UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 16, 2014**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**68-0533453**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On September 16, 2014, Sunshine Heart, Inc. (***"Sunshine Heart"*** or the ***"Company"***) announced that follow-up data from six patients implanted with the C-Pulse® Heart Assist System at St. Luke's Hospital — Mid America Heart Institute, as part of a FDA approved, North American Feasibility Trial, will presented by Dr. Sanjeev Aggarwal, MD, Director of Mechanical Circulatory Support at Saint Luke's Mid America Heart Institute. Prior to his clinical presentation at TCT Conference, Dr. Aggarwal will present these case studies and a COUNTER HF study update to the investment community at Sunshine Heart's fourth annual analyst and investor breakfast that begins at 7:00am (EDT) at the Grand Hyatt Washington on September 16, 2014. Dr. Christopher Bowles, PhD, Royal Brompton and Harefield NHS Foundation Trust and Imperial College London, and Dr. William E. Cohn, MD, Texas Heart Institute, will also present at the breakfast. Following the event, the presentations will be available on the investor section of the Sunshine Heart website at http://ir.sunshineheart.com/index.cfm.

Limitation of Incorporation by Reference

In accordance with General Instruction B.2. of Form 8-K, this information including Exhibits 99.1, 99.2, 99.3 and 99.4, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release - Sunshine Heart to Provide Case Studies from North American Feasibility Trial and Updates on OPTIONS HF and COUNTER HF™ at 2014 Transcatheter Cardiovascular Therapeutics (TCT) Conference
99.2	Presentation - Dr. Sanjeev Aggarwal, Director of Mechanical Circulatory Support at St. Luke's Mid America Heart Institute
99.3	Presentation - Christopher Bowles, PhD, Artificial Heart Specialist at Royal Brompton and Harefield NHS Foundation Trust & Imperial College London
99.4	Presentation - Dr. William E. Cohn, Director of Minimally Invasive Surgical Technology at Texas Heart Institute at St. Luke's Medical Center

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Dated: September 16, 2014

SUNSHINE HEART, INC.

By: /S/ JEFFREY S. MATHIESEN
Name: Jeffrey S. Mathiesen
Title: Chief Financial Officer

EXHIBIT INDEX

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Sunshine Heart to Provide Clinical Updates from the North American Feasibility Study and OPTIONS HF European Post-Market Study at 2014 Transcatheter Cardiovascular Therapeutics (TCT) Conference

EDEN PRAIRIE, Minn., September 16, 2014 (GLOBE NEWSWIRE) — Sunshine Heart, Inc. (Nasdaq: SSH) announced today that follow-up data from six patients implanted with the C-Pulse® Heart Assist System at St. Luke's Hospital — Mid America Heart Institute, as part of a FDA approved, North American Feasibility Study, will be presented later today by Dr. Sanjeev Aggarwal, MD, Director of Mechanical Circulatory Support at Saint Luke's Mid America Heart Institute. Prior to his clinical presentation at the TCT Conference, Dr. Aggarwal will present on a few of these patients who demonstrated clinical signs of myocardial recovery to the investment community at Sunshine Heart's fourth annual analyst and investor breakfast that begins at 7:00am (EDT) today at the Grand Hyatt Washington. Dr. Christopher Bowles, PhD, Royal Brompton and Harefield NHS Foundation Trust and Imperial College London, and Dr. William E. Cohn, MD, Texas Heart Institute, will also present at the breakfast. Following the event, the presentations will be available on the investor section of the Sunshine Heart website at: http://ir.sunshineheart.com/index.cfm .

"Myocardial Recovery in Ambulatory Heart Failure Patients Treated with the C-Pulse Cardiac Assist System: A Single-Center Experience," will be presented by Dr. Aggarwal in Session II: Mechanical Circulatory Support for Chronic CHF at 4:48 p.m. (EST) in Level 1, Room 152A/B. The patient data outlined on Dr. Aggarwal's poster demonstrates that six NYHA Class III patients were successfully implanted with the C-Pulse System, using minimally invasive surgical (MIS) techniques, from July 2010 to April 2012 as part of the North American Feasibility Study. Safety endpoints at 6 months demonstrated that there were no device related deaths, neurological events, aortic disruptions, myocardial infarctions, and mediastinal infections. Quality of life was evaluated using two standard cardiac disease, self-assessments, MLWHF and KCCQ. One patient was transitioned to an implantable LVAD 97 days post C-pulse implantation due to worsening heart failure symptoms. Two patients remain clinically stable on C-Pulse support at 1178 and 982 days respectively, and have showed improvement in NYHA class, 6-minute walk test, and quality of life scores. The other three patients all demonstrated clinically significant improvement allowing for discontinuation of C-Pulse support with explantation of the percutaneous lead and continue to be followed. The mean duration of support was 659 days (range 534-793), the mean ejection fraction of blood pushed from the left ventricle out of the heart increased from 18.3% to 29.3%, and the mean reduction in Left Ventricle End Diastolic Dimension (LVEDD) was 1.1cm. Mean follow-up time post weaning was 335 days (range 52-565).

Dr. Bowles' presentation provides a detailed case study of the first patient to be implanted with the C-Pulse System in the UK as part of the OPTIONS HF Study. OPTIONS HF is a post-market, multi-center, perspective, open label study for NYHA Class III and ambulatory Class IV heart failure patients being conducted in the EU. Dr. Bowles will discuss how the first patient qualified for the study, the patient's heart failure history and classification, comorbidities, surgical outcome, and current condition.

Dr. Cohn's presentation highlights C-Pulse II. C-Pulse II is a totally implantable device that has the same non-blood contacting, non-obligatory and MIS implantation characteristics as the current C-Pulse System alleviating the need for the percutaneous drive line.

About the C-Pulse® Heart Assist System

The C-Pulse Heart Assist System, or C-Pulse System, an investigational device in the United States, Canada and countries that do not recognize the CE mark approval, utilizes the scientific principles of intra-aortic balloon counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as left ventricular assist devices (LVADs), artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the results from our feasibility study, we also believe that some patients treated with our C-Pulse System will be able to be weaned from using the device due to sustained improvement in their heart failure condition as a result of the therapy.

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

About Sunshine® Heart

Sunshine Heart, Inc. (NASDAQ: SSH) is an early-stage medical device company focused on developing, manufacturing and commercializing the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. Sunshine Heart has completed an approved U.S. Food and Drug Administration (FDA) feasibility clinical study of the C-Pulse System and presented the results in November 2011. In March 2012, the FDA notified the Company that it could move forward with an investigational device exemption (IDE) application. Sunshine Heart received unconditional approval from the FDA in November 2012 to initiate its pivotal study. In July 2012, Sunshine Heart received CE Mark approval for its C-Pulse System in Europe. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with a wholly owned subsidiary in Australia. The Company has been listed on the NASDAQ Capital Market since February 2012.

Forward-Looking Statements

Certain statements in this release are forward-looking statements that are based on management's beliefs, assumptions, expectations, and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including, without limitation, future clinical study activities and results including patient enrollment in studies. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical studies do not meet their enrollment goals, meet their endpoints or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility that we may be unable to raise the funds necessary for the development and commercialization of our products, that we may not be able to commercialize our products successfully in the EU and the other risk factors described under the caption "Risk Factors" and elsewhere in our filings with the SEC. You should not place undue reliance on forward-looking statements because they speak only as of the date when made and may turn out to be inaccurate. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking

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statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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SUNSHINE HEART

TCT Breakfast Session

September 16, 2014

www.sunshineheart.com

Forward Looking Statement

SUNSHINE HEART

- This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including timing, clinical enrollment, clinical results, financing availability, product sales and marketing or efficacy of products, and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission, including our Annual Report or Form 10-K for the fiscal year ended December 31, 2013.
- Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.
- Caution: C-Pulse ® is an investigational device. The device is limited by federal (United States) law to investigational use only.
- C-Pulse is a registered trademark of Sunshine Heart Inc.

Agenda

• Welcome	Jeff Mathiesen
• Company Updates and Introductions	Dave Rosa
• OPTIONS HF Post Market Multicenter Trial: Early Experience in Europe: a case study Harefield Hospital UK	Christopher Bowles, PhD
• Progress of Fully Implantable Pump	Dr. William E. Cohn
• Single Center Experience with Patient Weaning from the US Feasibility Trial and thoughts from a leading enroller in the COUNTER HF™ US Pivotal Study Can C-Pulse Use Lead To Left Ventricular Recovery?	Dr. Sanjeev Aggarwal
• Q&A	

Introductions

Dave Rosa

C-Pulse® System

Feasibility Study with a Non-Blood Contacting Extra-Aortic Counterpulsation System in Patients with Moderate to Severe Ambulatory Heart Failure

Sanjeev Aggarwal, MD
Director, Mechanical Circulatory Support
Saint Luke's Mid America Heart Institute
Kansas City, MO

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

Disclosures

Saint Luke's MID AMERICA HEART INSTITUTE

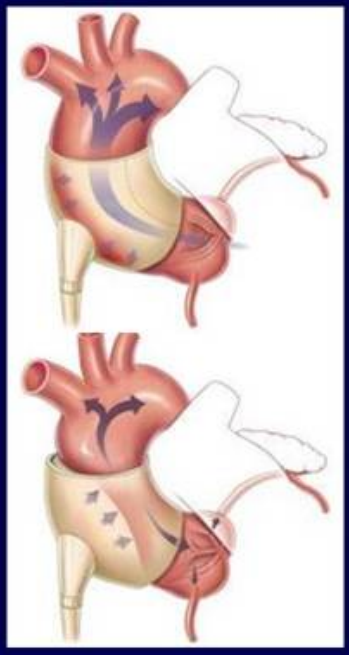
- No financial disclosures

C-Pulse Heart Assist System

- Implantable components:
  - Inflatable balloon placed around the ascending aorta
  - Epicardial ventricular sensing leads
  - Percutaneous driveline for system control and pneumatic actuation

C-Pulse Heart Assist System

- Efficacy of counterpulsation therapy
- Implantation without cardiopulmonary bypass
- Extravascular location without the need for systemic anticoagulation
- Untethering
- Minimally invasive implantation



Goals of the C-Pulse Feasibility Study

- A prospective, open label, single arm study
- Demonstrate feasibility of device and procedure
  - Assess learning curve
  - Refinement of technology and implant technique
- Safety
- Efficacy
- Support conduct of subsequent pivotal trial

C-Pulse Trial: Primary Safety Endpoints* (6 Months)

- Death
- Aortic Disruption
- Neurologic Dysfunction
- Myocardial Infarction
- Major Infection
- Any other device-related adverse event (as adjudicated by the CEC)

*Device related events as defined by INTERMACS event classifications

C-Pulse Trial: Primary Efficacy Endpoints (6 Months)

- NYHA Class ranking
- Quality of Life - Minnesota Living with Heart Failure Score (MLWHF)
- 6 Minute Walk Test
- Peak VO_2

C-Pulse Trial: Other Efficacy Measures (6 Months)

- Hemodynamics/ RHC (CO/ CI, PAP, PCWP)
- Quality of Life KCCQ
- Blood analysis (Na, Cr, Bili, Hgb, LFTs)
- Concomitant cardiovascular medications
- Re-hospitalization (HF and all cause)
- Duration of Support/ survival duration
- LOS (ICU/ discharge)
- Device usage/ compliance

Patient Characteristics

	N = 20
Mean Age ± SD years (range)	56 ± 9 (34-71)
Gender	
Female	8
Male	12
Race	
African American	3
Caucasian	17
NYHA Class Ranking	
Class III	18
Class IV	2
INTERMACS Classification	
3. Stable but inotrope dependent	3
5. Exertion intolerant	8
6. Exertion limited	7
7. Advanced NYHA Class III	2
Etiology	
Ischemic	8
Non-ischemic	12

Characteristics of Implant Procedure

Measure	All Patients (N=20)
Incision to Dressing Time (minutes)	165.7 ± 42.4 (19) 156.0 [98.0, 247.0]
Anatomical Approach	
Full Sternotomy	70.0% (14/20)
Partial Sternotomy	10.0% (2/20)
Right Parasternal	20.0% (4/20)
Time in ICU (days)	2.2 ± 2.6 (19) 1.1 [0.6, 11.1]
Time in Hospital (days)	9.9 ± 4.2 (19) 8.0 [4.0, 19.0]

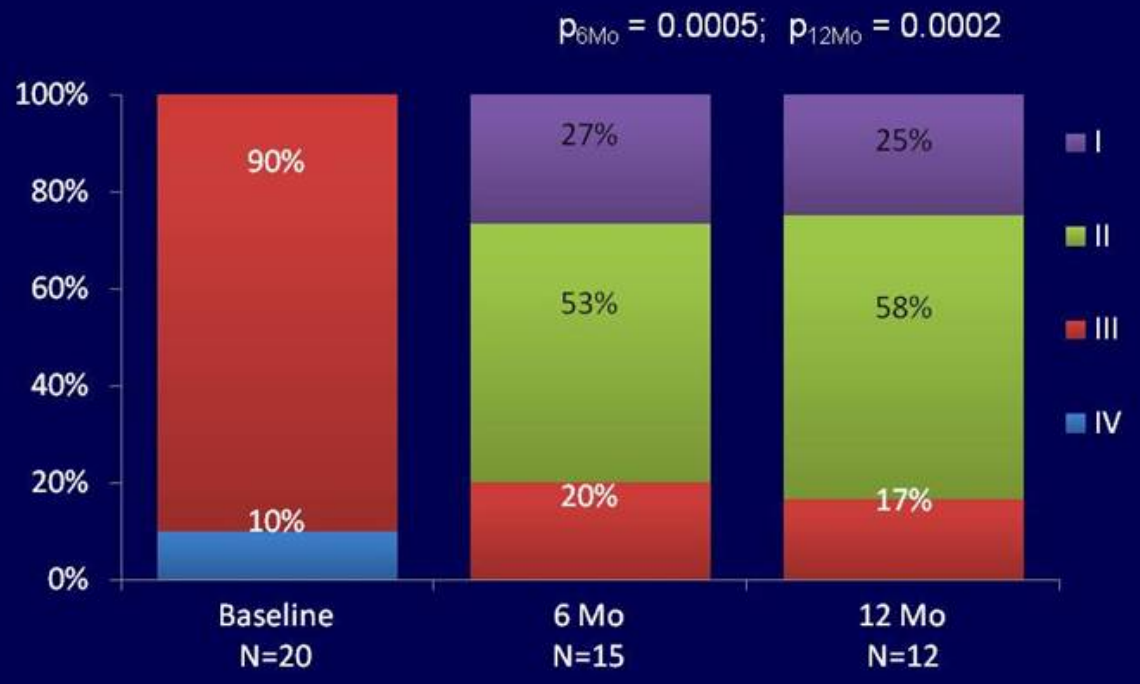
Numbers are Mean ± SD (N), Median [Min, Max] for Continuous variables and Percent (Count/N) for discrete variables.

