Surgical Heart Failure in 2023: Rise of the Machines

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Cardiac Surgeon
Minneapolis Heart Institute

Objectives

- Review current indications for mechanical circulatory support
- Explore the latest devices available for support of patient with heart failure
- Discuss the use of organ preservation and perfusion systems in DCD and DBD heart procurement
Disclosures...

A Case.... Of Course!

- 68 Year Old Male
- PMHx: DM, smoker

- Presented with late anterior STEMI:
  - 100% ostial LAD
  - Severe LCx, RCA disease
  - LAD and Cx stented
  - Left femoral IABP placed
Post Procedure

- Initial TTE: EF 20-25%, normal RV and valves
- In ICU:
  - DCCV for a fib
  - Initially some improvement in hemodynamics with IABP and inotropy but now...

Hemodynamics

- PA 30/15 (20)
- CVP 10
- PCWP 22
- O2M 47
- CO 3.57
- CI 1.77
- SVR 1142

Dobutamine 5
Milrinone 0.375
Amio 44/hr
IABP 1:1
“Hey Carly, Can you see this guy in bed 38 for consideration of advanced therapies?"

The Heart Failure Decision Tree

- Type of shock
- INTERMACS classification
- Which pump is the problem
- Oxygenation issues
- Clinical considerations
Short Term MCS Options

- ECMO
- Centrimags
- IABP
  - Femoral
  - Axillary
- Impella
  - CP
  - Axillary 5.5

DURABLE LVAD?
HEART TRANSPLANTATION?
Surgical Heart Failure Commandment:
You must always think about the long term goal!

Surgical Heart Failure Commandment:
Use “bridges” to your advantage
**Impella**
The little pump that could

**Impella - A Brief History**

Archimedes Screw
Hemopump

Dr Richard Wampler

1985

Nimbus Hemopump

- Continuous flow intra vascular pump
- Pumps from LV to aorta
- Purge assembly for blood seal integrity
- Hydrodynamic lubrication
- Console for power to pump and purge
Nimbus Hemopump

- Femoral, direct aortic access (Abdominal aorta)
- Provided up to 3.5L/min of flow
- No need for LV contribution or synchronization
- Provides LV decompression

Wampler et al. 1991

First In-Human Implant

Dramatic debut for a device that can save cardiac patients

by Nathan Medical Inc., of Roseland, New Jersey. Although a second patient was
undergoing surgery at the time the pump was implanted, the device was not used.

The patient, a 35-year-old man, was suffering from a serious heart condition
that required urgent surgery. The device was designed to provide temporary
support while the patient was being operated on. The surgery was successful,
and the patient made a full recovery. The device has now been approved for use in
the United States and is expected to be commercially available soon.

Hemopump

- 53 patients with refractory cardiogenic shock
- Successful insertion in 41/53
- Significant hemodynamic improvement
- Minimal hemolysis
- No leg ischemia
- 30 day survival 31.7%

Treatment of Cardiogenic Shock With the Hemopump Left Ventricular Assist Device
Richard K. Wampler, MD, O. Howard Frazier, MD, Allan M. Lansing, MD, PhD, Richard W. Smalling, MD, PhD, John M. Nicklas, MD, Steven J. Phillips, MD, Robert A. Guyton, MD, and Leonard A. R. Goldberg, MD

Yentis, Inc. Research Center, California, Texas Heart Institute and Hermann Hospital, Houston, Texas; Hansa Hospital Audubon, Louisville, Kentucky; The University of Michigan Medical Center, Ann Arbor, Michigan; Mercy Hospital Medical Center, Des Moines, Iowa; Emory University and CoxHealth Long Hospitals, Atlanta, Georgia; and The Cleveland Clinic Foundation, Cleveland, Ohio.

