rescue therapy, resuscitation, failure to wean, etc
- Quick and easy initiation of support (usually!)
- Provides cardiac and respiratory support
- Historically was the only MCS option in pediatric patients
- But how is it as a bridge to transplant?

ECMO: BRIDGE TO NOWHERE?

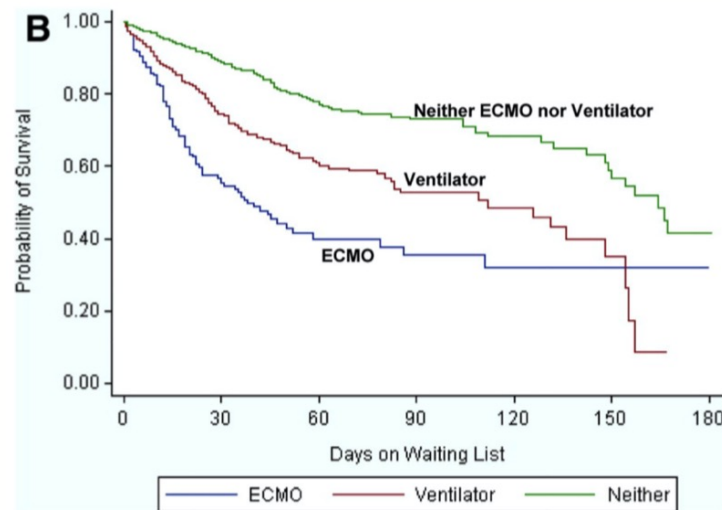
Waiting List Mortality Among Children Listed for Heart Transplantation in the United States

Christopher S.D. Almond, MD, MPH[#], Ravi R. Thiagarajan, MBBS, MPH[#], Gary E. Piercey, BS, Kimberlee Gauvreau, ScD, Elizabeth D. Blume, MD, Heather J. Bastardi, NP, Francis Fynn-Thompson, MD, and T.P. Singh, MD, MSc

Department of Cardiology (C.S.D.A., R.R.T., G.E.P., K.G., E.D.B., H.J.B., T.P.S.), Cardiac Surgery (F.F.T.), and the Pediatric Transplant Center (C.S.D.A., E.D.B., H.J.B., F.F.T., T.P.S.), Children's Hospital Boston; the Department of Pediatrics, Harvard Medical School; and the Department of Biostatistics (K.G.), Harvard School of Public Health; all in Boston, Mass.

[#] These authors contributed equally to this work.

Circulation 2009



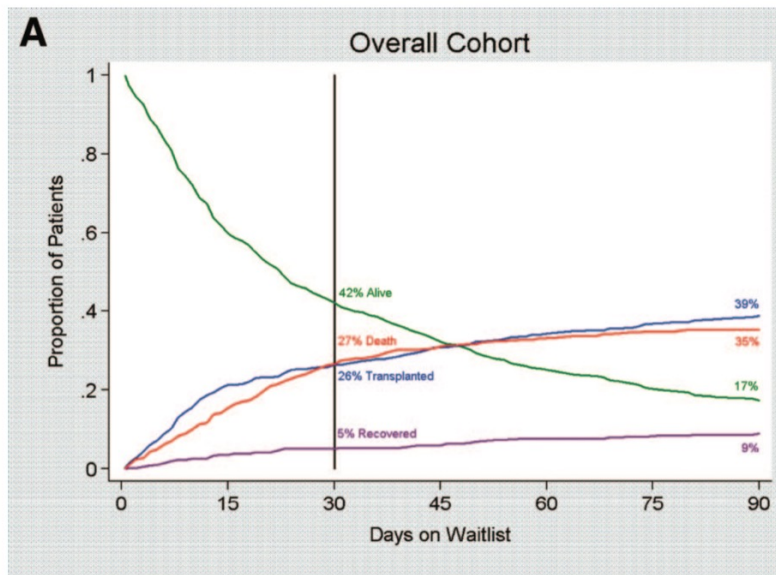
ECMO: BRIDGE TO NOWHERE?

Extracorporeal Membrane Oxygenation for Bridge to Heart Transplantation Among Children in the United States

Analysis of Data From the Organ Procurement and Transplant Network and Extracorporeal Life Support Organization Registry

Christopher S. Almond, MD, MPH; Tajinder P. Singh, MD, MSc; Kimberlee Gauvreau, ScD;
Gary E. Piercey, BS; Francis Fynn-Thompson, MD; Peter T. Rycus, MPH;
Robert H. Bartlett, MD; Ravi R. Thiagarajan, MBBS, MPH

Circulation 2011



BUT ARE VADS BETTER?

Modern Outcomes of Mechanical Circulatory Support as a Bridge to Pediatric Heart Transplantation

Brody Wehman, MD, Kristen A. Stafford, MPH, Gregory J. Bittle, MD, Zachary N. Kon, MD, Charles F. Evans, MD, Keshava Rajagopal, MD, PhD, Nicholas Pietris, MD, Sunjay Kaushal, MD, PhD, and Bartley P. Griffith, MD

Division of Cardiac Surgery, Department of Surgery, Department of Epidemiology and Public Health, and Division of Pediatric Cardiology, Department of Pediatrics, University of Maryland School of Medicine, Baltimore, Maryland