"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

Device Related Primary Safety Endpoints (6 months and 12 months)

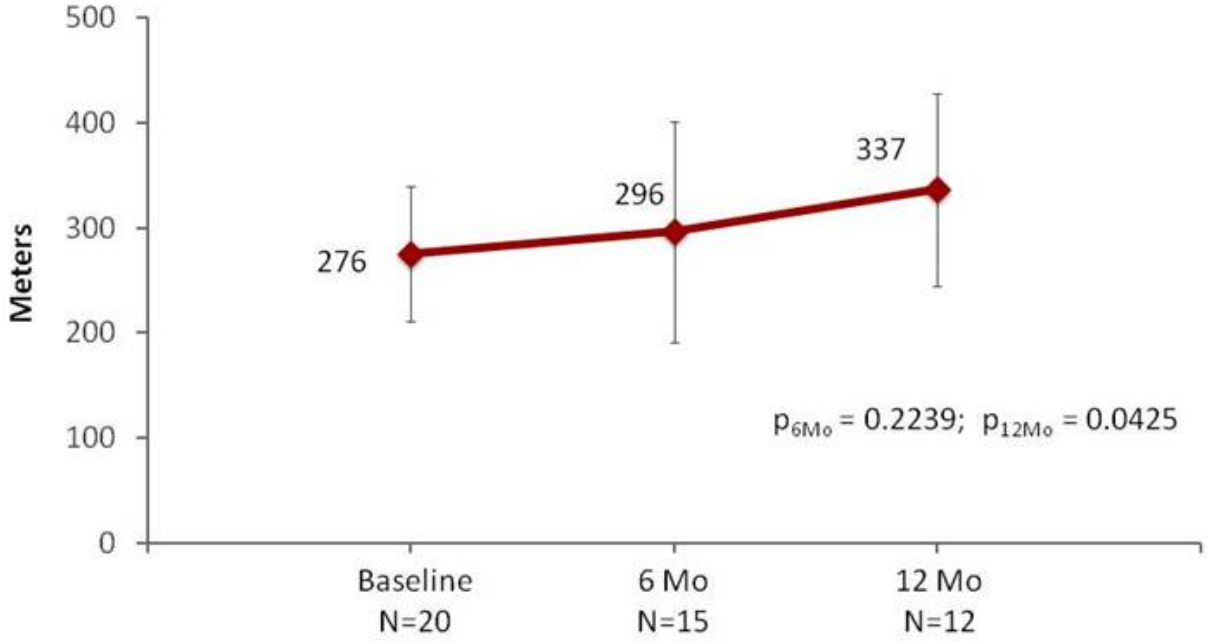
- Death
  - 0 at 30 days
  - 1 at 6 months
- Aortic Disruption
  - 1 at 137 days post implant
    - Sternal wound infection (mediastinitis) post surgery
    - CEC adjudicated as major infection, localized, procedure related
    - Infection unresolved despite repeated surgical interventions
    - Aortic rupture occurred at time of third surgical intervention
- Neurological Dysfunction: None
- Myocardial Infarction: None
- Major Infection: 9 patients
  - 8 exit site related
  - 1 PICC line

Results: NYHA Class



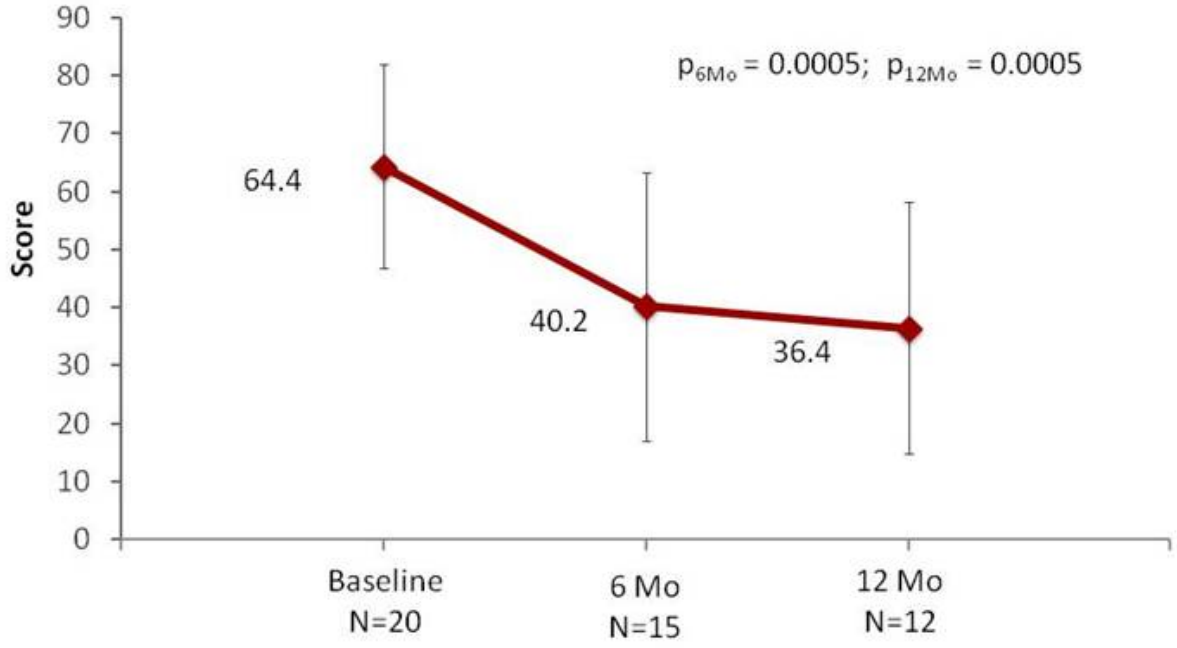
"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

Results: 6MWT



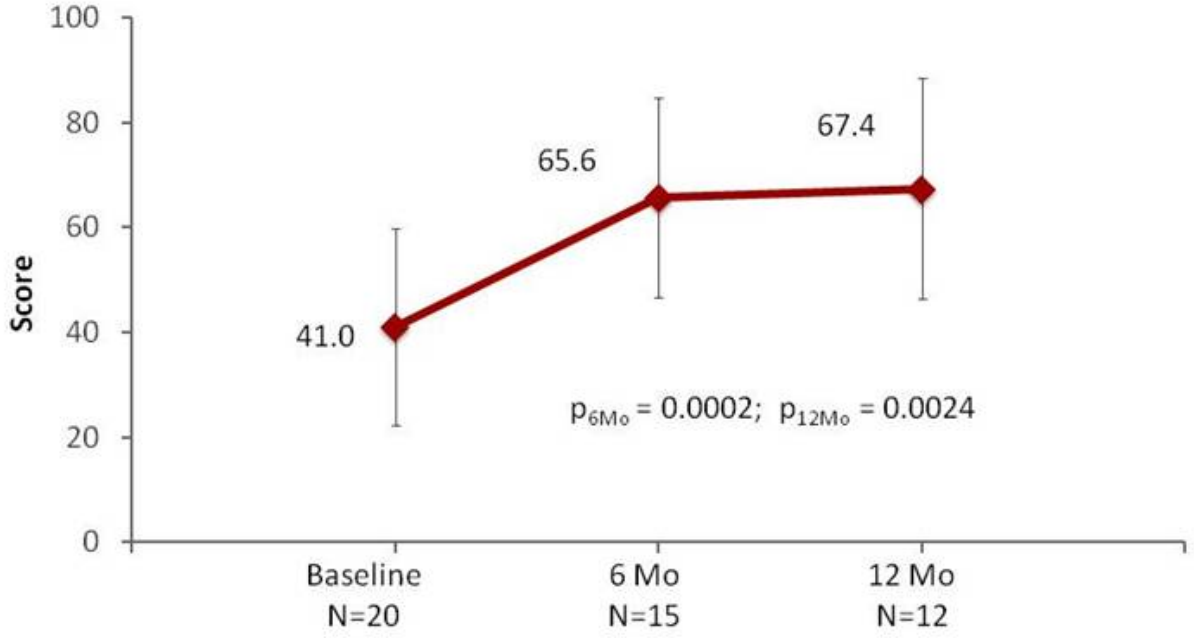
"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

Results: MLWHF



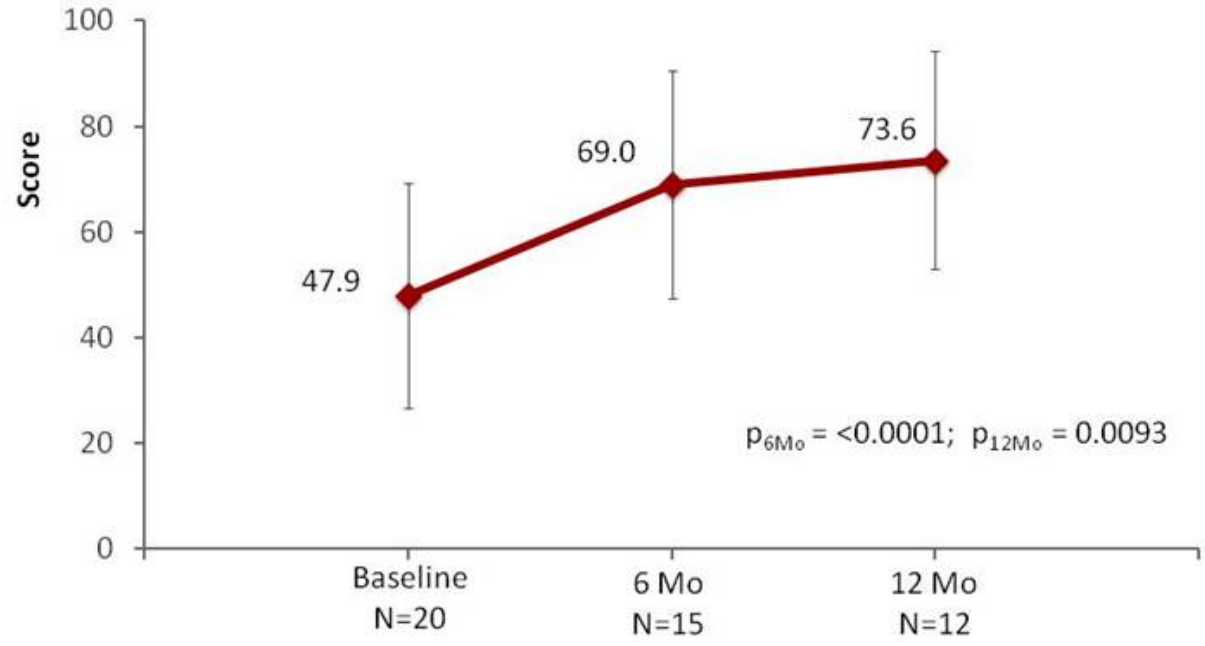
"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

