Artificial Hearts

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Motivation

- Around 5 million Americans suffer from some form of heart failure
- In severe cases (stage D) a heart transplant is the only treatment
- Artificial hearts can help in two ways:
  - Temporarily replace the heart to strengthen patient for next surgery and give them more time to wait for a heart donor
  - Permanently replace the heart removing the need for a heart donor
The Human Heart

8: Pulmonary valve
5: Tricuspid valve
1: Right atrium
2: Right ventricle
3: Left atrium
4: Left ventricle
7: Mitral valve
8: Aortic valve
Heart Failure

- Heart failure is defined as the inability of the heart to supply the body with sufficient blood flow.

- A survey of 130,000 people, conducted by the National Center for Health Statistics, ranks the primary causes for heart failure:
  - Ischaemic Heart Disease 62% (reduced blood supply to heart)
  - Cigarette Smoking 16%
  - Hypertension 10% (high blood pressure)
  - Obesity 8%
  - Diabetes 3%
  - Valvular Heart Disease 2% (much higher in older populations)
Classification of Heart Failure

- In 2001 the American Heart Association introduced the following classification system:
  - Stage A: Patients at high risk for developing Heart Failure in the future but no functional or structural heart disorder
  - Stage B: a structural heart disorder but no symptoms at any stage
  - Stage C: previous or current symptoms of heart failure in the context of an underlying structural heart problem, but managed with medical treatment
  - Stage D: advanced disease requiring hospital-based support, a heart transplant or palliative care
- Artificial hearts are for stage D patients
Brief History of Artificial Hearts

- In 1957 Dr. Willem Kolff implanted an artificial heart into a dog, the dog survived for 90 minutes
- In 1973 a calf was given an artificial heart and survived for 30 days
- In 1976 Kolff’s student, Robert Jarvik, designed a heart that kept a calf alive for 184 days
- In 1981 the Jarvik 7 was implanted into a human who was hours away from death and kept the patient alive for 112 days
- Today there are two hearts that are implanted into humans
Current FDA Approved Artificial Hearts

- **CardioWest temporary Total Artificial Heart**
  - Approved as a bridge to transplant device only (2004)

- **AbioCor Replacement Heart**
  - Approved under the humanitarian device exemption (affects less then 4000 people per year) (2005)
CardioWest Artificial Heart

- Purpose of this device is to provide patient with a heart until a donor heart is available
- It is the successor to the Jarvik 7
- Ventricles are made out of polyurethane
- The heart is powered by air pressure which is provided by the driver
**Figure 5:** This picture shows an illustration of the Jarvik-7 blood pump. Air enters the driveline from the console and pushes on the diaphragm layers. The diaphragm layers expand to propel blood through the Aortic valve [Quaal, 1993].
CardioWest Wave Form

Figure 6  TAH flow waveform.
Figure 5  TAH pressure waveform.
Pneumatic Drivers

In the USA:

In Europe:

Not FDA Approved
Not Available in the U.S.
Some Data

- The CardioWest Artificial Heart was implanted in 95 patients from 1993 to 2002 who were in imminent danger of death.
- 79% of patients survived to time of donor transplant compared to 46% of the control.
- 69% of alive patients survived donor transplant compared to 37% of control group.
- 70% of surviving patients were alive 1 year after surgery compared with 31% of control.
More Data

Figure 7  U.S. multi-center trial overall survival curve.
Bridge to Transplant Device

- The CardioWest artificial heart successfully helps patients survive until time of donor heart transplant and increases chance for successful donor heart surgery.
- The pneumatic driver which powers the heart limits its value to temporary use only.
- Is it possible to make a heart that could permanently replace the human heart?
AbioCor Artificial Heart

- The AbioCor is approved by the FDA as a permanent artificial heart
- There is no large external drive system
Diagram of AbioCor

**Figure 14:** The design Abiocor blood pump is shown in the diagram above. The pump has two motors. One motor operates the valves while the other motor induces hydraulic motion to a pusher plate that pushes flexible plastic membranes. The membranes contract and expand to expel and draw in blood from the body [Abiomed, 2002].

Sources: Steven Parnis, Texas Heart Institute, Abiomed, Inc.
The AbioCor System
The AbioCor System

- External Transcutaneous Energy Transfer (TET): Silicon ring containing a wire coil used to transfer energy to internal TET
- Internal TET: Converters received power from external TET into a current used to charge the battery and run heart
- Implanted battery: provides up to 45 min of power while free from all external connections
- Patient Carried Electronics (PCE): Batteries carried by patient that power the system most of the time
- Implant Controller: This unit controls all other components and makes sure the heart is pumping blood correctly
- Thoracic Unit: This is the artificial heart, it weights about 2 pounds and takes over for the removed heart
Transcutaneous Energy Transfer (TET)
The Surgery

- Procedure lasts 7 hours
- Patient must be placed on and then removed from a heart and lung machine
- Heart is held in location by hundreds of stitches and attached to the remaining heart with synthetic grafts
Results

■ Fourteen patients were given the AbioCor heart in 2004

■ They were chosen if prognosis for survival was less than 30% for the next 30 days

■ They also were not eligible for a donor heart
  – Over 65
  – High blood pressure
  – Irreversible kidney or liver dysfunction
  – Cancer in last 5 years
  – Etc.
• Two patients did not survive the implant surgery
• There were two device failures
MLHF (Minnesota living with heart failure): lower score means better quality of life
Is This Really a Permanent Heart

- **Pros**
  - The AbioCor provides extended life and increased quality of life for patients with no other options
  - It is the first total artificial heart to receive FDA approval so it should get better with time

- **Cons**
  - Patients did not survive very long (possible due to their health and not the heart)
  - 2 out of 14 devices failed so its not too reliable
  - It still requires some external components
  - Recovery time from surgery is very long
Conclusion

- Both hearts successfully replace the human heart for a relatively short period of time.
- More development is needed before an artificial heart could replace the human donor heart.
- While some of this data looks fairly bad it is important remember that most of these patients will die in 30 days without these devices.
References

- Summary of Safety and Probable Benefit - H040006, AbioCor Implantable Replacement Heart, FDA, 2004
- Artificial Hearts, Kurtuluş GÖKDUMAN, Middle East Technical University
- Marvin J, Slepian, Richard G. Smith, Jack G. Copeland CardioWest Total Artificial Heart, University of Arizona Sarver Heart Center,
- Syncardia Temporary CardioWest Total Artificial Heart (TAH-t) - P030011, FDA, 2004
- SynCardia Website, CardioWest
- AbioMed Website, AbioCor
- Texas Heart Institute Website, Jarvik 7
- Free Patents Online, TET
- Wikipedia, Artificial Hearts
- Wikipedia, Willem Kolff
Questions

- The CardioWest Artificial heart is approved by the FDA as a “bridge to transplant device,” what does this mean?
  - It is implanted at the same time as the donor heart to help the donor heart survive
  - It is implanted into the patient before their dysfunctional heart is removed
  - It is used during surgery to keep the patient alive when the heart transplant is taking place
  - It is implanted in the patient as a replacement heart that will only last until a donor heart is available

- Which of the following is not part of the AbioCor system?
  - Thoracic Unit
  - Emergency Thoracic Unit
  - Internal Battery
  - Patient Carried Electronics (PCE)
comments

- History slide to next side transition
- Image of normal heart to compare artificial hearts
- How to attach heart to arteries
- Explain basics of air flow graph
- Can hearts change heart rate
- MLHF test details
- Patients don’t live long because of health or device?