Ann Thorac Surg 2016;101:2321-8

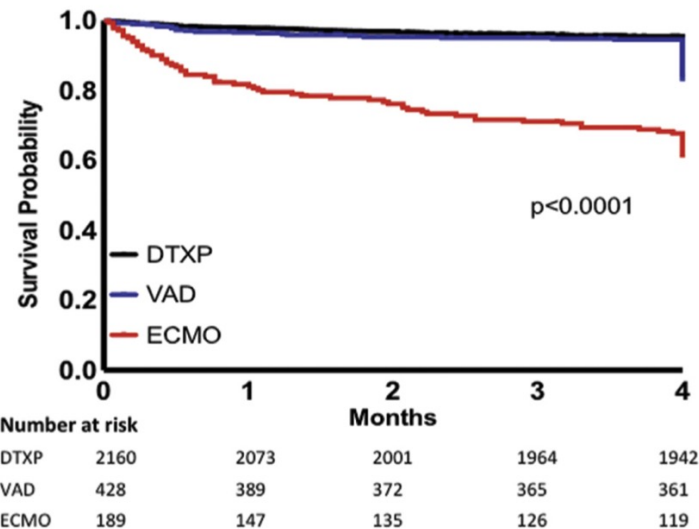
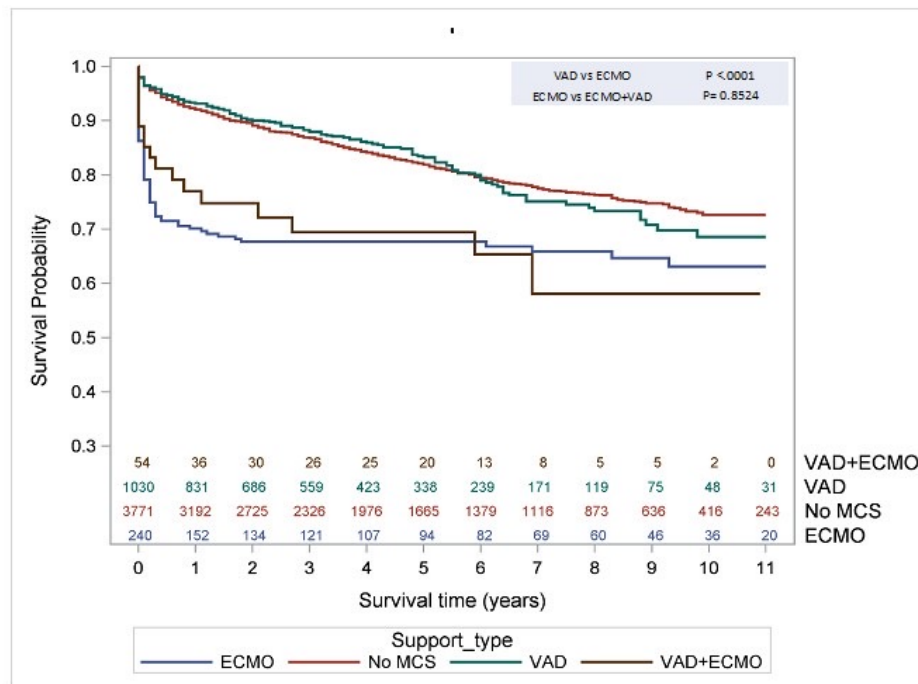


Fig 2. Kaplan-Meier survival curve for the first 4 months after transplant by bridge to transplant type (Wilcoxon $p < 0.0001$). (DTXP = direct transplantation [black line]; ECMO = extracorporeal membrane oxygenation [red line]; VAD = ventricular assist device [blue line].)

ECMO + VAD = BAD

Figure 2: Post-Transplant Survival Based on Pre-Transplant MCS:



ISHLT data
registry from
2005 to 2017

VADS ON VADS ON VADS

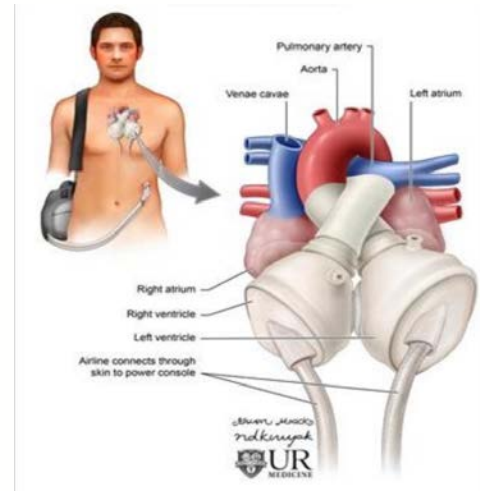
Heartmate 3



Berlin Heart



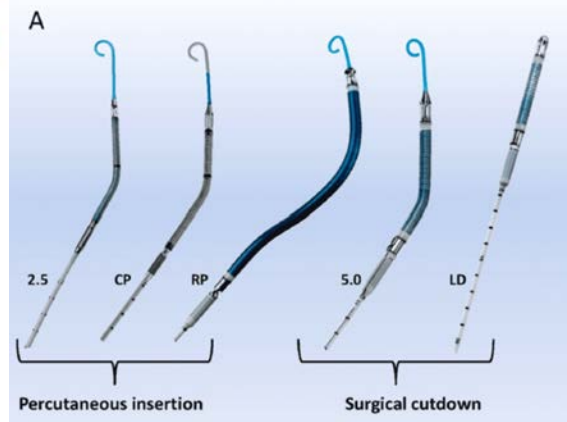
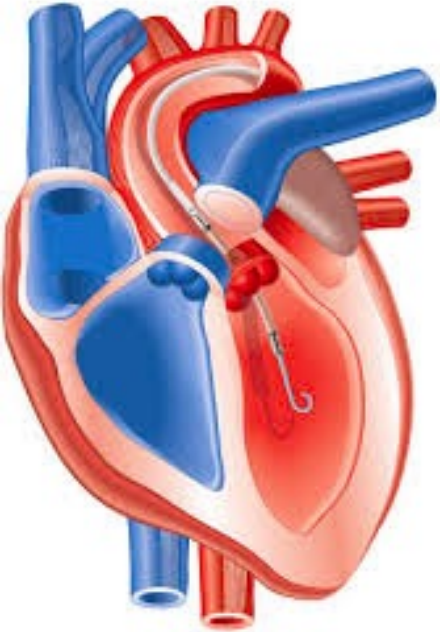
Total Artificial Heart (Syncardia)



Heartware HVAD



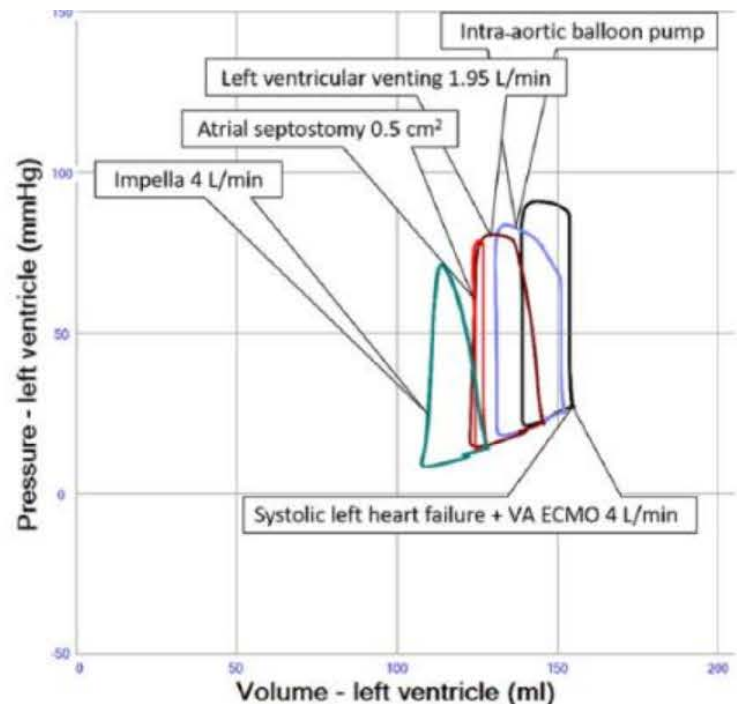
IMPELLA



- Percutaneous, catheter based, impeller
- Multiple sizes
- R sided support possible (not approved in BSA<1.5)
- >5L flow possible
- Hemolysis with smaller pumps
- Vessel size determines pump size
- Must consider vascular anatomy
- Weeks to months of support depending on device