Results: KCCQ Overall



"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

Results: KCCQ Clinical Score



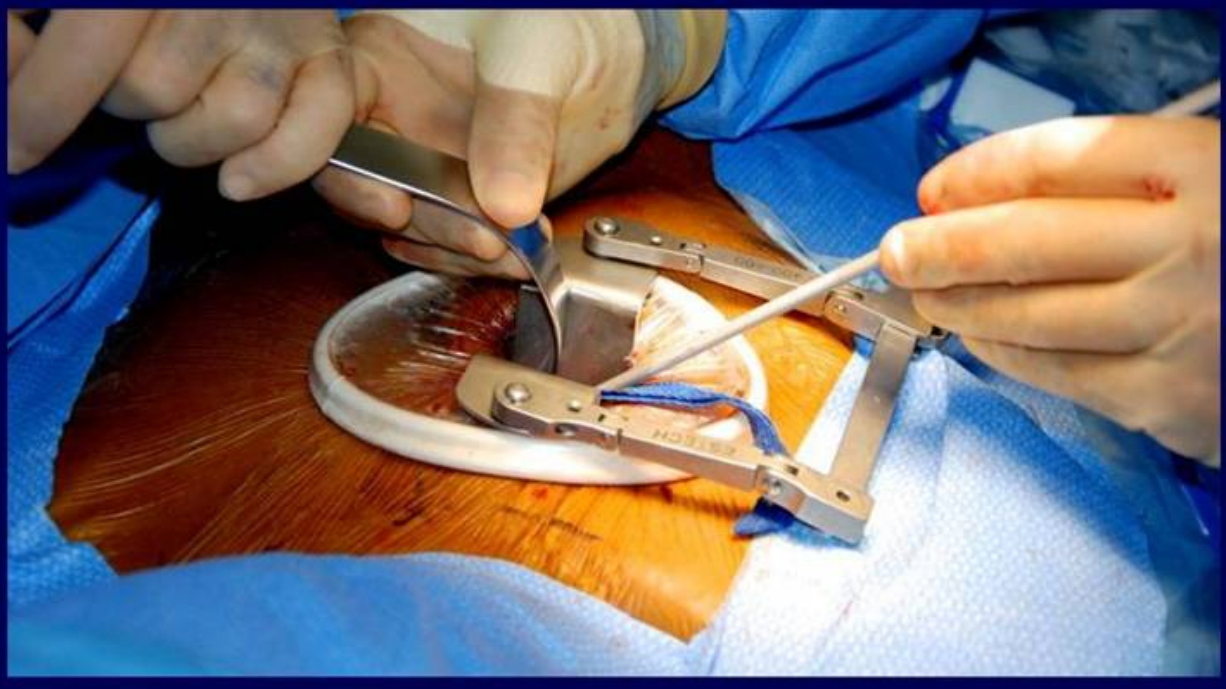
"Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Severe Chronic Heart Failure". Submitted for publication, Feb 2014. In review.

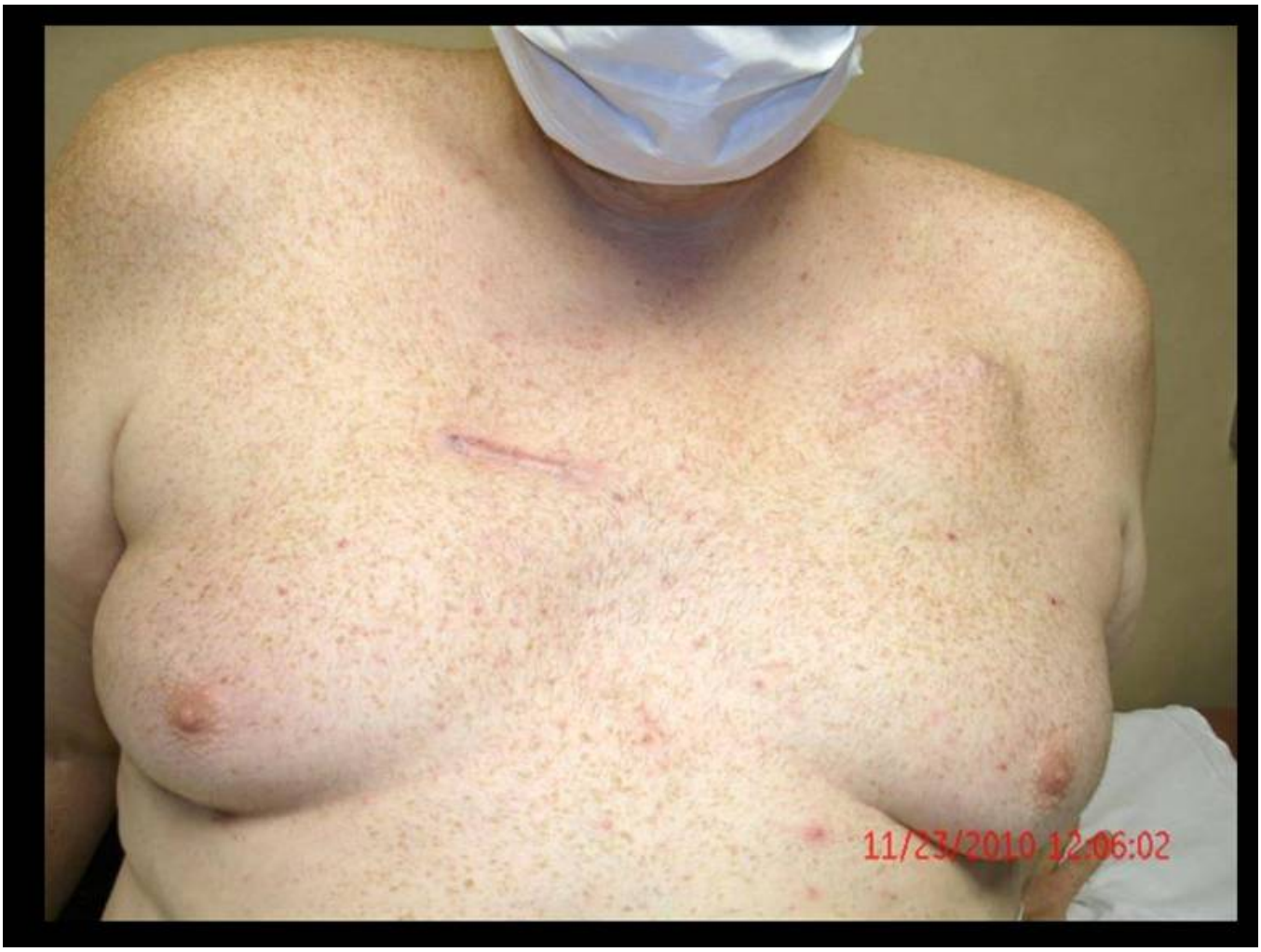
Worsening HF Hospitalizations

- Three (3) subjects had worsening heart failure rehospitalizations
  - Two were rehospitalized at 205 and 208 days
    - Did not maintain compliance with device usage
  - One went to LVAD at 4 months

Subject ID	Date of Implant	HF Rehospitalizations	Days to HF Event
08-001	21-Jul-10	14-Feb-11	208
08-003	26-Aug-10	18-Mar-11; 06-Aug-11	205 and 345 days
08-005	14-Jan-11	15-Feb-11; 07-Mar-11	33 and 52 days

Minimally Invasive Surgical Approach

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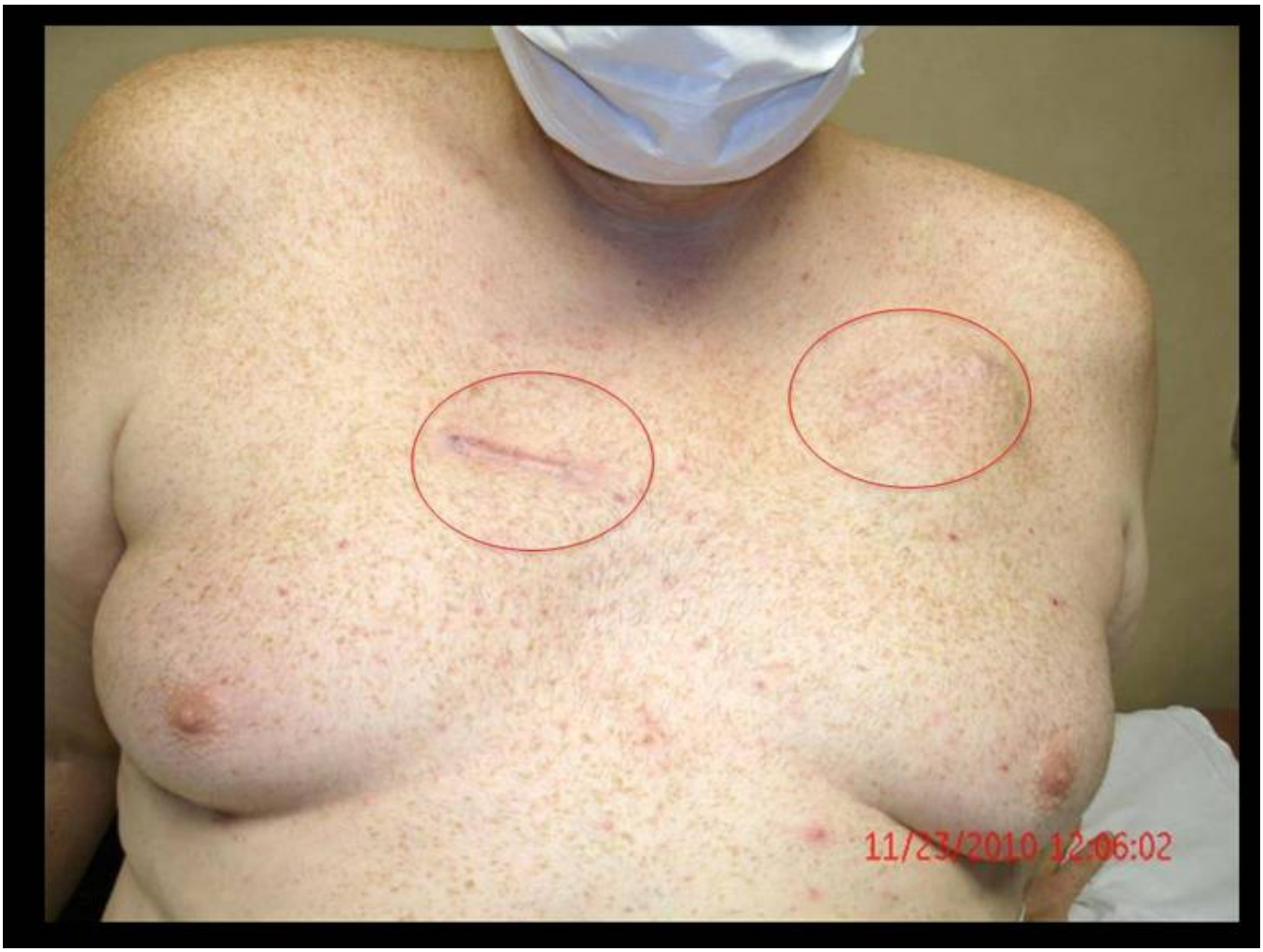
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Additional Observations

- 30.9 total patient-years of follow-up
- Diuretic doses reduced/discontinued in 6 patients
- Inotropes discontinued in all inotrope-dependent patients
- 4 patients successfully bridged to transplant
- 3 permanently discontinued from therapy after sustained improvement

Myocardial Recovery

Three of six patients showed clinically significant improvement allowing for discontinuation of device support with explantation of the percutaneous lead

Myocardial Recovery

- Mean duration of support with C-Pulse was 659 days (range 534 – 793 days)
- Mean EF improved from 18.3% to 29.3% (one patient EF has improved from 21% to greater than 40%)
- Mean reduction in LVEDD of 1.1cm
- No readmissions for heart failure (follow up time range approximately 1-2.5 years)

