What’s new with VADs and the TAH?

Scott Lick, MD
Professor of Surgery
Director, Thoracic Organ Transplantation
Banner University Hospital
• I will be discussing off-label use of FDA-approved devices.
• I will be discussing devices in trials not (yet?) approved by the FDA.
  -and-

• I have no financial interests to disclose.
Why a pulse?

• Clear post-stenotic areas of stasis
• Vascular endothelial cells sense wall shear stress (WSS)
• If WSS low, constrictive remodeling
• If WSS high, expansive remodeling.
Why rotary pumps?

- Efficiency of power (no air compressor)
- Efficiency of space (once displacement chamber gone, no compliance chamber)
- Efficiency of complexity (one moving part)
- Efficiency of cost (both to make, and to run)
Archimedes’ screw pump
Axial and Centrifugal
• Heartware
• Passive magnets + thin layer of blood = bearing
HeartWare H-VAD

- No pocket needed
- Lower speed (2500 rpm)
- Large clearance blood bearing
- Up and coming: mag levitation bearings, constantly adjustable (Heartmate 3).
Frankenstein’s rule of surgery:

• He who creates the monster takes care of it.
THEY WON'T STAY DEAD!

NIGHT OF THE LIVING VAD

They keep coming back in a bloodthirsty lust for HUMAN HEARTS!...

Pits the VAD against the living in a struggle for survival!

STARRING
JUDITH O’DEA  DUANE JONES  MARYLYN EASTMAN  KARL HARDMAN  JUDITH RIDLEY  KEITH WAYNE

Produced by Russell W. Streiner and Karl Hardman  Directed by George A. Romero  Screenplay by John A. Russo  A Walter Reade Organization Presentation — Released by Continental
IN THE EVENT OF ZOMBIE ATTACK

3 STEPS TO SURVIVING INFESTATION

1. Avoidance
2. Termination
3. Disposal

1. AVOIDANCE

All zombie infestations render the location uninhabitable. The citizen’s first duty is to vacate the area and proceed immediately to an authorized Rescue Station. Only authorized Z.E.R.O. personnel will manage relocation—but the key to an effective evacuation is COMPLETE AVOIDANCE OF HAZARDOUS CONDITIONS while en route.

- **EVACUATE**
  - Gather family and essential small valuables only. DO NOT attempt to secure or defend property or possessions.

- **RELOCATE**
  - Proceed immediately to the Rescue Station assigned to your area. In the absence of Z.E.R.O. Relocation Management personnel, monitor local radio broadcasts for directions.

DO NOT ENGAGE!

It is critical to remember that any zombies encountered during relocation are NOT family or friends but REANIMATED CORPSES INFECTED WITH A DEADLY CONTAGION. Under NO circumstances should you engage one in any kind of interaction. Contagion is transmitted via a bite, and ANY interaction with a zombie results in repeated attempts to bite.

IN THE EVENT OF A BITE...

- Apply pressure to the wound with padding found in the supplied BITE KIT until proper medical supervision can be accessed.
- IF THE WOUNDED INDIVIDUAL EXPIRES after being bitten, VACATE THE PREMISES IMMEDIATELY or execute guidelines found in next section.

2. TERMINATION

Engage this step only if in an unsecured location, and ONLY if you have positively identified a zombie by using the Zombie Classification Cards (supplied). Otherwise, any terminations should be referred to and executed by a duly authorized member of Z.E.R.O. or your local licensed Zombie Exterminator.

- **CEREBRAL NEUTRALIZATION**
  - The ONLY known method for effectively terminating a zombie, either by cranial penetration or blunt force trauma (A, B, C) or decapitation (D).

- **CENTER MASS**
  - For stopping or slowing down target ONLY when distance does not permit a head shot. NOT an effective termination method.

- **LOWER EXTREMITIES**
  - For stopping or slowing down target ONLY when distance does not permit a head shot. NOT an effective termination method.

3. DISPOSAL

"TAPE & TAG"

After terminating the zombie(s), mark the perimeter to enable Z.E.R.O. Disposal Unit personnel to locate the remains and ship to a Mobile Acid Disintegration (M.A.D.) unit for disintegration. This can be completed in two simple "Tape & Tag" steps:

1. Mark area surrounding the remains with an appropriate length of CAUTION: ZOMBIE OUTBREAK ZONE tape (supplied).
2. Attach a FORM 2BD tag (supplied) to the toe of the corpse.

DO NOT INCINERATE!

Incineration releases airborne toxins which spread infection to the uninjured deceased or in areas of heavy humidity or precipitation, the recently infected deceased. This exponentially increases infection levels.