IMPELLA AS VENT



- ECMO + heart failure increases afterload
- Many possible venting strategies
- Vent is cannula size dependent
- Septostomy unloads but doesn't allow ejection, which can increase venous HTN
- Impella provides superior unloading without additional surgical procedures or septostomy

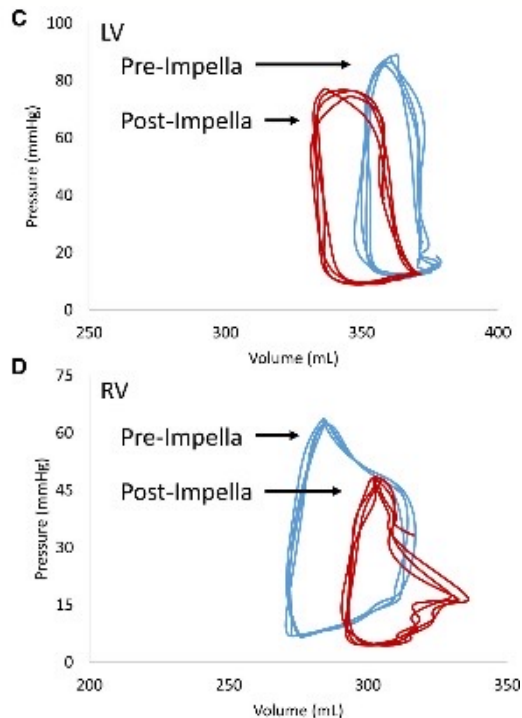
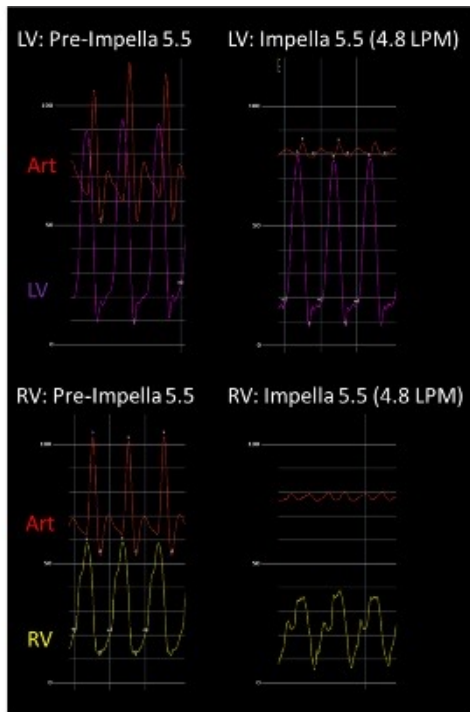


IMPELLA IN ACTION

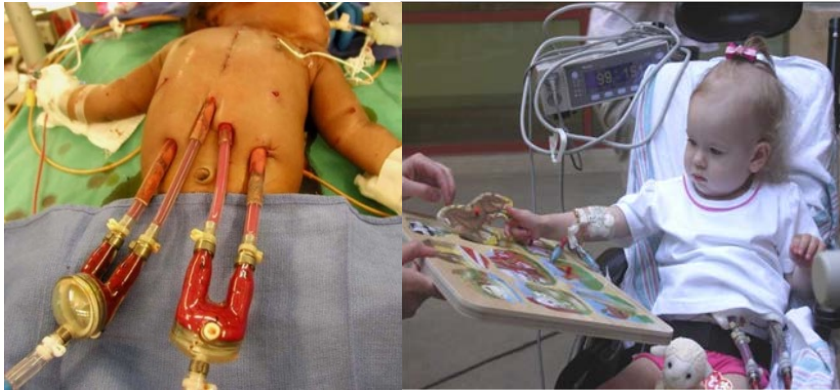
IMAGES AND CASE REPORTS IN HEART FAILURE

Acute Effects of Left Ventricular Support With Impella 5.5 on Biventricular Hemodynamics

Kay D. Everett¹, MD, PhD¹; Pankaj Jain², MD, PhD²; Richard Botto, BS³; Michael Salama, MD⁴; Satoshi Miyashita, MD⁵; Lara Reyelt⁶, BS⁶; Masashi Kawabori, MD⁷; Navin K. Kapur⁸, MD⁸



BERLIN HEART



- Extracorporeal
- Pulsatile
- Various cannula and pump sizes
- BW 2.5kg to adult size
- Easily changeable
- BIVAD relatively easy
- Can increase size as patient grows
- Non dischargeable
- Stroke risk



BERLIN HEART

Table 2 Outcomes of Patients in the PSS Group Compared With Those of Patients in the BHS Group

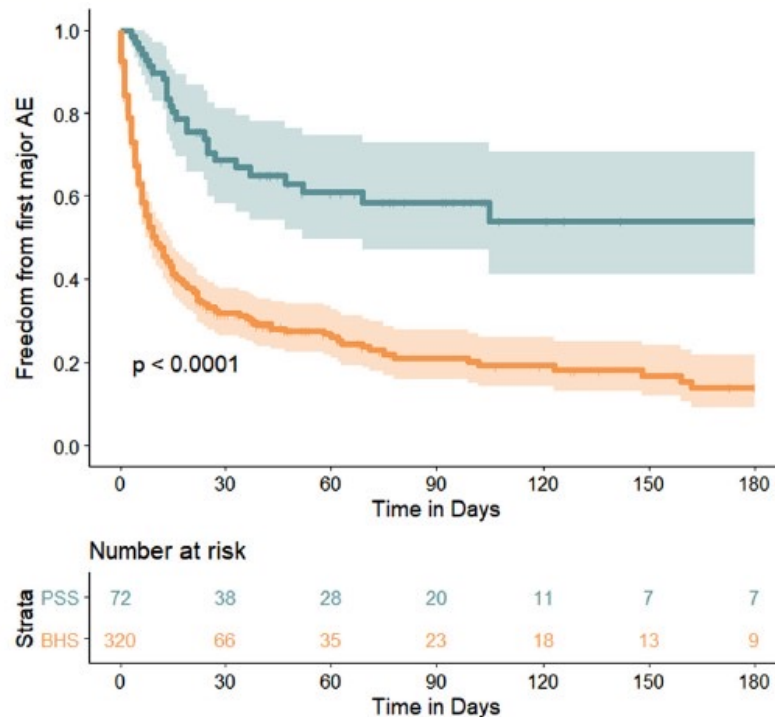
Outcome at 180 days	BHS group, <i>n</i> = 320	PSS group, <i>n</i> = 72	<i>p</i> -value
Transplanted	193 (60.3)	41 (56.9)	
Weaned	13 (4.1)	2 (2.8)	
Wean failure	2 (0.6)	0 (0.0)	
On device at 180 days	30 (9.4)	12 (16.7)	
Transitioned to other devices	9 (1.8)	8 (11.1)	
Death	73 (22.8)	9 (12.5)	0.055
Success ^a	236/311 (75.9)	55/64 (85.9)	0.099
EXCOR support time (days)	40.5 (15–98)	76.0 (38–122)	0.001 ^b

Abbreviations: BHS, Berlin Health study; EXCOR, Berlin Heart EXCOR Pediatric; IQR, interquartile range; PSS, post-market approval surveillance study.