Annals of Thoracic Surgery

A Minnesota Connection
Hemopump -> Impella

- Hemopump - no commercial success, discontinued
- Germany: early 1990s modified Hemopump design
  - Short rotating impeller rather than long screw
  - Mini motor on the catheter
- Experimental studies of impella in Belgium

Impella - the next generation
Impella 2.5 and CP

- Retrograde femoral approach
- 2.5 L/min, 4.0 L/min flow
- Approved for use:
  - 4 days (Cardiogenic shock)
- Primary Uses:
  - High risk PCI
  - Cardiogenic, Post cardiotomy shock
  - LV unloading - ECMO

Impella CP

- **Issues**
  - Limited flow capability
  - Small device
    - Hemolysis
    - CP = “Crushing Platelets”
    - Groin access- impaired mobility, vascular injury/bleeding
  - Limited duration of use
  - Upsizing to larger device often necessary for severe shock
Surgical Impellias

- **Impella 5.0/LD**
  - 4-5LPM
  - 7F pigtail at tip
  - 21F motor
  - 23F sheath
  - Femoral or axillary cut down
  - LD: direct aortic
  - Approval 14d

- **Impella 5.5**
  - 5.5 LPM
  - No pigtail, shorter motor
  - 19F motor
  - Smart Assist- positioning
  - Axillary cut down or direct aortic
  - Approval 14 d FDA, 30D CE

Improved clinical outcomes associated with the Impella 5.5 compared to the Impella 5.0 in contemporary cardiogenic shock and heart failure patients

Danny Ramzy, MD, PhD,* Edward G. Soltesz, MD, MPH, Scott Silvestry, MD,†
Mani Daneshmand, MD,‡ Manreet Kanwar, MD,* and
David A. D’Alessandro, MD¶

From the *Department of Cardiovascular Surgery, UTHealth McGovern School of Medicine Houston, Texas; †Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, Ohio; ‡Advocate Health Transplant Institute, Advocate Health Orlando, Orlando, Florida; ‰Division of Cardiothoracic Surgery, Emory University School of Medicine, Atlanta, Georgia; ¶Cardiovascular Institute at Allegheny Health Network, Pittsburgh, Pennsylvania; and the Division of Cardiovascular Surgery, Massachusetts General Hospital, Boston, Massachusetts.

- Impella 5.0 vs 5.5 for acute MI shock, cardiomyopathy, post cardiotomy shock
- 1238 patients in Impella Quality (IQ) registry
- 290 US centers, Oct 2019- Dec 2020
- Impella 5.5- higher survival for all indications. **WAHOO IMPELLA 5.5!**
- Higher percentage 5.5 CM patients bridged to transplant
- Impella 5.5 patients had higher rate of successful weaning in PCCS
- Duration of support longer with 5.5 in AMICS (9.2 d vs 6.1d) and CM (10.7d vs 8.1d)
- Lower hemolysis with 5.5 CM patients (?no more pigtail, easier repositioning)

**Original Article**

**Early Outcomes of the First 200 US Patients Treated with Impella 5.5: A Novel Temporary Left Ventricular Assist Device**

Danny Ramsey¹, MD, PhD, Mark Anderson⁴, MD, George Batsides², MD, Masahiro Ono¹, MD, Scott Silvestry³, MD, David A. D’Alessandro¹, MD, Masaki Funamoto¹, MD, PhD, Elias A. Zia³, MD, Anthony Lemaire¹, MD, and Edward Soltice³, MPH, MPH

- IQ registry retrospective analysis, October 2019 to MArch 2020
- 200 patients at 42 centers
- **CM, AMICS, PCCS**
- 88% via right axillary artery, 6% left ax, 6% aorta
- Median duration support 10 d (0.001 to 64.4 d)
- 35 patients (17%)- ECPELLA
5 patients (2.5%) adverse event
- Bleeding - 4 (hematoma 2, anastomosis 1, GI 1)
- CVA - 1 (LV thrombus, VT, shocks)
- 74% weaned or bridged (ie. survived)
- 19% died/withdrawal of care (almost half of these-ECPELLA)

GOOD OUTCOMES, LOW COMPLICATION RATES

Impella 5.5 - Bridge to Transplantation

OPTIMIZE!!!
- End organ dysfunction
- Pulmonary hypertension
- Reduction in vasoactives
- Mobilization potential
  - NO GROIN
- Prolonged use/support
  - Facilitate workup/buys time
- Status 2....
UNOS Listing Criteria Change

1999-2018

- Status 1A
  - Admitted with TAH/IA BP/ECMO
  - LVAD with complications
  - Continuous ventilation
  - Continuous single or multiple inotropes requiring hemodynamic monitoring
  - Dischargeable LVADs for 30 days

October 2018

Status 1
- ECMO (up to 7 days)*
- Non-dischargeable surgically implanted VAD
- MCSD with life threatening ventricular arrhythmia