Courtesy: Zombie Emergency Response Operations: Information Branch

FORM #078-INFO-998033-2A (rev. 11.09.04)
• No detectable pulse
• No detectable pulse
• To the casual observer, he had no heart
• No detectable pulse
• To the casual observer, he had no heart
Known to shoot humans in the face
Pre-op issues

• LV size (big enough for inflow cannula. Bigger is better, up to a point).
• Body size (pocket).
• Driveline routing and exit.
• CVP< PCWP. CVP<< PA mean.
• If CVP = PA mean, bad sign!
• Compliant, responsible patient... another talk.
Intra-op echo issues

• ASD or PFO (R → L shunt)
• TR
• LAA clot
• MS or MR (repair?)
• LV clot
• AI (central stitch, oversew, or replace with tissue).
Late post-op

- Anticoagulate like mechanical valve
- Off inotropes
- Don’t over-diurese!
- Find patient’s “sweet spot”
  -- too much vad flow: aortic valve closed (late AI?), septum to left
  -- too little vad flow: short of breath, MR
Heyde’s Syndrome

- Initially described with aortic stenosis
- GI bleeding -- resolved after AVR!
- High shear breaks down VWf
- Low pulsatility makes one prone to AVM (VEGF-driven)

So high incidence GI bleeding in continuous-flow VAD patients.
RV failure after LVAD

- High PVR in chronic LV failure
- Secondary TR
- Septum pulled toward LV by LVAD
Protek Duo (ECMO or RVAD)
Protek Duo as temporary RVAD
Upon weaning from bypass after implant, a patient with an LVAD becomes hypoxic. The most likely cause is:

A. Atalectasis
B. Vasodilator-induced blunting of hypoxic vasoconstrictive response.
C. Patent Foramen Ovale.
D. Oops! Wrong ventricle! (RV→Aorta)
Survival current VADs

- BTT 80% 1 year
- DT around 70% 1 year
- Around 12% /yr neurologic complications
- World’s longest survivor on same VAD 8 years.
- Always at risk for infection (driveline).
- Most common reason for pump exchange is low-grade pump thrombus (high LDH, high power draw to maintain a given rpm).
Beyond standard Transcutaneous Energy Transmission Systems (TETS)

• Free-Range Resonant Electrical Energy Delivery (FREE-D)

• Exploits phenomenon that metal coils resonating at the same frequency transmit energy particularly efficiently

• Works at off angles and distance up to meters.
Free-range resonant electrical delivery (FREE-D)

<table>
<thead>
<tr>
<th></th>
<th>FREE-D</th>
<th>TETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 90% efficiency separation distance (cm)</td>
<td>71.0</td>
<td>3.0</td>
</tr>
<tr>
<td>&gt; 50% efficiency separation distance (cm)</td>
<td>120</td>
<td>6.4</td>
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<tr>
<td>&lt; 10% efficiency separation distance (cm)</td>
<td>160</td>
<td>10.0</td>
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<tr>
<td>&gt; 90% efficiency angular misalignment (°)</td>
<td>60°</td>
<td>5°</td>
</tr>
<tr>
<td>&gt; 50% efficiency angular misalignment (°)</td>
<td>83°</td>
<td>10°</td>
</tr>
<tr>
<td>&lt; 10% efficiency angular misalignment (°)</td>
<td>88°</td>
<td>12°</td>
</tr>
<tr>
<td>Patient contact needed (yes/no)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Tethered operation (yes/no)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Energy transfer range</td>
<td>Meters*</td>
<td>10cm</td>
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</table>

* Energy transfer range depends on the size of the resonator. The FREE-D measurements in Table 1 correspond to the basic FREE-D resonator configuration in Fig. 2 with a drive resonator diameter of 31cm and a Tx and Rx resonator diameter of 59cm. The TETS data corresponds to the inductively coupled coils from [19] with a coil diameter of 85mm.
FREED (Free-range Resonant Electrical Energy Delivery)
A tether-free Left Ventricular Assist Device (LVAD)

FREE-D system

Image Courtesy of Pramod Bonde
Which valve lesion **most** clearly needs operative correction at time of LVAD implant?

A. Moderate Tricuspid Regurgitation.
B. Moderate Mitral Regurgitation.
C. Moderate Aortic Regurgitation.
D. Severe Aortic Stenosis.
The Total Artificial Heart
TAH Replaces the Human Ventricles

Total Artificial Heart

Human Heart
TAH Eliminates

Types of Support
- Defibrillator
- Pacemaker
- Balloon pump
- ECG/arrhythmia monitoring
- Swan-Ganz catheters

Native Heart issues
- Ventricular thrombus
- VSDs
- Mechanical valves
- Heart/graft preservation
- Right heart failure/dysfunction
- Native valves (aortic/tricuspid insufficiency)

Other
- CPR
- Concern with pulmonary pressures
- Device pocket
- End organ dysfunction due to low flow and elevated filling pressures

Medications
- Anti-arrhythmics
- Beta blockers
- Inotropes
- Immunosuppressives
- Pulmonary dilators
Implantable TAH Features