Case #1

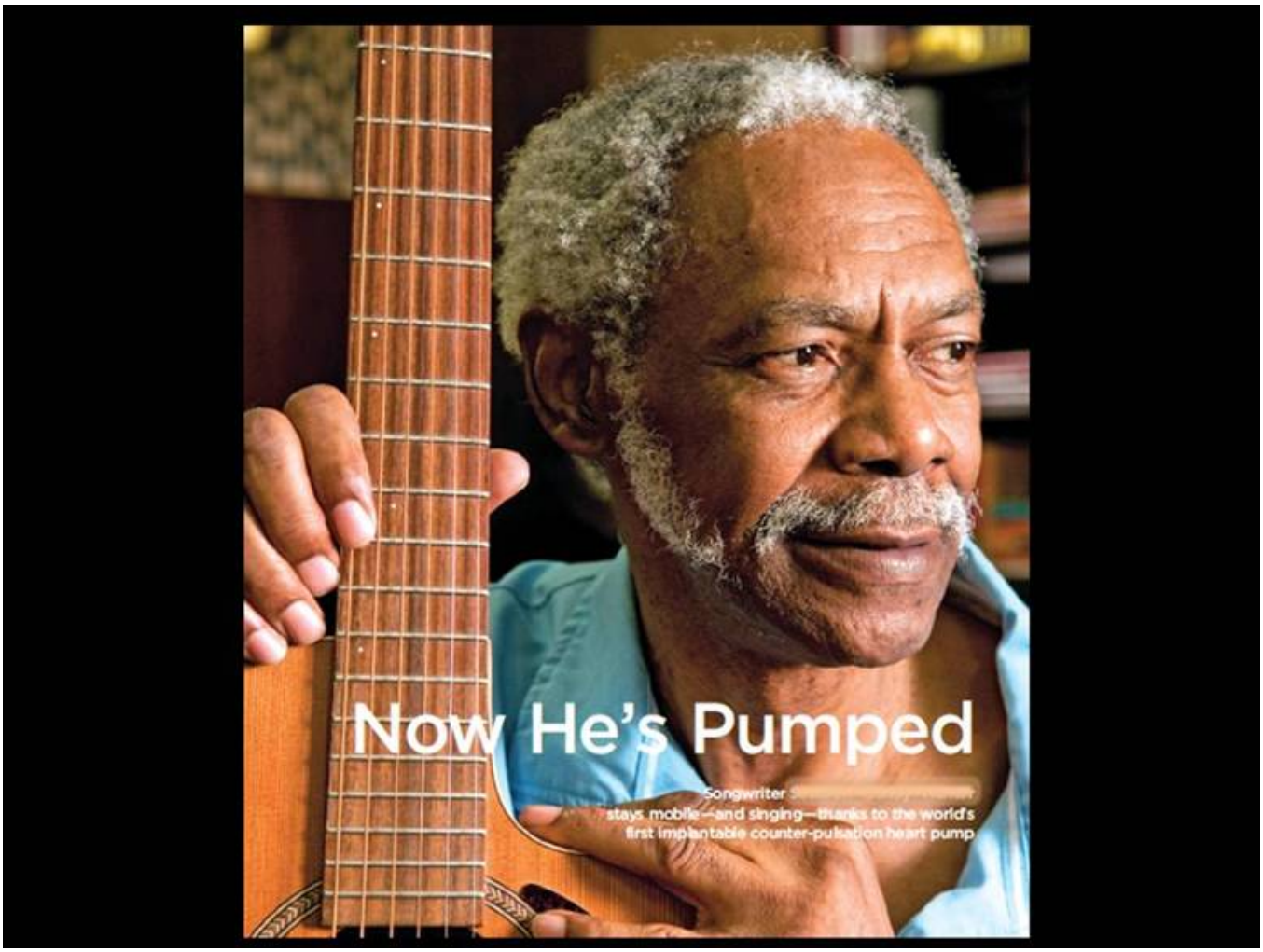
- 36 year old male NICM/ chronic systolic heart failure
- Significant exercise intolerance, DOE
- Cpulse implant 4/10/2012
- Discharged home POD#7
- Pre discharge echo demonstrated improvement in EF from 21% to >40%
- Last use of device 9/25/2013 (533 days of support)
- PIL Explanted 4/2014
- No readmissions for heart failure (>350 days F/U)

Case #2

RA 8	RA 7
PAP 39/21/26	PAP 47/25/31
PCWP 11	PCWP 10
CO/ CI 4.3/2.2	CO/CI 4.2/2.2

Conclusions

- The C-Pulse Study demonstrates the feasibility and shows the preliminary safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure
- FDA approved the IDE for the COUNTER HF randomized controlled trial to demonstrate the effectiveness of the device



A lifetime of specialist care

Royal Brompton & Harefield NHS
NHS Foundation Trust

Options HF C-Pulse System European MultiCentre Study

Case Presentation

Dr Christopher Bowles
Artificial Heart Specialist

Dr Nicholas Banner
Consultant in Cardiology
Transplant and Mechanical Circulatory Support

EU: C-Pulse is CE Marked
US: Caution: Investigational Device. Limited by Federal (or United States) law to investigational use.[1]

OPTIONS HF: Key Study Qualifications

Major Inclusion Criteria

- LVEF ≤35%
- Both ischemic/non-ischemic
- NYHA Class III/Ambulatory Class IV
- On Optimal Medical Therapy
- Evaluated or have CRT/CRT-D

Major Exclusion Criteria

- Ascending aortic calcification or CABG
- Mitral Valve Incompetence, Grade 4+
- Aortic Valve Incompetence, Grade 2-4+

54 yr old male patient

Blood Group: A Rh D Positive

Height: 5ft 11inch

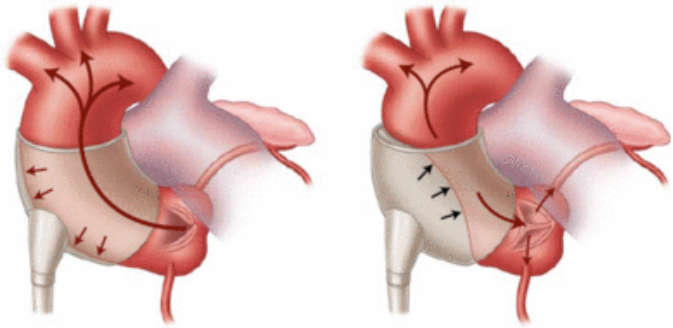
Wt: 90.6kg

Body Mass Index: 28

Background

- Acute myocardial infarction whilst on vacation in 2002 (required resuscitation following cardiac arrest)
- Primary percutaneous coronary intervention to right coronary artery (RCA) & left anterior descending (LAD) artery (the latter was unsuccessful resulting in LAD obstruction). Circumflex artery unobstructed
- Persistent New York Heart Association Class III symptoms since 2002, fatigue and shortness of breath on minimal exertion, loss of employment
- Atrial fibrillation treated with:
  - AV node ablation: 1 Nov 2012
  - Biventricular ICD pacemaker
- Type 2 diabetes
- Advanced heart failure with C-Pulse system intended as a destination to heart transplantation

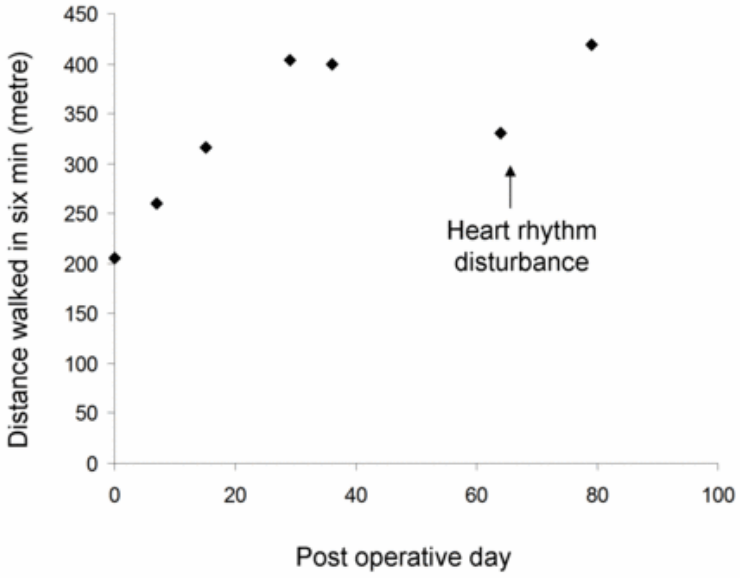
- Fulfilled multi-centre study entry criteria
- C-Pulse implanted at Harefield Hospital, London on 16 June 2014
- The first C-Pulse case in the UK



Post-operatively

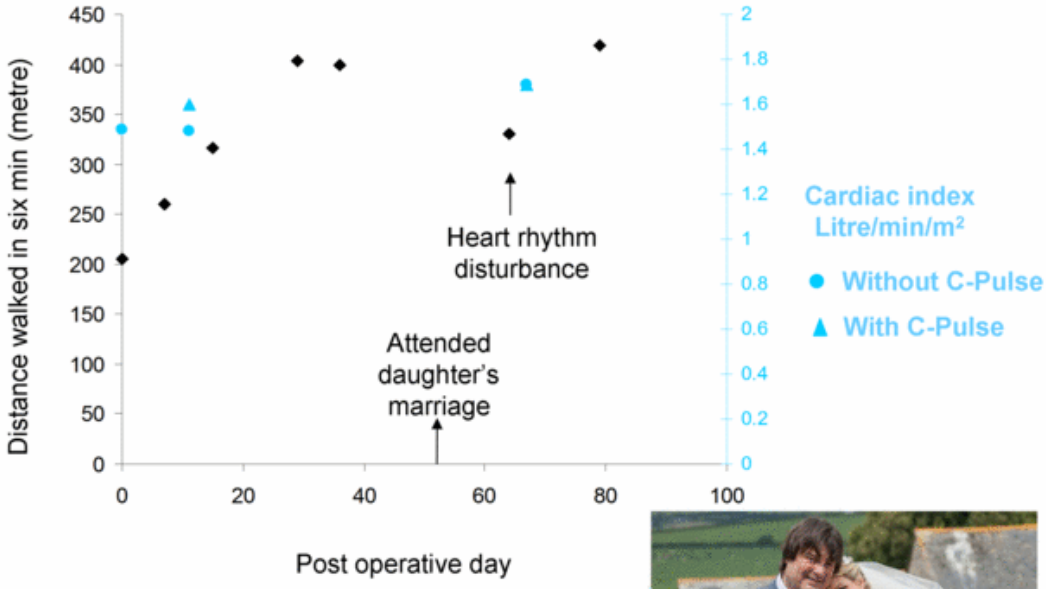
- Uncomplicated surgical procedure and short Intensive Care Unit stay (28 hours)
- Increased inflammatory markers after surgery
  - No source of infection identified
  - Given empirical antibiotic therapy
- Continuing signs of heart failure reflecting poor pre-operative heart function
  - Treated with high dose diuretics.
- Discharged home on post operative day 22
- Readmitted post operative day 47 to 52 with diarrhoea possibly due to antibiotic therapy
- Readmitted post operative day 64 to 79 with deterioration in exercise capacity attributed to heart rhythm disturbance
  - Treated with short course of i.v. milrinone and higher beta blocker dose

Functional capacity improvement as a result of C-Pulse therapy



- New ventricular ectopies are an early sign that previously-thought ischemic (or lost) tissue is being perfused

Functional capacity improvement and changes in heart function as a result of C-Pulse therapy



Summary

- 54 year old man
- Advanced heart failure due to ischaemic cardiomyopathy
- Uneventful C-Pulse implantation as a bridge to heart transplant
- Has needed medical management for heart failure since surgery
- Limited improvement in resting hemodynamics
- Yet marked improvement in functional capacity possibly due to increased blood perfusion
- Remains a suitable candidate on the active heart transplant list

Implications

- Caution: Single patient experience
- Preliminary findings concur with large scale studies with B-blockers[1,2] and cardiac resynchronisation therapy pacemakers[3]

  - Subtle improvements in heart function can result in clinically important benefits, i.e. improved exercise tolerance and quality of life.

1.NEJM 1996; 334:1349 2.NEJM 2001;344:1651 3. NEJM 2002;346:1845

SUNSHINE HEART

Progress of the Fully Implantable System

Sep 16, 2014

www.sunshineheart.com

C-Pulse II Overview

Fully Implantable System

Internal electro-hydraulic converter and TETS eliminate the percutaneous drive line and associated infection risks.

1. **Non-blood contacting**
2. **Non-obligatory**

CAUTION: Investigational Device. Limited by Federal (or United States) Law to Investigational Use.

C-Pulse II Overview

Fully Implantable System

Internal electro-hydraulic converter and TETS eliminate the percutaneous drive line and associated infection risks.

1. **Non-blood contacting**
2. **Non-obligatory**
3. ***No percutaneous drive line***

C-Pulse II Overview

Fully Implantable System

Internal electro-hydraulic converter and TETS eliminate the percutaneous drive line and associated infection risks.