Data are presented as *n* (%) or median (IQR).

^aSuccess is defined as transplantation, weaned off the device for recovery, or alive on device therapy at 180 days.

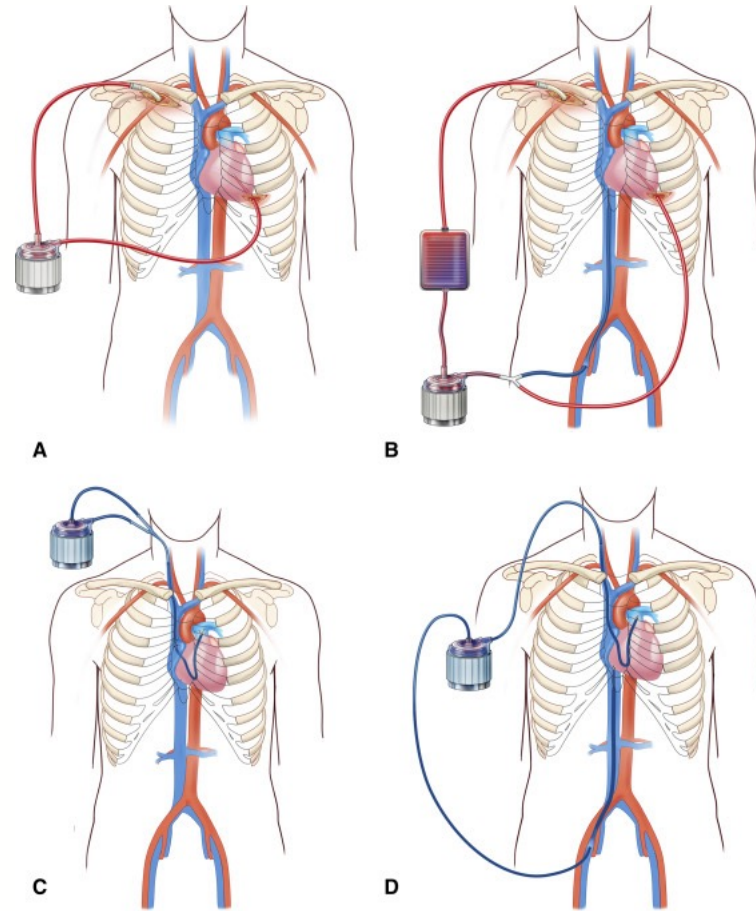
^b*p*-values that are significant (<0.05).



BHS group (pre-approval study): 2004-2017
PSS group (post approval): 2018-2020

ROTAFLU/CENTRIMAG

- Paracorporeal, nonpulsatile
- Simpler, higher flows achievable
- Can splice in an oxygenator
- Works with a variety of cannulae
- Easy to change
- More peripheral/less invasive cannulation possible.



HEARTMATE 3

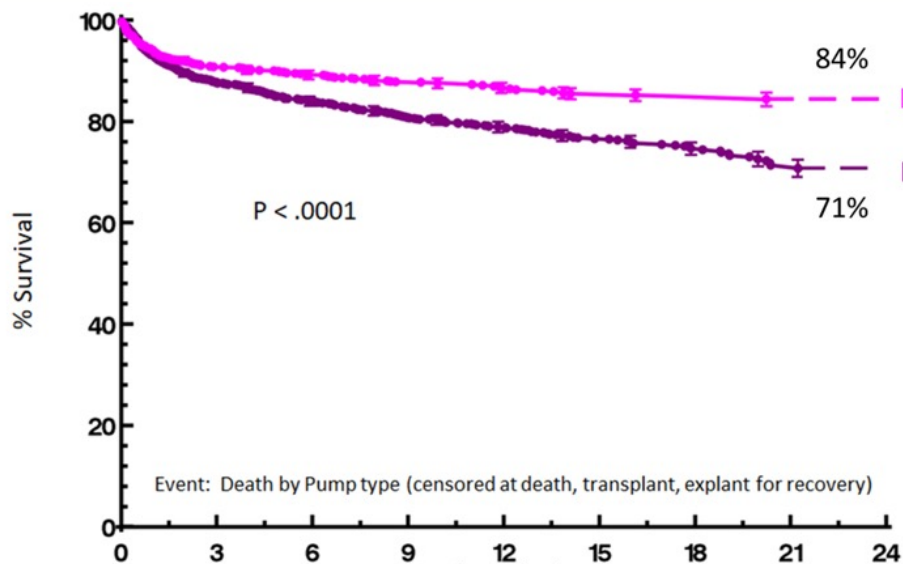


- Intracorporeal
- Continuous flow
- Fully levitated
- Intrinsic pulsatility
- Relatively large device size (>20kg, smallest BSA implanted was 0.76)
- BiVAD difficult in children (But not impossible)

IN MEMORIUM: HEARTWARE



- Smaller size
- Smallest implant was 10kg
- Higher stroke rate
- No longer on the market