Status 2
- Intra-aortic balloon pump (up to 14 days)*
- Sustained Ventricular tachycardia/ventricular fibrillation
- Non-dischargeable, surgically implanted, non-endovascular LVAD (up to 14 days)*
- MCSD with device malfunction/ mechanical failure
- Total artificial heart
- Dischargeable BI/VAD or RVAD
- Acute endovascular percutaneous circulatory support (up to 14 days)*

Status 3
- Dischargeable LVAD for up to 30 days
- Multiple inotropes or single high dose inotropes with continuous hemodynamic monitoring
- MCSD with device infection, hemolysis, pump thrombosis, right heart failure, mucosal bleeding, and aortic insufficiency
- ECMO after 7 days or any other temporary MCSD after 14 days

[Sidebar- Axillary IABP]

- Alternative bridging strategy
- Status 2
- Less hemodynamic support than impella 5.5
- Allows mobilization
- Positioning issues...
- Specific populations
  - NB mechanical aortic valve, LV thrombus, severe AS etc.
UNOS Database

Sept 2019 (FDA Approval)-Dec 31, 2021

464 patients

Impella 5.5 at any time while on wait list

54% DCM, 23% ICM

Median time on wait list: 19 days

10 d if listed with impella

37 days if added later

Median duration of support 16 days

86.8% transplanted

96% BTT directly

3.8% device removed prior to txp

11 patients - device failure, 4 patients- LVAD
Excellent 1 year survival
Low rates of complications

TABLE 4  Post-transplant complications among patients bridged with Impella 5.5.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Kidney Injury requiring Dialysis</td>
<td>55 (15.7)</td>
</tr>
<tr>
<td>Stroke</td>
<td>14 (4.0)</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>3 (0.9)</td>
</tr>
<tr>
<td>Acute rejection episode</td>
<td>21 (4.5)</td>
</tr>
</tbody>
</table>
WORLD RECORD IMPELLA 5.5
RUN:
269 DAYS (SINGLE DEVICE)
BTT IN FLORIDA!

Direct Aortic Impella

- Post cardiotomy cardiogenic shock
- Low EF cardiac surgery - planned implantation
- FDA approved implant technique and use.
- Provides significant hemodynamic support in periop period
- Avoid open chest, return to OR for removal (bedside ICU)
Contraindications to Impella

- Mural thrombus in LV
- Mechanical AV or heart constrictive device
- Aortic stenosis/calcification (EOA < 0.6cm²)
- Mod-severe AI
- Severe arterial disease precluding placement
- Significant RHF
- LV rupture
- Tamponade
- Combined cardio respiratory failure
- ASD [or VSD (including PIVSD)]
Our case - Impella 5.5 Insertion
ANW and Impella 5.5

What about the right side?

Impella RP
Protek Duo
Centrimag
Impella RP FLEX

Coming soon...

BIVADS

Centrimag- historically
A new era of BIVADS

- BIPELLA
- Impella CP/5.5 + Impella RP
- Impella 5.5/Protek

Advanced Heart Failure Therapies:
Durable Options
Advanced Heart Failure Therapies: A Bridge to...Durable LVADs

ABBOTT HEARTMATE 3

Medtronic Heartware HVAD

- Biggest competition for Heartmate 3 until...

Medtronic HVAD™ System

Medtronic has stopped the distribution and sale of the HVAD™ system as of June 3, 2021, and has notified physicians to cease new implants of the Medtronic HVAD™ system and transition to an alternative commercial LVAD for all future implants.

Indications, Safety, and Warnings

ProductDetails
FDA Activities Related to the HVAD System

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 25, 2022</td>
<td>The FDA issued a recall notice indicating the FDA classified the June 2022 recall related to the increase in battery electrical faults due to an interaction between the battery software and an internal component as Class 1.</td>
</tr>
<tr>
<td>June 23, 2022</td>
<td>The FDA issued a recall notice indicating the FDA classified the May 2022 recall related to a welding defect affecting internal HVAD Battery components from a single lot as Class 1.</td>
</tr>
<tr>
<td>June 10, 2022</td>
<td>The FDA issued a recall notice indicating the FDA classified the April 2022 recall related to actions to alert healthcare providers to a possibility of a weld defect in the internal pump as Class 1.</td>
</tr>
<tr>
<td>April 20, 2022</td>
<td>The FDA issued a letter to health care providers to alert health care providers to the possibility that patients who have the Medtronic HVAD System and appear to present with pump thrombosis may have a weld defect in the internal pump causing the pump to malfunction.</td>
</tr>
<tr>
<td>August 12, 2021</td>
<td>The FDA issued a recall notice indicating the FDA classified the June 3, 2021 actions to stop the sale and distribution of the HVAD System as Class 1.</td>
</tr>
<tr>
<td>June 3, 2021</td>
<td>The FDA issued a letter to health care providers stating that Medtronic has stopped the sale and distribution of the HeartWare Ventricular Assist Device (HVAD) System because:</td>
</tr>
<tr>
<td></td>
<td>• There is an increased risk of neurological adverse events and mortality associated with the internal pump.</td>
</tr>
<tr>
<td></td>
<td>• There is a potential for the internal pump to stop. If the internal pump stops, it may delay restarting or fail to restart.</td>
</tr>
</tbody>
</table>