1. **Non-blood contacting**
2. **Non-obligatory**
3. ***No percutaneous drive line***
4. ***No implanted battery***

CAUTION: Investigational Device. Limited by Federal (or United States) Law to Investigational Use.
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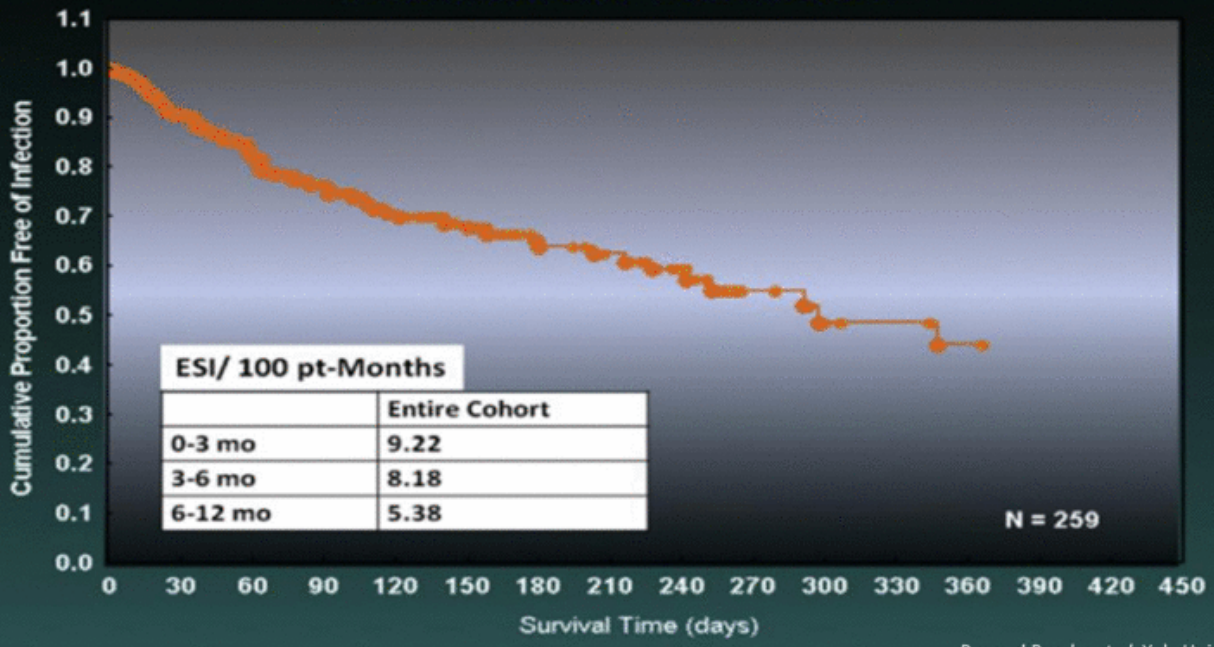
Freedom From VAD Exit Site Infection
01/01/1996 to 12/31/2008



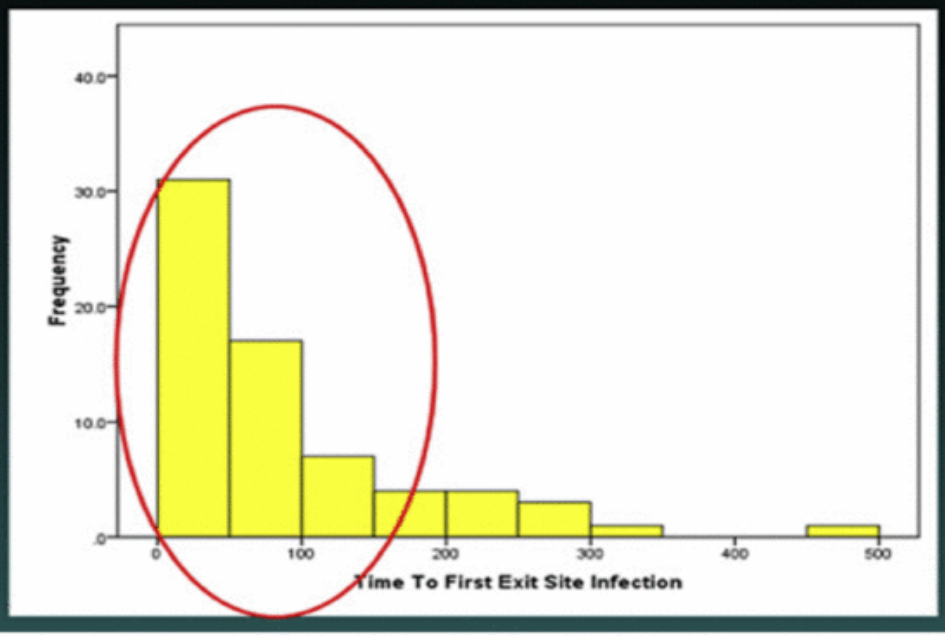
ESI/ 100 pt-Months

	Entire Cohort
0-3 mo	9.22
3-6 mo	8.18
6-12 mo	5.38

N = 259

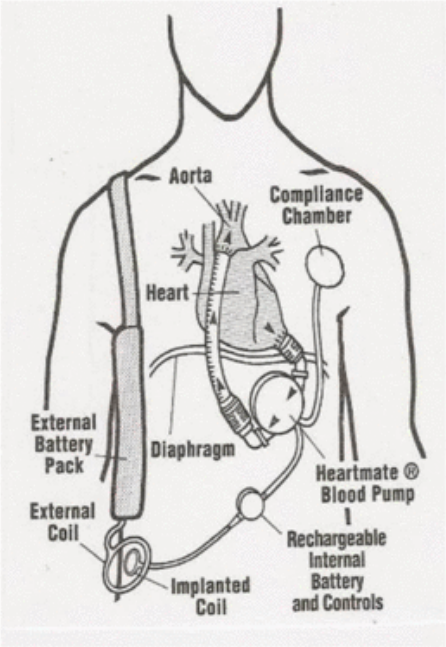
Pramod Bonde, *et al.* Yale University

Distribution of Initial VAD Exit Site Infections
01/01/1996 to 12/31/2008



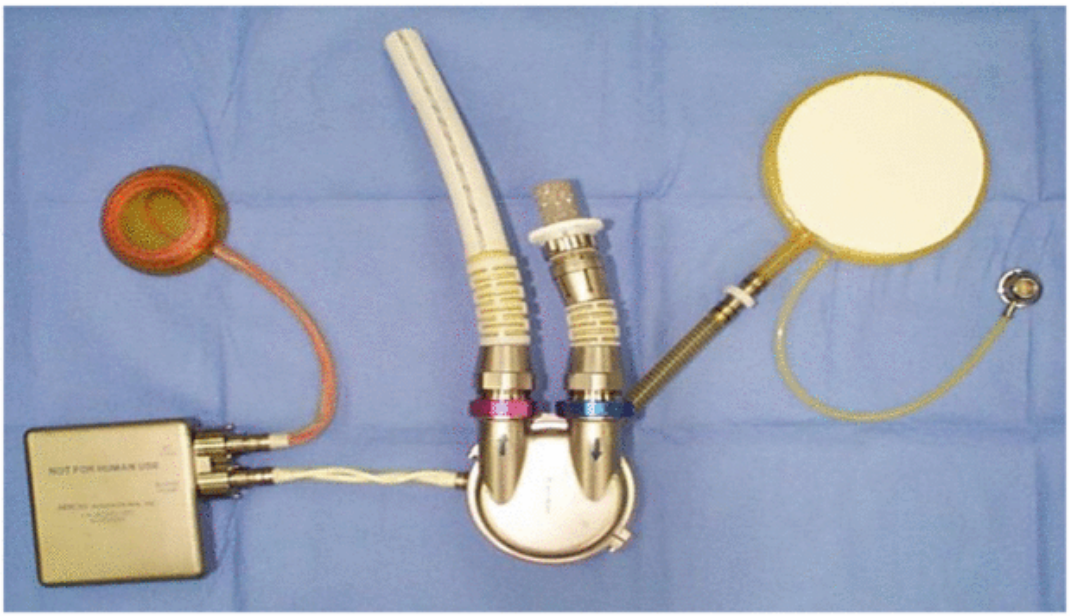
Pramod Bonde *et al.* Yale University

Eliminating the driveline is *not* a new idea…



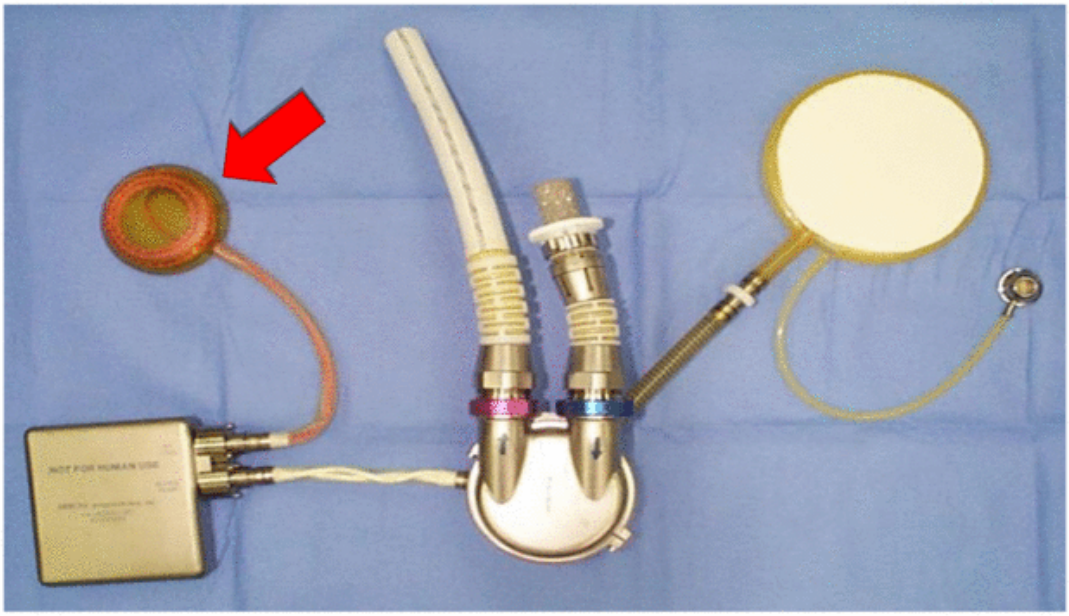
Circa 1985

Arrow LionHeart LVAD



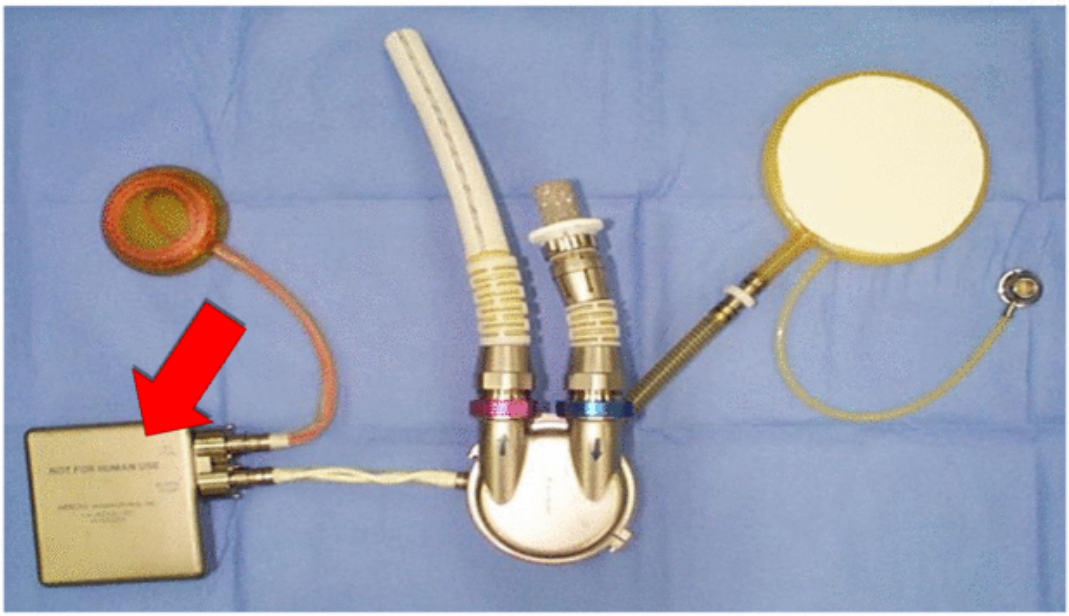
First clinical TETS system

Arrow LionHeart LVAD



First clinical TETS system

Arrow LionHeart LVAD



First clinical TETS system

Penn State Arrow Lionheart

summary Nov 9, 2003

- 23 male patients enrolled between Oct 1999 and Dec 2002
- 10/23 discharged home with device
- 8/23 alive at 2 years
- 1/23 alive at 3 years
- Mean duration 347 days (17-1259)
- 5/23 serious infections (.17/patient year vs. .60/patient year REMATCH… no deaths due to infections)
- No serious TETs complications

Penn State Arrow Lionheart

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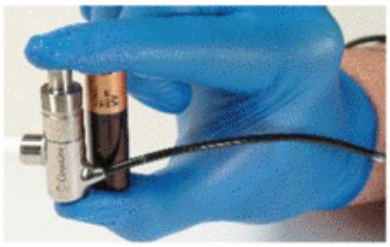
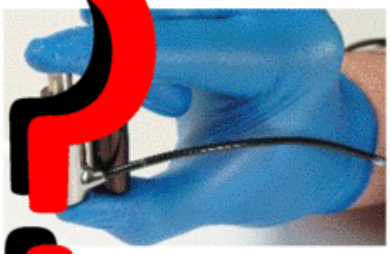
Where will clinical implementation of TETS technology first find traction?