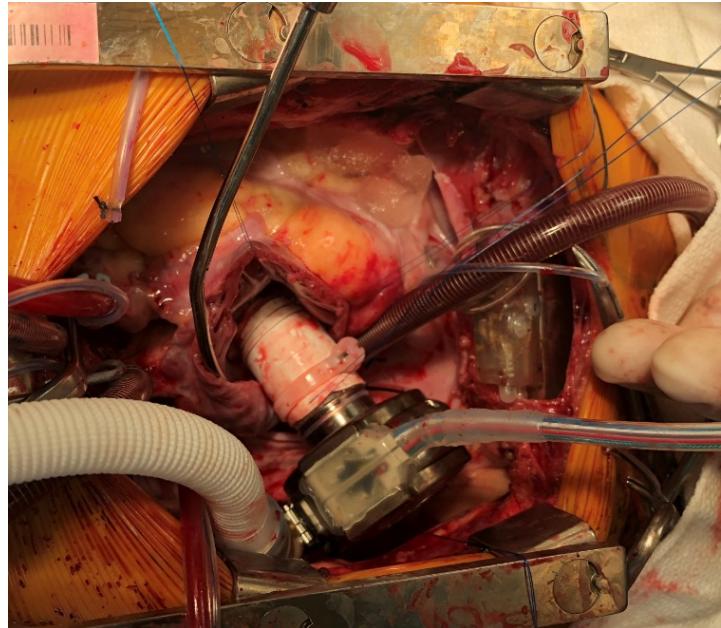
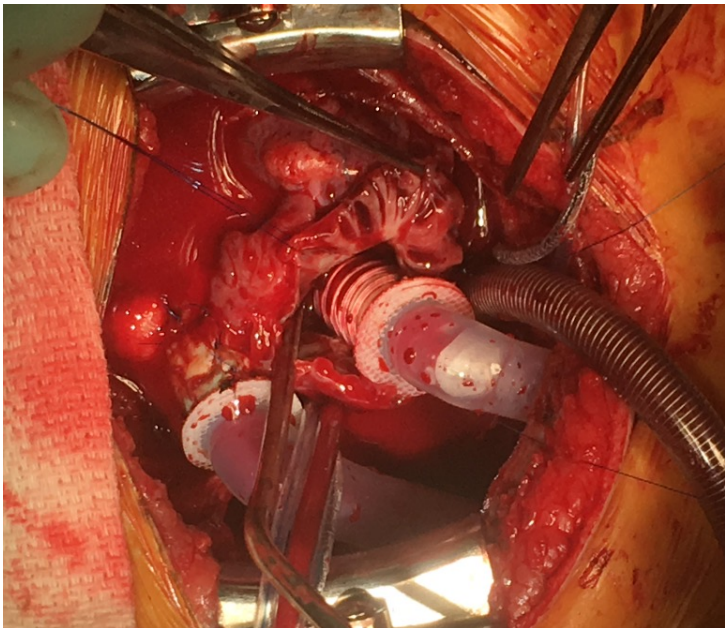


SPECIFIC CHALLENGES IN PEDIATRICS

- Device size
- Variable native and surgical anatomy
- RVAD, LVAD and BIVAD

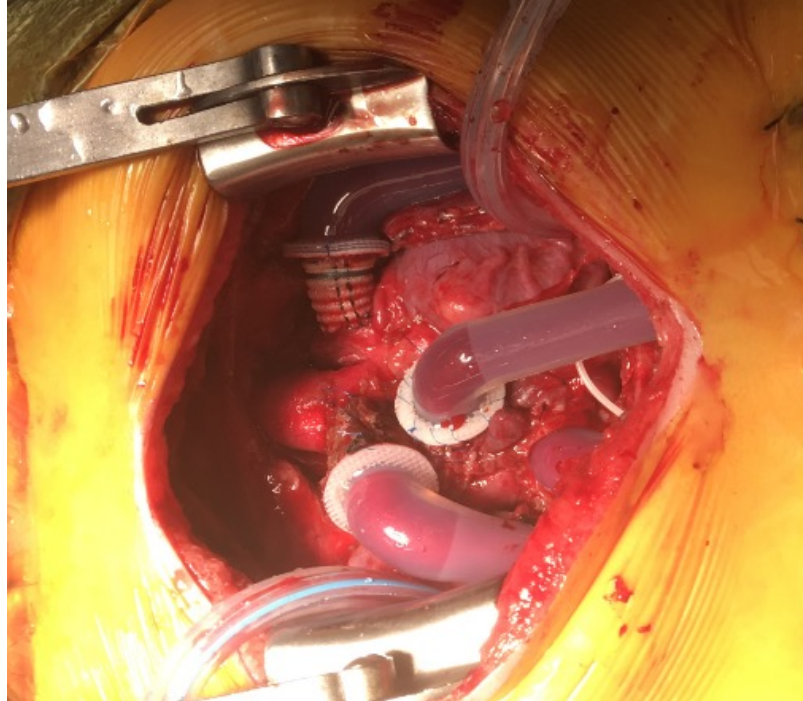
SPECIAL CANNULATION TECHNIQUES

- Atrial cannulation for small ventricles (HCM, restrictive CM)