Multiple Recalls:
- Batteries
- Failure to restart
- Auto log issues

So now what?

- How to improve upon HM3?
- Driveline infection
- External power source

FILVAS??
The Road to FILVAS

- Engineering hurdles
  - How to make efficient?
  - Temperature issues
- Multiple acquisitions
- How do we get there?

Cardiomems + HM3

- Use of cardiomems for hemodynamic monitoring and optimization of the LVAD pre and post op
HM2/HM3 + Cardiomems

- Reduction in PAD at 6 mo, improved 6mwt, if PAD < 20mm = less heart failure hospitalizations
- Feasible, functional and clinical benefits.

Advanced Heart Failure Therapies: A Bridge to... Heart Transplantation
Donor Heart Management: Machine Perfusion

- Revolutionizing donor heart management
- Expanding the donor pool
- Improving transport over longer distances

Remember - Two Types of Donors!

- DBD- Donation after Brain Death
- DCD- Donation after Circulatory Death
Donor Type - DBD vs DCD

DBD - They must be confirmed brain dead!!

Donor Type - DCD

- Modified Maastricht criteria for donation after cardiac death

### Modified Maastricht Criteria for Donation after Cardiac Death

<table>
<thead>
<tr>
<th>Sub-category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I—Found dead (Uncontrolled)</td>
<td>IA Unexpected cardiac arrest out of hospital without attempted resuscitation</td>
</tr>
<tr>
<td></td>
<td>IB Unexpected cardiac arrest in hospital without attempted resuscitation</td>
</tr>
<tr>
<td>Category II—Witnessed cardiac arrest (Uncontrolled)</td>
<td>IIA Unexpected cardiac arrest out of hospital with unsuccessful resuscitation</td>
</tr>
<tr>
<td></td>
<td>IIB Unexpected cardiac arrest in hospital with unsuccessful resuscitation</td>
</tr>
<tr>
<td>Category III—Withdrawal of life support (Controlled)</td>
<td>Expected, planned cardiac arrest after withdrawal of care</td>
</tr>
<tr>
<td>Category IV—Cardiac arrest whilst brain dead (Uncontrolled, controlled)</td>
<td>Sudden cardiac arrest following brain death but prior to planned organ recovery</td>
</tr>
</tbody>
</table>

Categories used to classify donation following cardiac death (73).
DCD Organ Donation

Severe injury (usually neurological)

Does not meet legal ‘Brain Death’ criteria, but therapy medically futile

Donation after Circulatory Death (DCD) pathway

Withdraw life sustaining therapies leads to asystole

Irreversible cessation of circulatory function = death definition

Asystole within timeframe

Asystole not within timeframe

No organ retrieval

DCD Pathway:

Proceed to Operating Room to retrieve organs

Functional Warm Ischemic Time (FWIT)

Withdrawal of Life Support

Systolic Blood Pressure <50 mmHg

Circulatory arrest

Mandatory stand off period (2-7 min)

Sternotomy and preparation

taNRP or Cold cardioplegia for DPP

Functional warm ischaemic time (fWIT)

Courtesy of Jacob N. Schroder
Two DCD Procurement Techniques

**Thoracoabdominal Normothermic Regional Perfusion**
- Occlusion of arch vessels
- Cannulate for cardiopulmonary bypass/ECMO
- Wean the heart from MCS and assess
- Cold preservation solution and explant all organs

**Direct Procurement and Perfusion**
- Collect 1L blood from donor
- Cold preservation solution and explant all organs
- Perfuse heart on OCS machine
- Reannex heart w cold preservation solution and remove from machine