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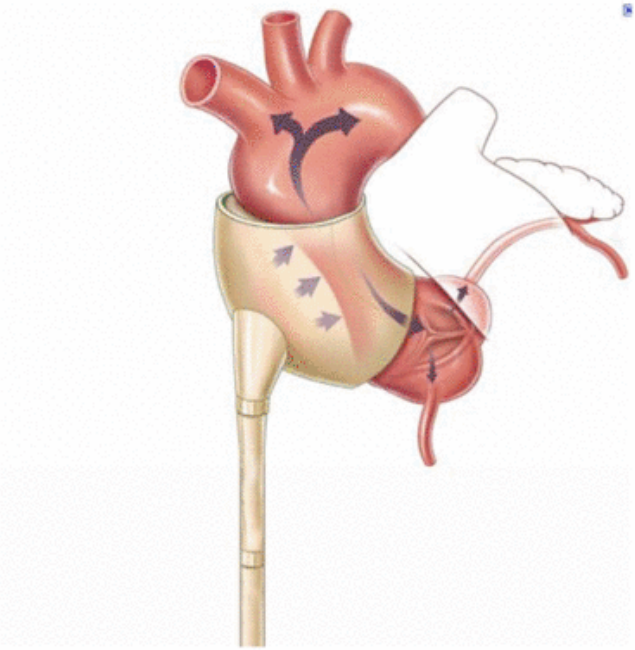
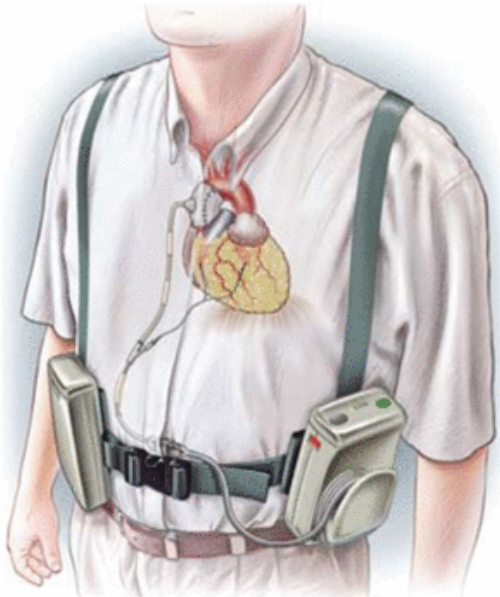
SUNSHINE HEART C-pulse Extra-Aortic Balloon Cuff





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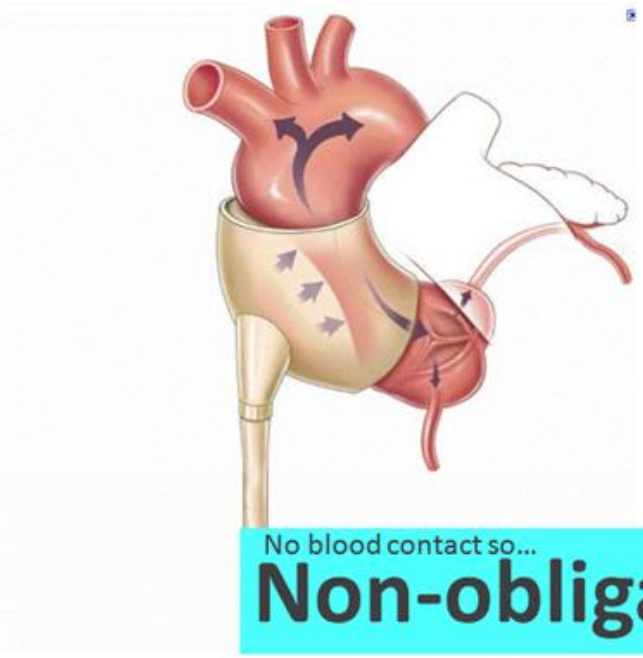
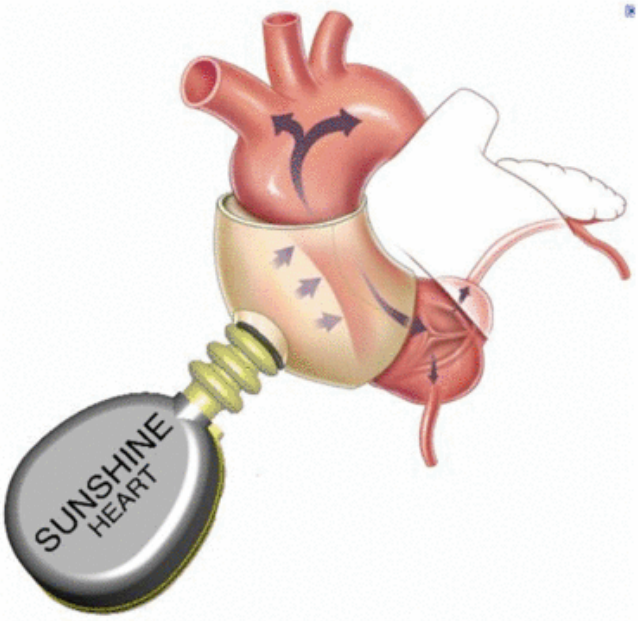
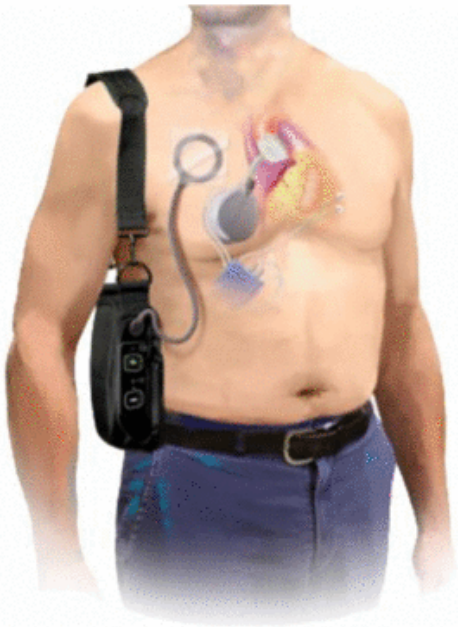


No blood contact so...

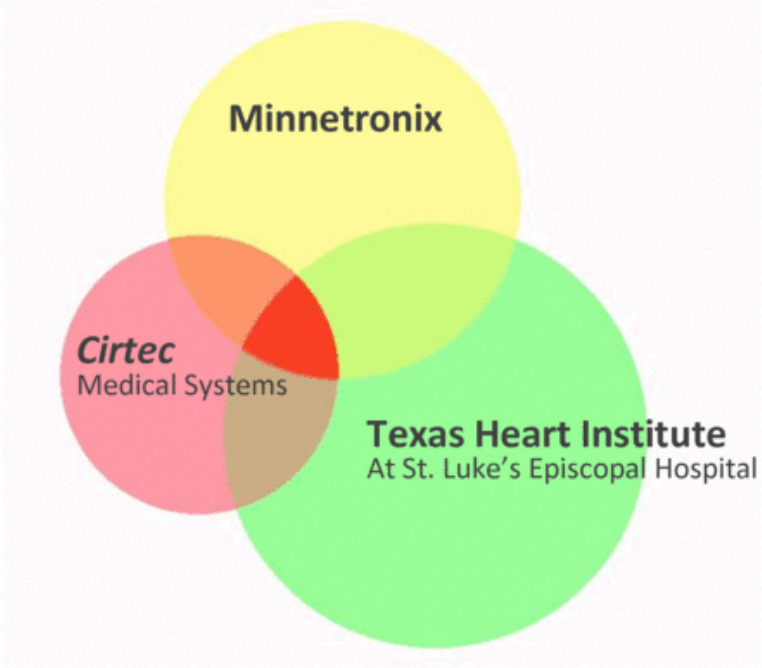
Non-obligatory

SUNSHINE HEART C-pulse II



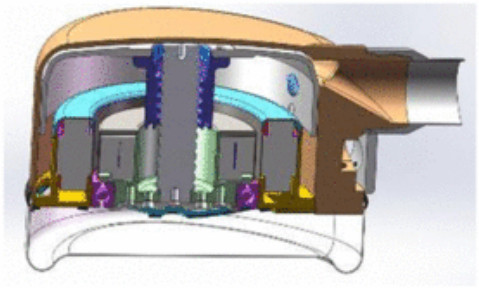


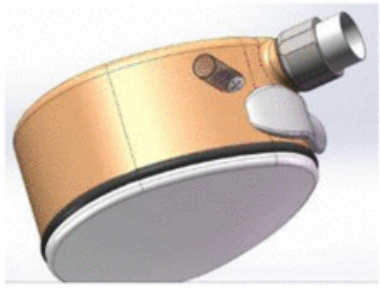
C-Pulse II – Leveraging powerful synergies



Electrohydraulic pump – *Cirtec* Medical Systems

- Rapidly inflates and deflates the extra-aortic balloon cuff
  (reproduces C-I physiology)
- EKG synchronized to provide counter-pulsation
- Balloon passively empties in the event of pump or power failure (essential)
- Leverages the incompressibility of silicone oil
- Compliance reservoir incorporated into the base of the pump





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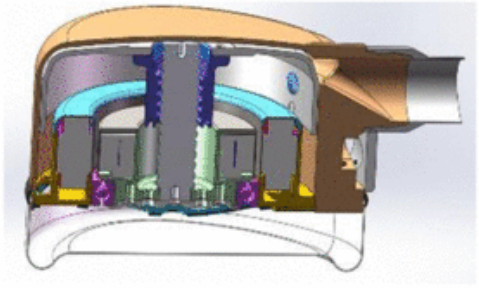
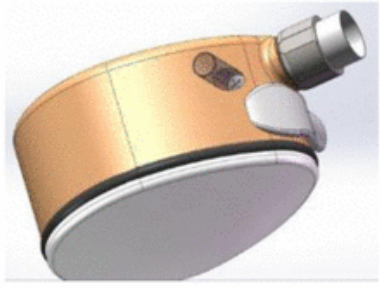


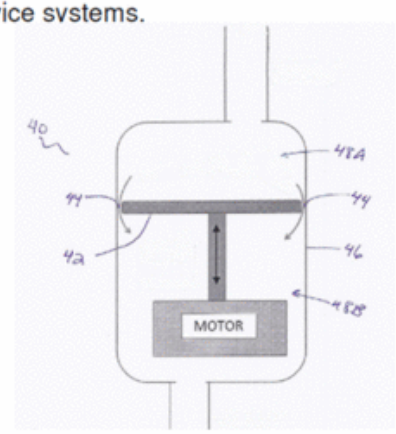


C-Pulse II – Important IP progress

METHODS, SYSTEMS, AND DEVICES RELATING TO A FAIL-SAFE PUMP FOR A HEART ASSIST DEVICE

Detailed Description

[001] The various embodiments disclosed herein relate to pumps for use in various medical device systems, including, for example, mechanical heart assist device systems.



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Detailed Description

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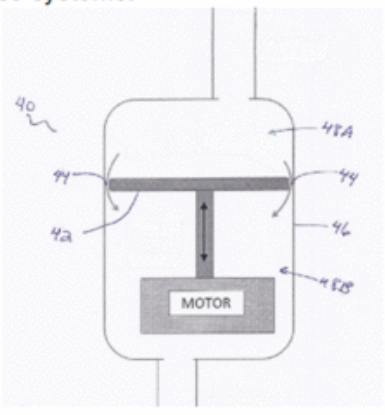
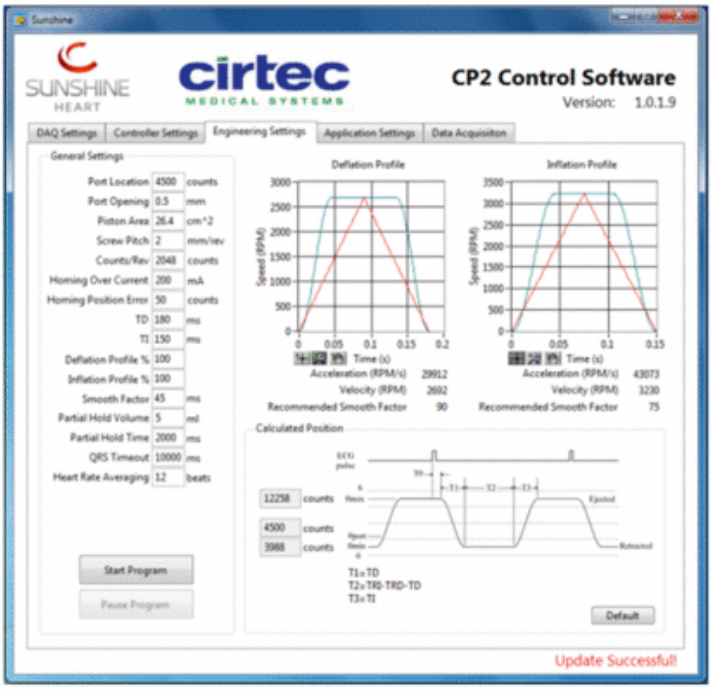
So no need for an implantable battery



Electrohydraulic pump- *Cirtec* Medical Systems



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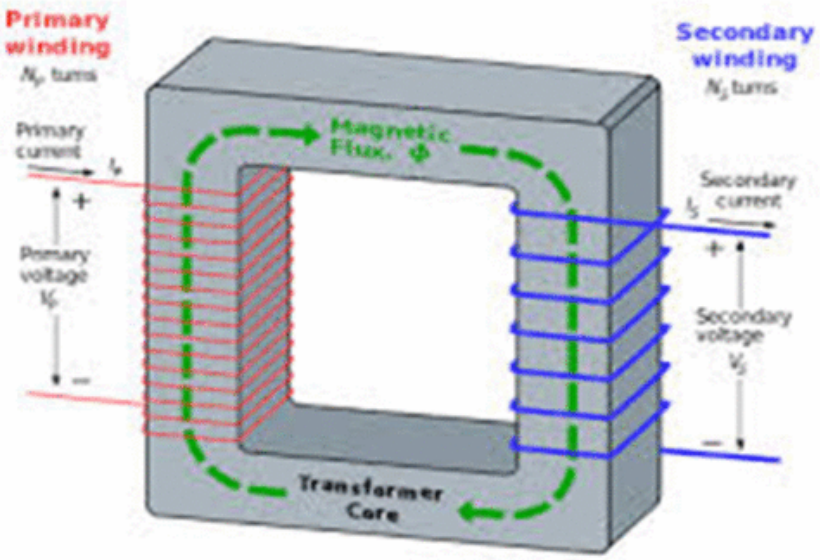
Trans-cutaneous Energy Transfer System (TETS)