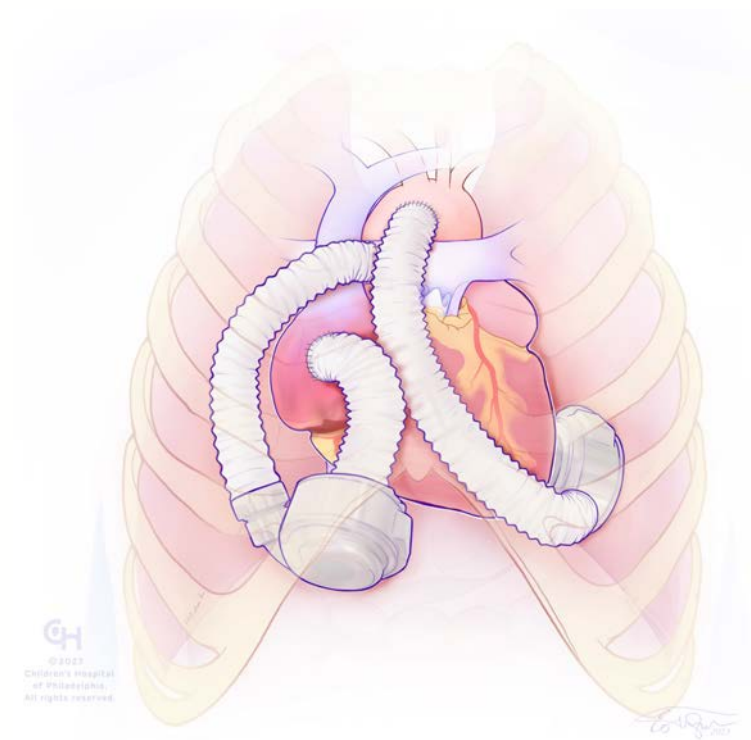


SPECIAL CANNULATION TECHNIQUES

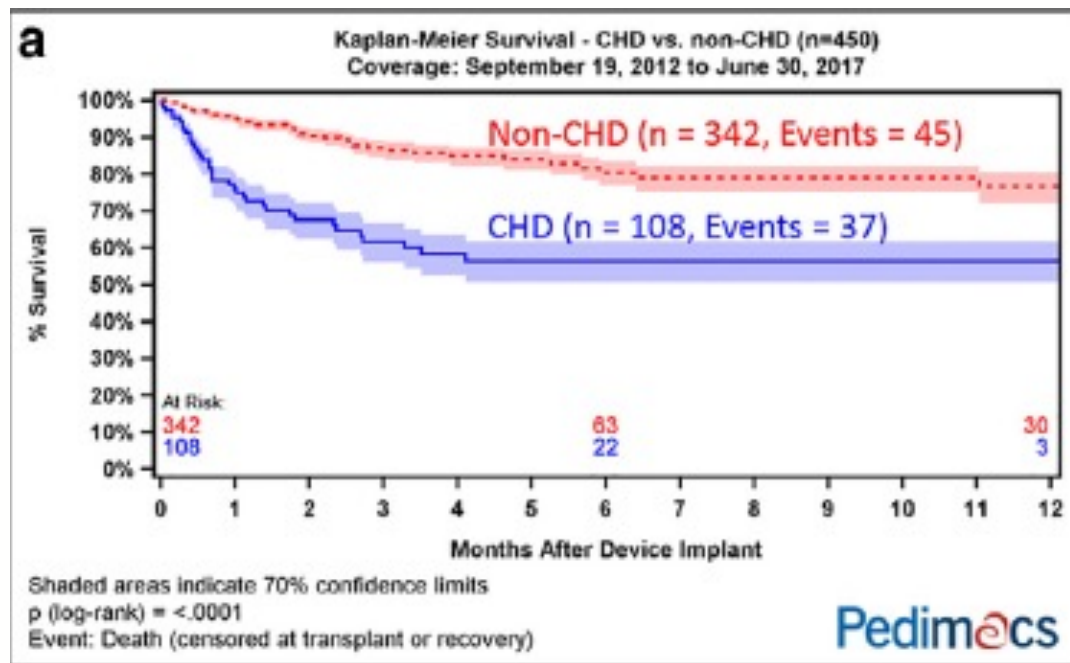
- Use of interposition graft from outflow cannula to decrease compression