Normothermic Regional Perfusion

**Papworth (UK)**
- 79 DCD Heart transplants
- 57 DPP, 19 NRP
- Equivalent 1-year survival
- Possibly some benefit to NRP (decreased MCS, increased survival)

Messer et al. JHLT December 20

**St. Vincent’s (AU)**
- 77 total DCD heart transplants
- No significant difference in 1 & 5 year survival

Molyeshar Joshua MD
Presented at ISHLT 2022
The international experience of in-situ recovery of the DCD heart: a multicentre retrospective observational study


- 157 taNRP DCD vs 673 DBD
- 15 centers
- TaNRP- 23% increase in transplant activity
- Similar 30d, 1 year and 5 year survival
- TaNRP= effective organ preservation and procurement

Normothermic Regional Perfusion

- **Advantages:**
  - Continuous warm blood perfusion- restores heart function, reduces myocardial injury, promotes energy storage and maintains homeostasis
  - Visual assessment of heart for viability
  - Reduces warm ischemia
  - Equipment less cumbersome than OCS
  - ? Cheaper
Normothermic Regional Perfusion

- **Disadvantages**
  - Ethical debate - concern for 'reanimation'
  - Donors 'alive' at time of organ recovery since circulation re-established
  - Logistics can still be challenging, need perfusionists as well

Direct Procurement and Perfusion (DPP)

- Most commonly used device - Transmedics Organ Care System (OCS)
- Cold preservation
- Procurement (DCD OR DBD)
- Preparation and placement on rig
- Warm perfusion
Transmedics OCS

- Parameters
  - Aortic pressure
  - Flow
  - Coronary flow
  - Heart rate
  - Metabolics - blood gas analysis, electrolytes

- Monitoring of cardiac function via arterial and venous lactates
  - Venous lactate higher = heart is secreting lactate
Transmedics OCS

**Advantages**
- Decreases ischemic time
- Warm organ perfusion
- Assessment of organ function
- Expand organ utilization
- Support for extended criteria donors
  - NB: Long ischemic times (9 hours!)

**Disadvantages**
- COST - module + disposables
- Equipment cumbersome - transport logistics
- Need perfusionist/preservationist
- Boggy hearts/RV dysfunction...
7 TM OCS Items:
- Rig
- Base
- Huge box
- Run bag
- Dolly
- Drug bag
- Cooler

OCS National Service Program – Transforming the Field

TMDX National Service Program

- Surgical Retrieval
- OCS Technology
- OCS Clinical Expert
- Transportation
TransMedics Signs Definitive Agreement to Acquire Summit Aviation to Expand TransMedics Aviation Capabilities for Organ Transplantation

Aug 1, 2023 at 11:00 AM EDT

Establishes the first national provider of air logistics dedicated to organ transplantation in the U.S.

ANDOVER, Mass., Aug. 1, 2023 /PRNewswire/ -- TransMedics Group, Inc. ("TransMedics") (Nasdaq: TMDX), a medical technology company that is transforming organ transplant therapy for patients with end-stage lung, heart, and liver failure, announced today that it has signed a definitive agreement to acquire Summit Aviation, a premier U.S. charter flight operator. The deal is expected to close in the third quarter of 2023, subject to the satisfaction of closing conditions. Upon closing, Ben Walton, Founder of Summit, will join TransMedics as VP of Aviation Services.

Transplantation Outcomes with Donor Hearts after Circulatory Death


RCT: DCD (OCS) vs DBD (cold storage)

180 patients (90 / 90)
13 centres
Higher incidence of moderate or severe PGD in DCD

PGD did not affect patient or graft survival at 30d or 1 year

Overall patient survival with original transplanted heart in DCD was higher than DBD at 1 year
OCS for DBD Hearts- The EXPAND Trial

Extended Criteria Donors

- Expected total cross clamp time of $\geq 4$ hours OR
- Expected total XC time of $\geq 2$ hours PLUS $\geq 1$ additional risk factor:
  - Age $\geq 55$y
  - Age 45-55 with no cath data
  - Reported down time $\geq 20$min with stable hemostat at final assessment
  - LVH 13-16mm
  - LVEF 40-50%
  - Angiogram with luminal irregularities with no significant CAD
  - CO poisoning with good cardiac function
  - Hx DM or alcoholism with good cardiac function
- Single arm trial, benchmarked long term results with standard criteria HTx outcomes in US (SRTR)

- 138 extended criteria DBD donors, 1813 std criteria DBD donors
  - EC DBD - 88% freedom from severe PGD
  - Long term survival to 2 years- not significantly different from concurrent controls
  - 92% at 6mo, 89% 1y, 85% 2y
Hypothermic Machine Perfusion

- Not currently available in US
- Continuous perfusion with cold oxygenated cardioplegia nutrient rich solution
- Potentially extend ischemic time for cold storage
- Better event free survival, decreased PGD compared to SCS
- Safer and simpler than NMP
Bridge to Life: Lifecradle...