- DC battery pack outside the body
- DC current is put through an oscillator to make AC
- AC current energizes external coil (1°) to generate an oscillating magnetic field
- Oscillating magnetic field goes through the skin
- Oscillating magnetic field is picked up by a tuned internal coil (2°) resulting in induction of AC current
- AC current rectified into DC used to run the internal device

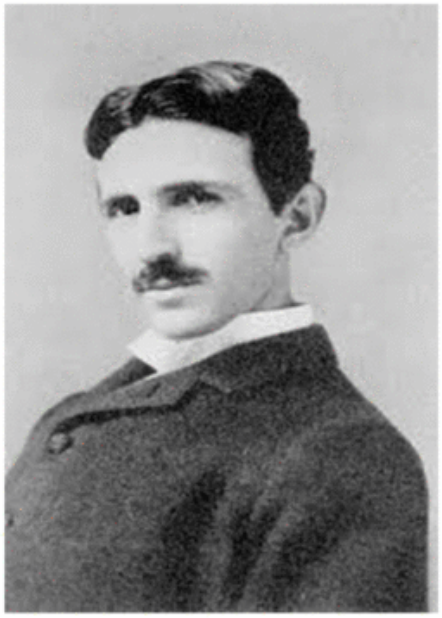
Standard transformer

Inductive coupling through an air-gap

Design minimizes risk of skin heating



Nikola Tesla



July 10 1856 – January 7 1943

Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

Newest systems are:

- Smaller size so easier to implant
- More energy efficient so improved battery life
- More tolerant of geometric misalignment

Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

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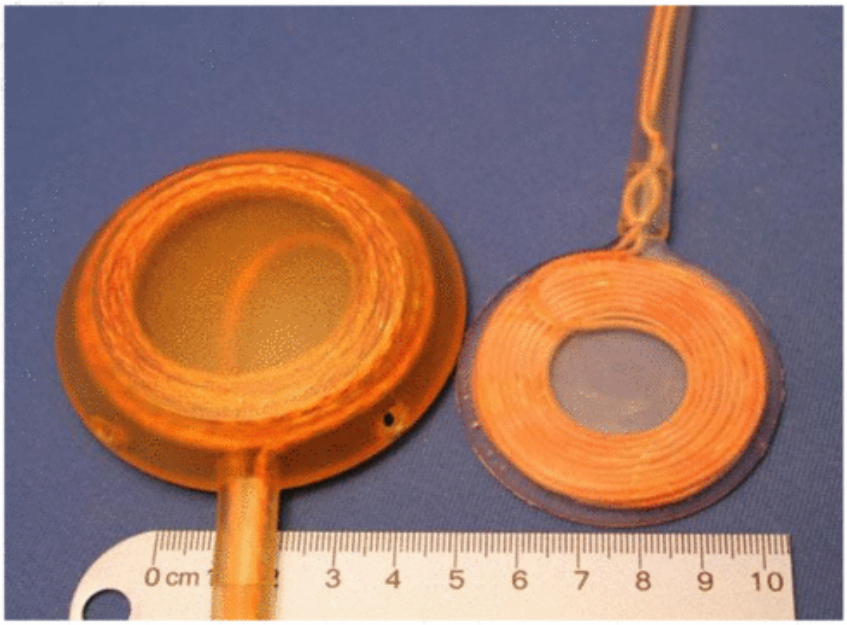
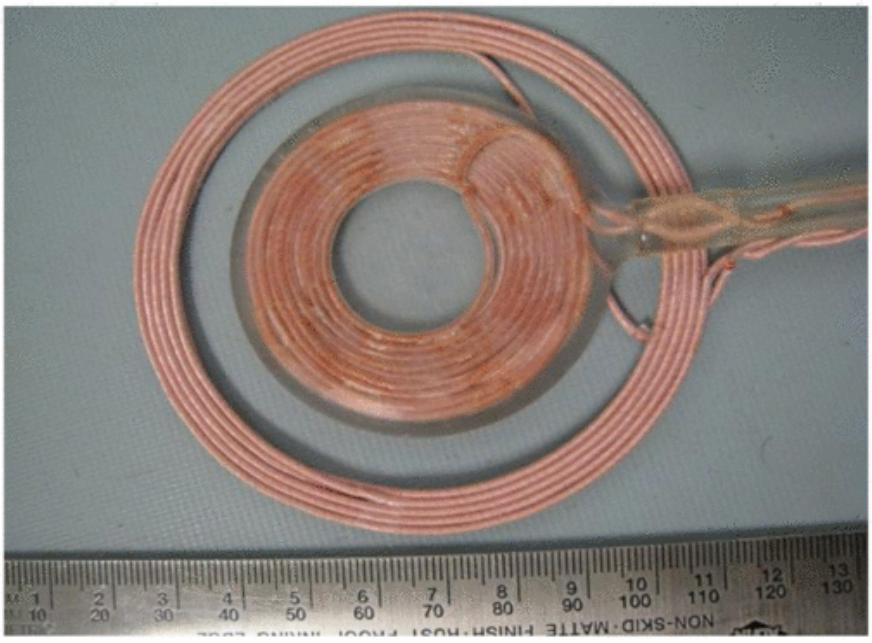
Minnetronix

Improvement in TETS component geometry and function



Minnetronix

Improvement in TETS component geometry and function



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How are we going to power it?

Where are we going to test it?

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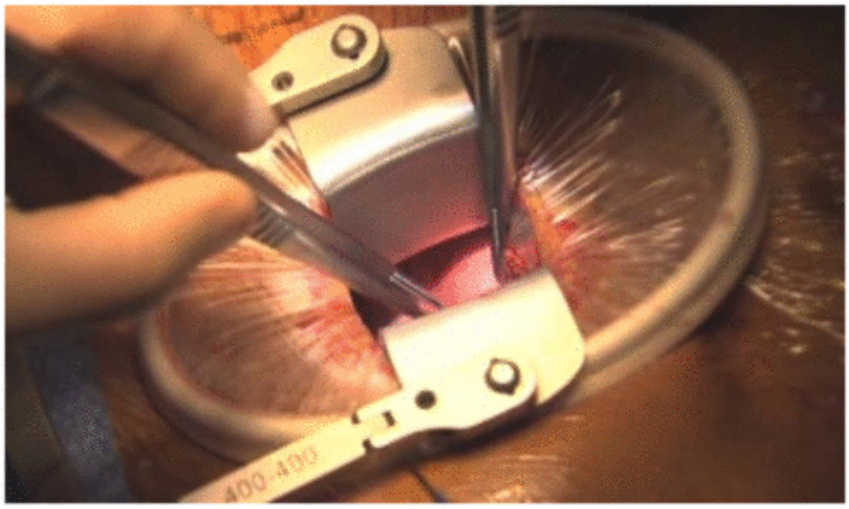
THI Cardio Vascular Research Lab ICU

Surgical Implant and System Integration

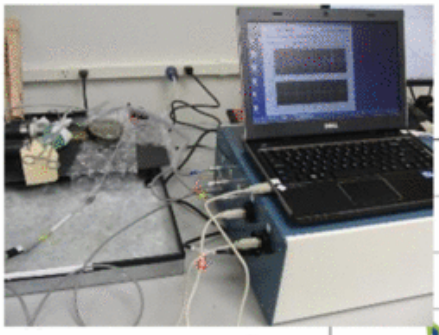
- THI's Cardio Vascular Research Lab
- The premiere large animal cardiovascular research lab in the world
- Non-clinical and pre-clinical safety testing are required by the global regulations prior to human trials'
- Domain dominance in development and implementation of heart failure technology
- Successful acute system implantation (first generation)

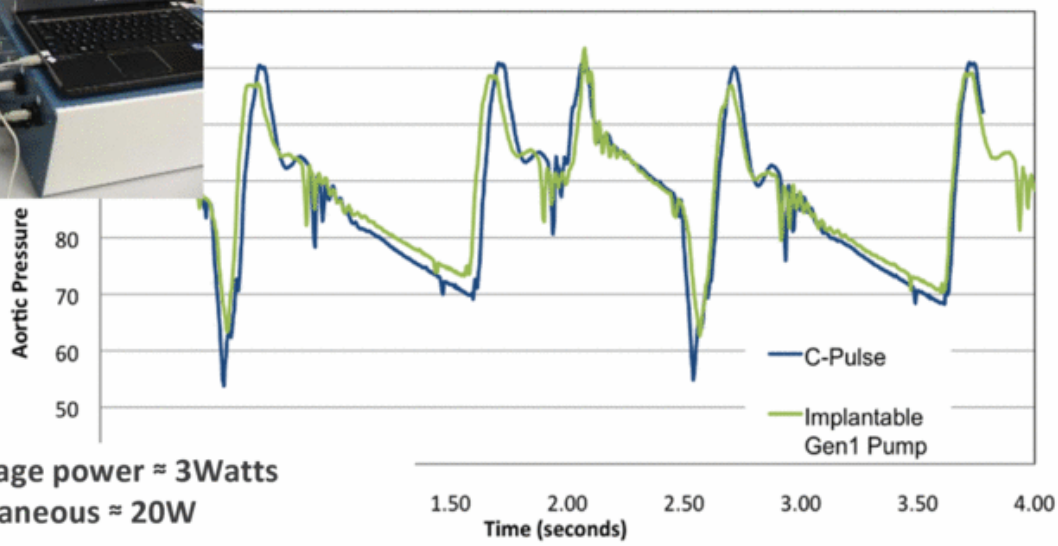
Minimally Invasive Implantation

- Small incision
- Sternal-sparing
- No cardiopulmonary bypass

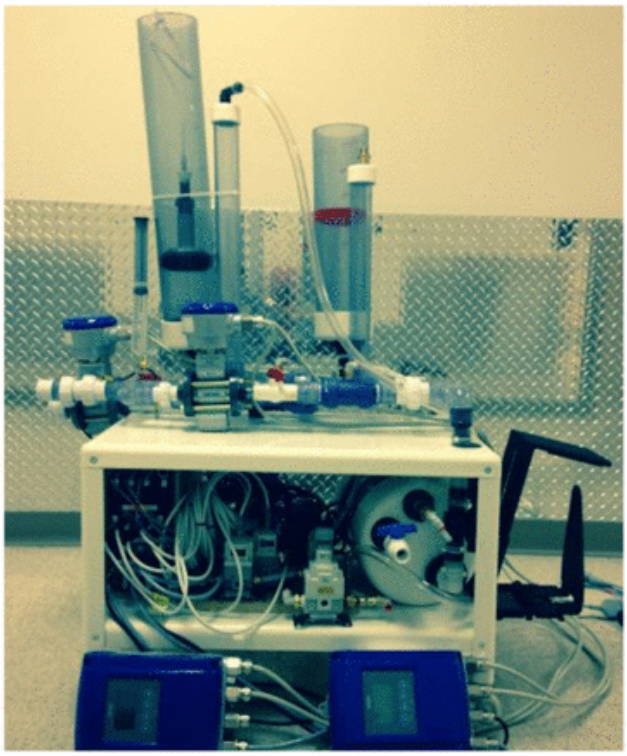


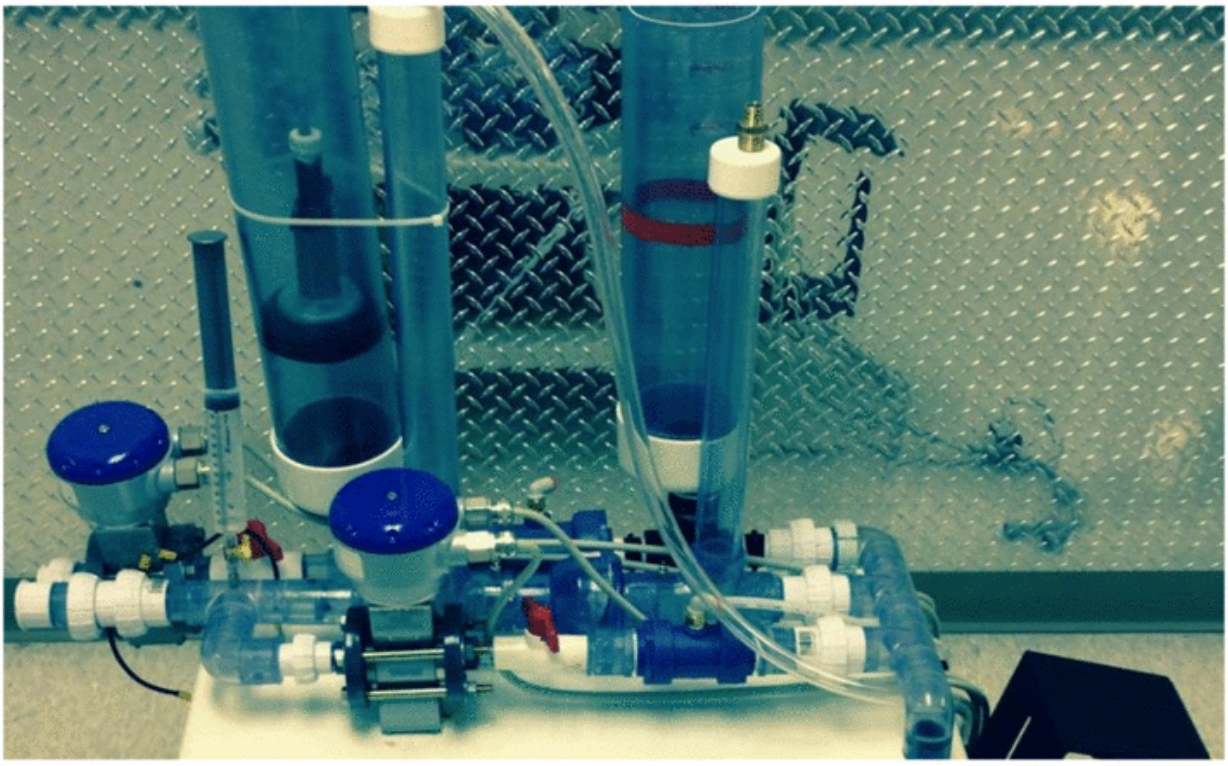
Recent Progress -Bench-Top Tests, CPII versus CPI