- Occupies space of diseased heart
  - Displaces 400 ml
  - Weighs 160 grams
- Blood flow path same as normal heart
  - Inflow <2 cm
  - Blood path <20 cm
- Adjustable ventricle orientation
- No surgical pocket required
Operating the TAH

- Partial Fill
  50-60ml

- Full Eject
TAH 70cc Output

Right Atrial Pressure (mmHg)

Normal Range

TAH-t Output L/M
TAH – Freedom Driver
SynCardia & the TAH Today
## TAH Implants in Humans 1969-2014

<table>
<thead>
<tr>
<th>TAH Type</th>
<th>Years Implanted</th>
<th># Implants</th>
<th># Centers</th>
<th>Duration</th>
<th>Size milliliters</th>
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<tbody>
<tr>
<td>Liotta</td>
<td>1969</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Akutsu</td>
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<td>1</td>
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<tr>
<td>Jarvik 7-100</td>
<td>1982-92</td>
<td>44</td>
<td>10</td>
<td>6 years</td>
<td>100</td>
</tr>
<tr>
<td>Phoenix</td>
<td>1985</td>
<td>1</td>
<td>1</td>
<td>11 hours</td>
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<tr>
<td>Penn St</td>
<td>1985-89</td>
<td>4</td>
<td>1</td>
<td>1 year</td>
<td>100</td>
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<tr>
<td>Jarvik 7-70</td>
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<td>159</td>
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<tr>
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<td>1</td>
<td>60 days</td>
<td>120L/100R</td>
</tr>
<tr>
<td>Unger</td>
<td>1986-90</td>
<td>4</td>
<td>3</td>
<td>50 days</td>
<td>100</td>
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<tr>
<td>Vienna</td>
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<td>1</td>
<td>18 days</td>
<td>87L/75R</td>
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<tr>
<td>BRNO</td>
<td>1988-90</td>
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<td>3</td>
<td>50 days</td>
<td>80</td>
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<tr>
<td>Poisk</td>
<td>1987-90</td>
<td>16</td>
<td>3</td>
<td>100 days</td>
<td>100</td>
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<tr>
<td>CardioWest</td>
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<td>10</td>
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<tr>
<td>Phoenix 7</td>
<td>1998</td>
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<td>1</td>
<td>15 days</td>
<td>100</td>
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<td>ABIOCOR</td>
<td>2001-06</td>
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<tr>
<td>SynCardia</td>
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<tr>
<td>Carmat</td>
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<td>2</td>
<td>4 months</td>
<td>65</td>
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<tr>
<td>SynCardia</td>
<td>2014</td>
<td>2</td>
<td>2</td>
<td>20 days</td>
<td>50</td>
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<tr>
<td><strong>Totals</strong></td>
<td><strong>1969-2014</strong></td>
<td><strong>1458 implants</strong></td>
<td></td>
<td><strong>449 Years</strong></td>
<td></td>
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</table>
TAH Centers

77 US Centers
65 new centers since July 2010
- 125 Banner University Medical Center Tucson
- 82 VCU
- 48 Cedars-Sinai
- 34 Mayo Clinic Phx
- 23 Cleveland Clinic

56 ROW Centers
33 new centers since July 2010
- 233 La Pitie Paris
- 179 Bad Oeynhausen Germany
- 62 Nantes France
- 31 Duisburg Germany
- 19 Montreal Heart Institute
# 50 cc TAH Compared to 70cc TAH

<table>
<thead>
<tr>
<th></th>
<th>70 cc TAH</th>
<th>50 cc TAH</th>
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<tbody>
<tr>
<td>BSA</td>
<td>&gt;1.7m²</td>
<td>1.2 – 1.7m²</td>
</tr>
<tr>
<td>T10</td>
<td>10 cm</td>
<td>7 cm</td>
</tr>
</tbody>
</table>

[Image: Three prototypes of the TAH device, labeled 70cc TAH and 50cc TAH, with specifications listed in a table showing differences in BSA and T10 dimensions.]
Need for 50cc TAH (Underserved Populations)

- Women (only 11.8% of TAH patients to date)
- Small-Statured Adults (with non-dilated native hearts)
- Younger (Non-Adult) Patients
- Patient conditions where native hearts are typically not enlarged
  - Transplant Rejection
  - Acute Heart Failure
  - Hypertrophic
  - Amyloid
  - Congenital
  - Restrictive Cardiomyopathy
BSA vs T10

BSA: 1.6m²  T10: 11.7  LVEDD: 80 mm

- BSA: ✗
- T10: ✓
- LVEDD: ✓
VAD, TAH and Transplant are group efforts!
All are good reasons to use a TAH instead of an LVAD except:

A. Transplant vasculopathy as a bridge to re-transplant.
B. Hypertrophic cardiomyopathy.
C. Irreparable post-infarct septal rupture.
D. Extensive LV clot
E. LVAD patients can be mistaken for Zombies.