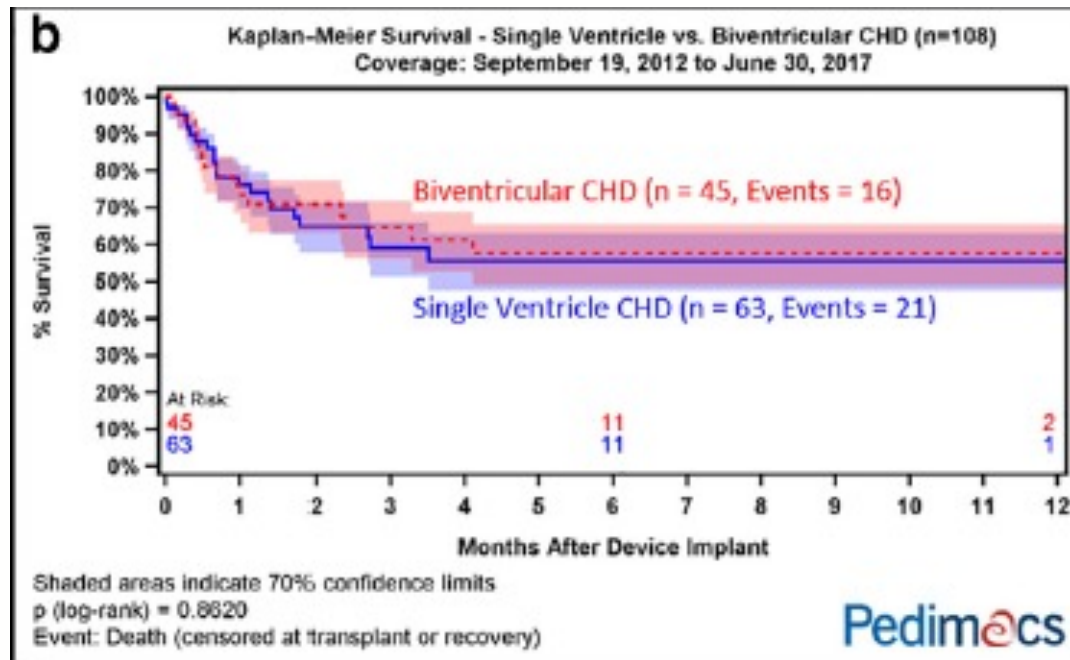
HEARTMATE III BIVAD TECHNIQUE



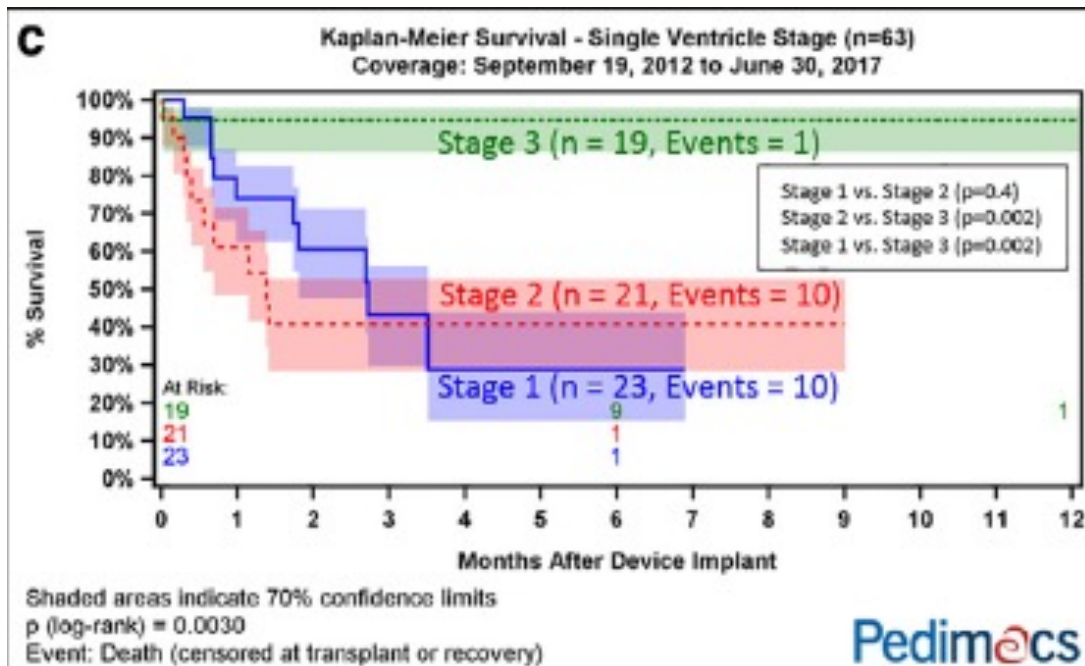
SINGLE VENTRICLE VAD CHALLENGES



SINGLE VENTRICLE VAD CHALLENGES



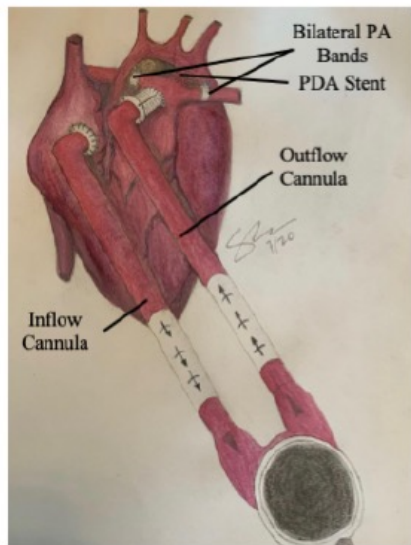
SINGLE VENTRICLE VAD CHALLENGES



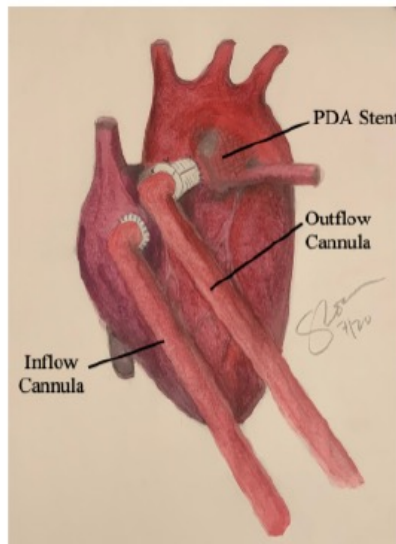
STAGE 1 VAD

PULSATILE VENTRICULAR ASSIST DEVICE AS A BRIDGE TO TRANSPLANT FOR THE EARLY HIGH-RISK SINGLE VENTRICLE PHYSIOLOGY

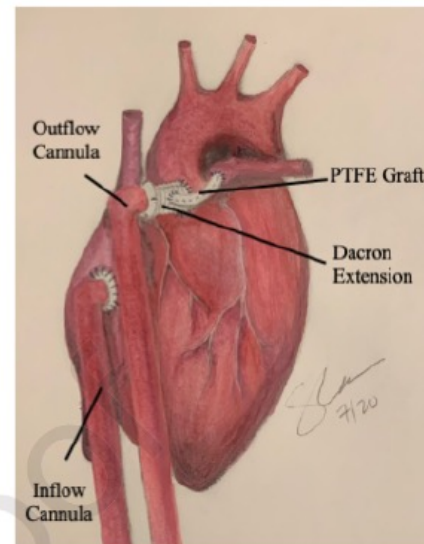
Joseph Philip, MD, Emma Powers, BS, Desiree Machado, MD, Dalia Lopez Colon, PhD, Dipankar Gupta, MD, Renata Shih, MD, Mohammad Ebraheem, MD, Curt Fudge, MD, Mark Bleiweis, MD



a. Ventricular assist device with Hybrid palliation. PDA stent and bilateral PA bands. Inflow cannula to the right atrium and outflow cannula to the PA. PDA: patent ductus arteriosus, PA: pulmonary artery

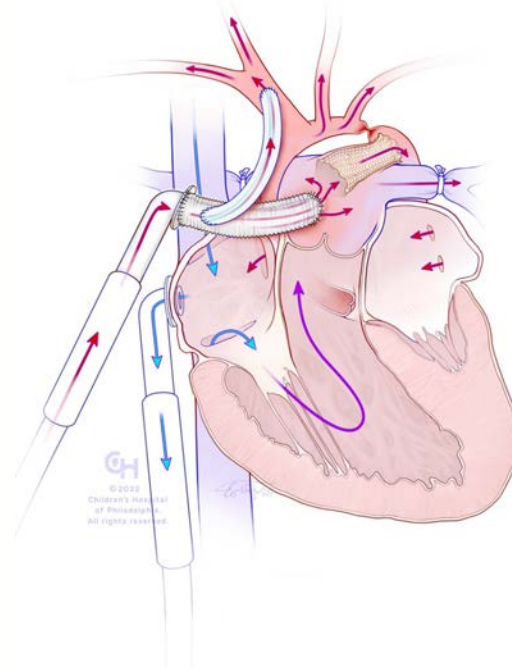
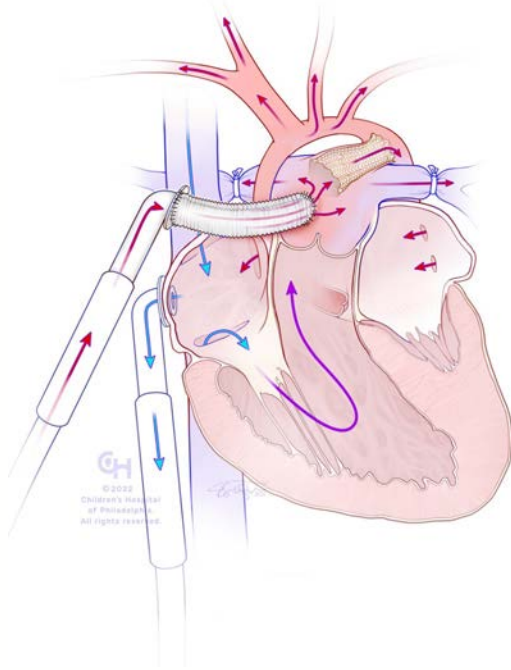


b. Ventricular assist device with PDA stent. Inflow cannula to the right atrium and outflow cannula to the ascending aorta. PDA: pulmonary ductus arteriosus

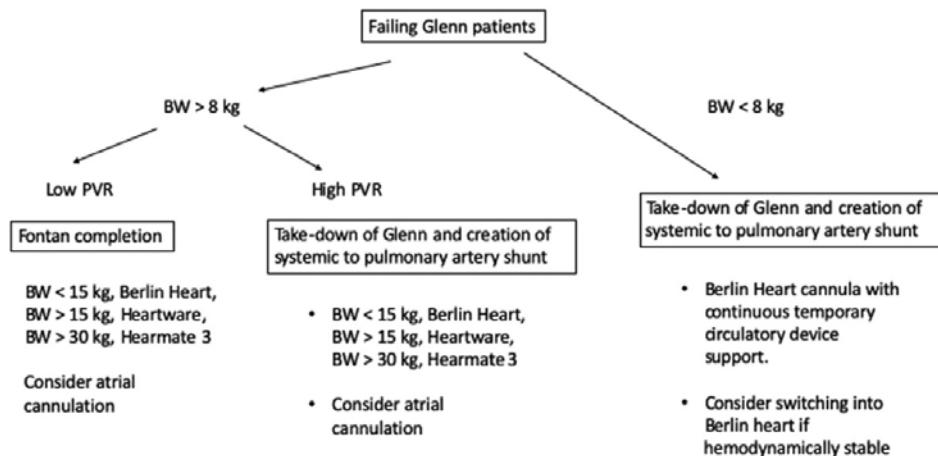
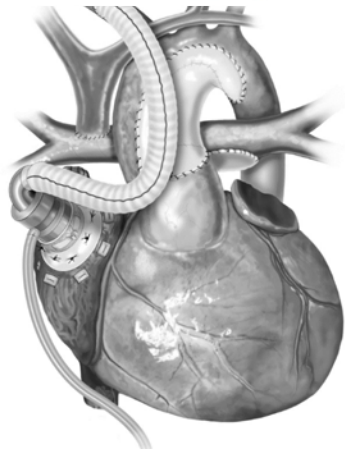
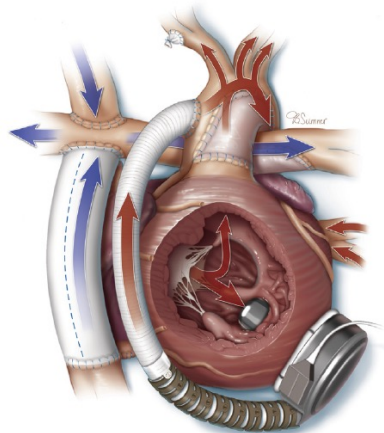


c. Ventricular assist device with a PTFE graft connecting the outflow cannula to the pulmonary artery. Inflow cannula to the right atrium and outflow cannula to the ascending aorta. PTFE: Polytetrafluoroethylene (Teflon)