Typical Average power ≈ 3Watts
Peak Instantaneous ≈ 20W





Recent Acute animals (x2)

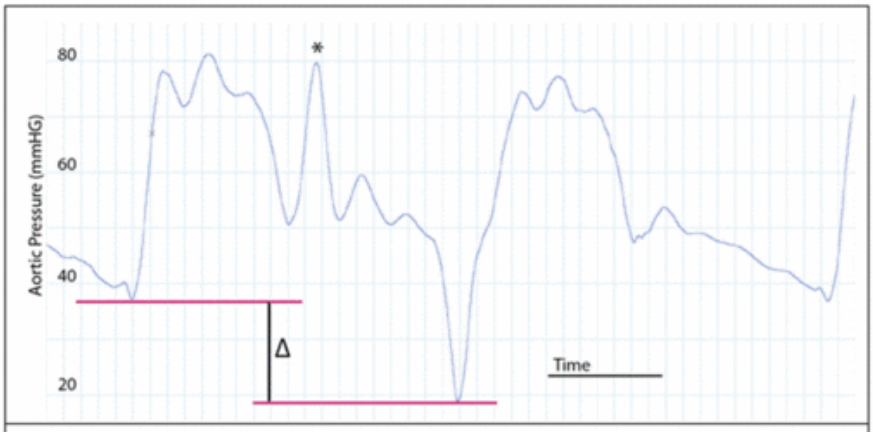
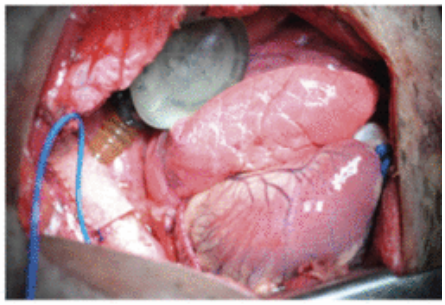
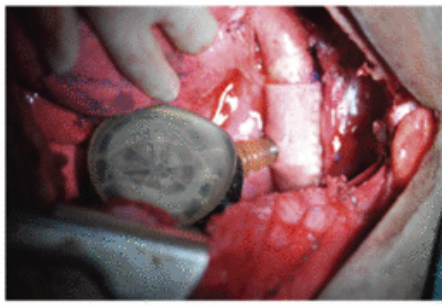
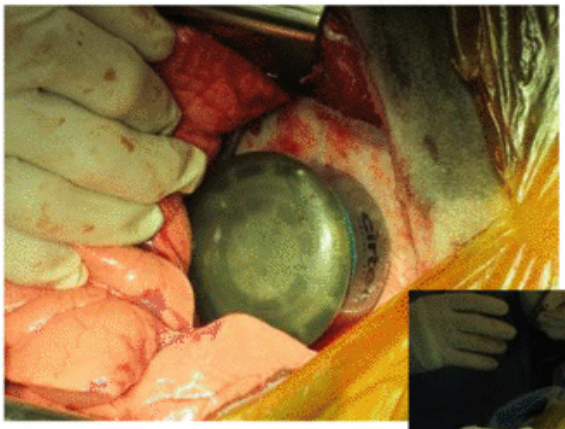


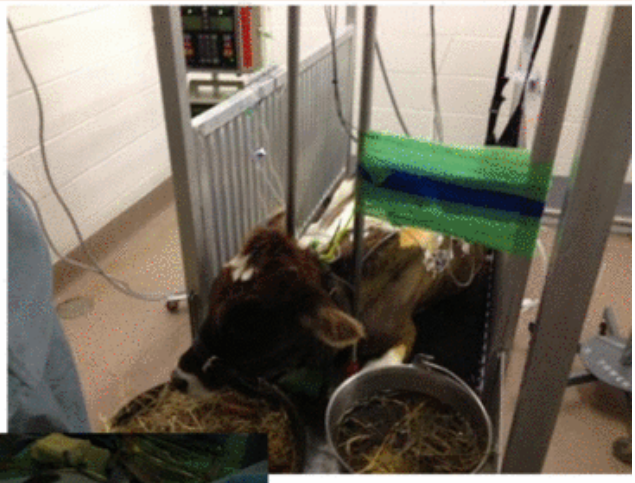
Figure 11. Hemodynamic performance of the CP2-Gen1 assembly operating in 1:2 mode during an acute bovine trial. Trace shows clear diastolic augmentation (*) and subsequent reduction in end diastolic pressure (Δ) of >15mmHg compared to the adjacent non-counterpulsated cycle.

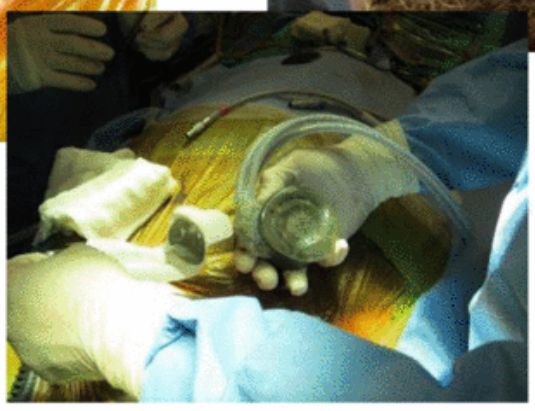


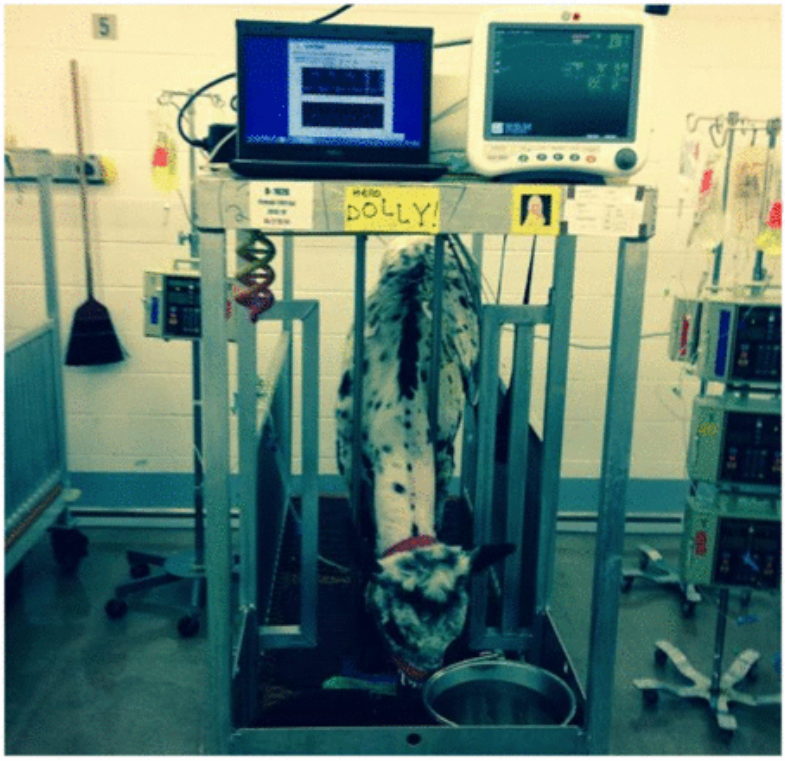


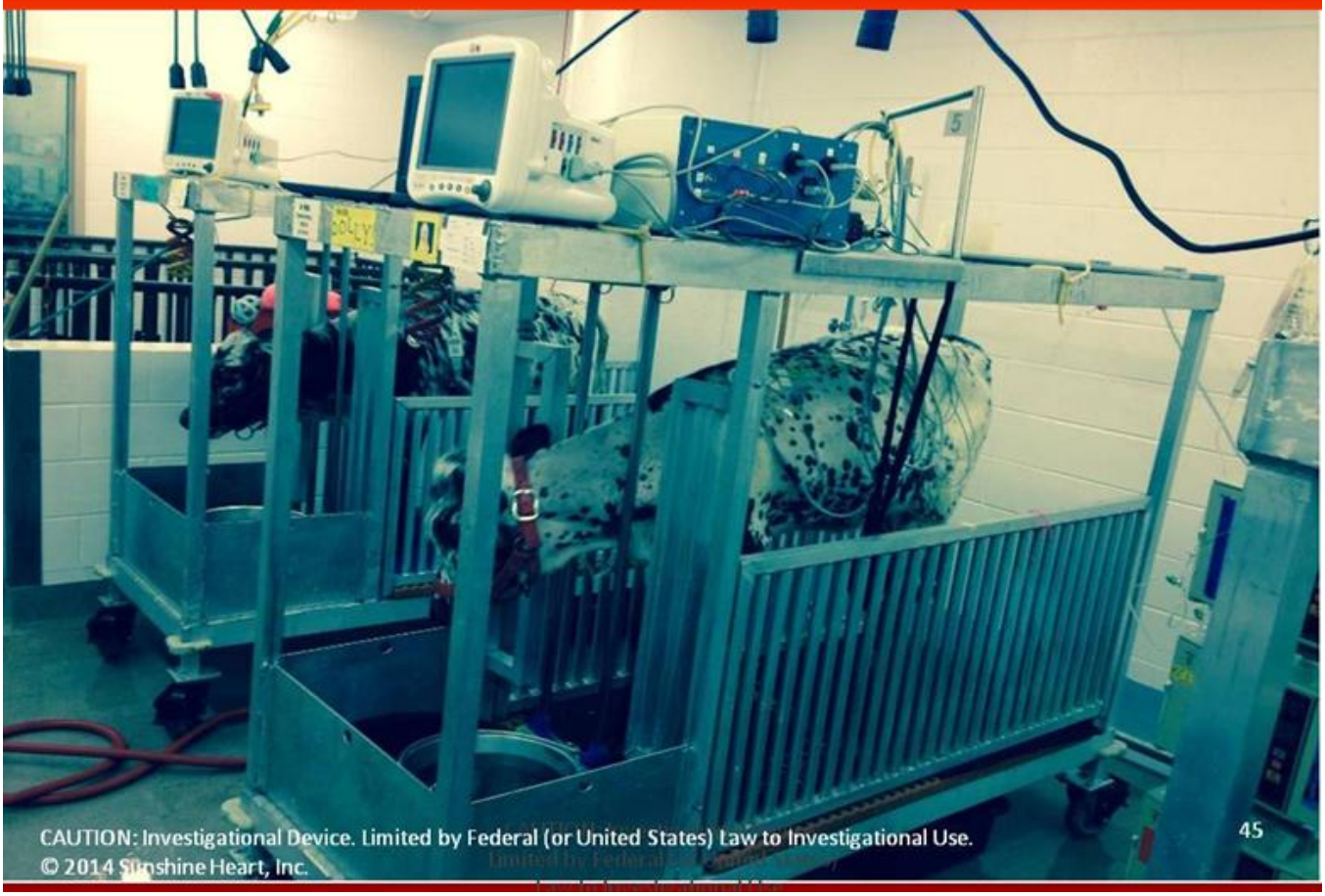
Recent Chronic animal
21 days continuous operation











In summary…

- The SUNSHINE HEART C-Pulse II has the potential to be the first completely self-contained therapy for heart failure since the bi-ventricular pacer
- Lack of blood contact and non-obligatory feature make it the most likely candidate to leverage TETS in a mechanical circulatory assist device
- Pump innovation has facilitated development of a novel technology, avoiding the safety and regulatory risks of an implantable battery
- The system is well suited for implantation off-pump through a small sternal sparing incision, making it well suited for patients earlier in the course of heart failure
- Early pre-clinical testing suggests the design is performing as intended and within established safety parameters