- Hypothermic oxygenated nutrient rich perfusion
- No blood required
- “Plug and play”
- “Streamlined workflow”

TransMedics Acquires Warm Perfusion EVOSS™ and Cold Perfusion LifeCradle® Technologies from Bridge to Life
Retrospective
1 year outcomes
Oct 2015-Jan 2022
569 US adults
Sherpapak - 255
Ice - 314

Sherpapak:
67% reduction severe PGD
PM: reduced severe PGD
Trend: improved 1 y survival, reduced MCS
Ischemic time >4 h - reduced MCS, severe PGD, better 30d survival
ICE- 3.4x increased chance of severe PGD
GUARDIAN CLINICAL RESULTS™

Post-Operative Cost Benefit Analysis

GUARDIAN registry data was analyzed to evaluate post-operative cost differences from improvements in clinical outcomes and their associated reductions in clinical interventions.

$28,597
IN AVERAGE SAVINGS PER PATIENT (P<0.024)

Cost Differences: Paragonix Sherpapak™ vs Ice Storage

<table>
<thead>
<tr>
<th></th>
<th>PGX</th>
<th>ICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL COSTS</td>
<td>$45,588</td>
<td>$28,597</td>
</tr>
<tr>
<td>(ALL PATIENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PER PATIENT</td>
<td>$45,588</td>
<td>$28,597</td>
</tr>
<tr>
<td>TOTAL COSTS</td>
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</table>

Development of GUARDIAN™ is protected by U.S. and international patent applications and patents owned or licensed to Paragonex Technologies, Inc. The data from this report is based on the GUARDIAN registry database and reflects all performed procedures. The outcomes were compared to the standard of care and the results reflect the clinical equipoise at the moment of database creation. The data is therefore presented without attribution to any commercial product. The PGX data is derived from the GUARDIAN registry database. The ICE data is derived from the literature and the best available evidence. This data is intended for use only as a learning tool and should not be used to make decisions in a clinical setting.
Pushing the Boundaries of Cold Storage

A heart was flown from Alaska to Boston, breaking a transplant record. Here's how it was done.

- 2506 miles
  - 7.5 hr travel time

- 2238 miles
  - ? 6 hr travel time
Aeson Carmat TAH

Biventricular, hemocompatible, autoregulated support

https://www.carmat-phrt.com
Case Report

- 39yo M ICM - admitted with CHF
- V fib - central VA ECMO
- Impella 5.5
- VT/RHF, end organ dysfunction
- Too sick to transplant

Supplemental Figure 1. Adequate antero-posterior dimension and adequate pulmonary artery to diaphragm dimension on axial (A) and sagittal (B) computed tomography imaging of patient chest; Pump outline overlayed in green.

Minimum Sternal to vertebral body distance 12.6cm
Patient Diaphragm to mPA distance 10.8cm
- Implanted per protocol
- Put in 'Autoregulatory mode' - beat rate changes with change in filling pressure
  - Maintained in this mode
- First 30 d - only one alarm, when patient bared down. Spontaneously resolved
- Anticoagulation: heparin -> daily enoxaparin + ASA
- Normalized platelets and VWF
- Correction of EOD
- No major complications

**FIGURE 2** Main display screen showing continuous real-time right and left pump pressures, average flows, inflow/outflow pressures, and pressure in the hydraulic fluid bag.
Happy Ending!

- Transplanted 4 months later
- 8 month post transplant follow up - good graft function

- Potential for fewer CVA/bleeding events with newer generation TAH
- Improved patient quality of life with autoregulation

  CARMAT clinical trial now ongoing again...
  - Primarily in Europe - France
Summary

- The world of surgical heart failure is rapidly changing!
- So many new tools in the toolkit!
- Art of medicine
  - When do we use what, and in whom...

Questions?