HYBRID STAGE ONE VAD CANNULATION



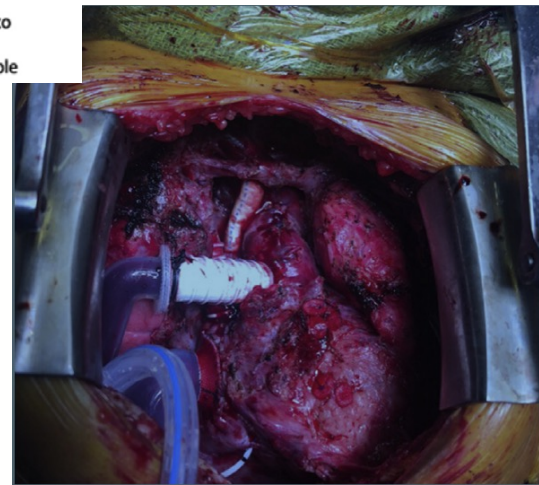
STAGE 2 VAD



Single Ventricular Assist Device Support for the Failing Bidirectional Glenn Patient

Katsuhide Maeda, MD, Teimour Nasirov, MD, Vamsi Yarlagadda, MD, Seth A. Hollander, MD, Manchula Navaratnam, MD, David N. Rosenthal, MD, John C. Dykes, MD, Beth D. Kaufman, MD, Chris S. Almond, MD, Olaf Reinhartz, MD, Jenna Murray, NP, and Sharon Chen, MD

Department of Cardiothoracic Surgery, Stanford University, Palo Alto, California; Department of Pediatrics, Stanford University, Palo Alto, California; and Division of Department of Anesthesiology, Stanford University, Palo Alto, California



STAGE 3 VAD

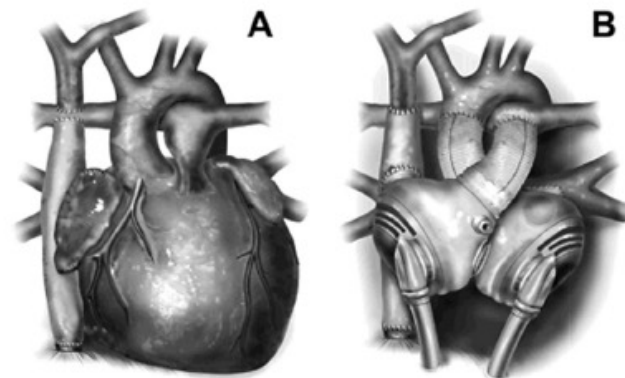
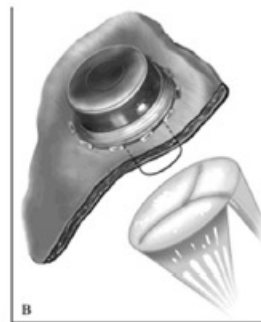
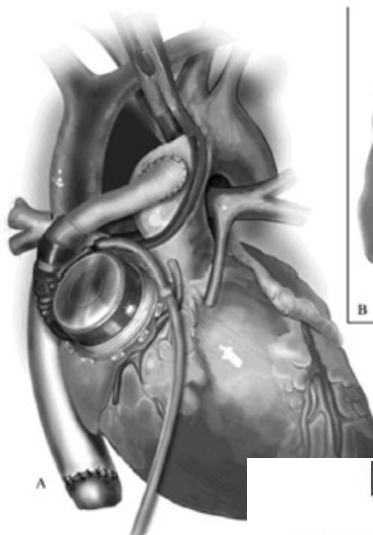
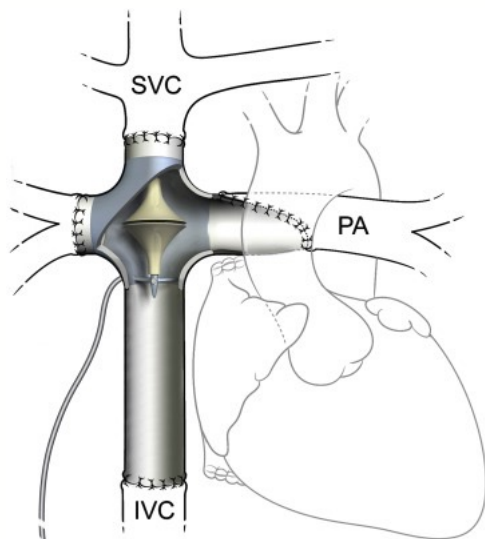
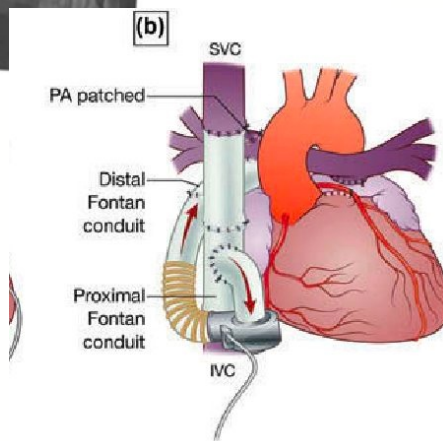


Figure 3. (A) Extracardiac conduit (ECC) Fontan. (B) Removal of ECC, creation of “neo-right atrium” to collect caval flow, and insertion of right and left ventricles for the total artificial heart. (From Rossano et al, Ann Thorac Surg. 2014 Apr;97(4):1438-40. Used with permission.)



IN SUMMARY

- ECMO: great for rescue, cardiopulmonary support, suboptimal long term strategy, avoid in BTT
- Intracorporeal: The best for long term, but size concerns, possible role for DT in pediatric patients, difficult to change if there are problems, persistent infection issues
- Paracorporeal: Greatest size range, best option for infants and small children, can be changed easily, nondischageable, stroke risk
- Transcatheter: Less invasive, moderate term support as standalone device, biventricular possibility, excellent ECMO adjunct, nondischageable
- While outcomes have improved in CHD VAD patients, especially in SV patients, better devices and approaches are needed

CARDIOLOGY 2023

THANK YOU!

Questions?

