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): **October 13, 2015**

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.

As previously disclosed in the Current Report on Form 8-K filed on October 8, 2015 with the Securities and Exchange Commission ("***SEC***"), on Wednesday, October 14th, Dr. Dimitrios Georgakopoulos PhD, the Chief Scientific Officer of Sunshine Heart, Inc. (***"Sunshine Heart"*** or the ***"Company"***), will present at the Transcatheter Cardiovascular Therapeutics ("***TCT***") scientific symposium, hemodynamic data collected from pre-clinical studies and patients implanted with the C-Pulse device during device optimization and from patients with implantable sensors. Prior to his clinical presentation at the TCT conference, Dr. Dimitrios Georgakopoulos will present this data to the investment community at Sunshine Heart's annual analyst and investor breakfast meeting, which begins at 7:00am (PST) on Tuesday, October 13th at the W Hotel San Francisco. Dr. Leslie W. Miller MD, an investigator in the COUNTER-HF trial, and Dr. William E. Cohn MD, Texas Heart Institute, Houston 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. This Form 8-K is being furnished to the SEC to furnish the presentation materials attached as Exhibits 99.1, 99.2 and 99.3 hereto.

Limitation of Incorporation by Reference

In accordance with General Instruction B.2. of Form 8-K, this information, including Exhibits 99.1, 99.2 and 99.3, 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 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	Presentation - Dr. Dimitrios Georgakopoulos PhD, the Chief Scientific Officer of Sunshine Heart, Inc.
99.2	Presentation - Dr. Leslie W. Miller MD, an investigator in the COUNTER-HF trial

99.3 Presentation - Dr. William E. Cohn MD, Texas Heart Institute, Houston

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: October 13, 2015

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Presentation - Dr. Dimitrios Georgakopoulos PhD, the Chief Scientific Officer of Sunshine Heart, Inc.
99.2	Presentation - Dr. Leslie W. Miller MD, an investigator in the COUNTER-HF trial
99.3	Presentation - Dr. William E. Cohn MD, Texas Heart Institute, Houston

Hemodynamics of C-Pulse: Aortic Counterpulsation and Beyond?

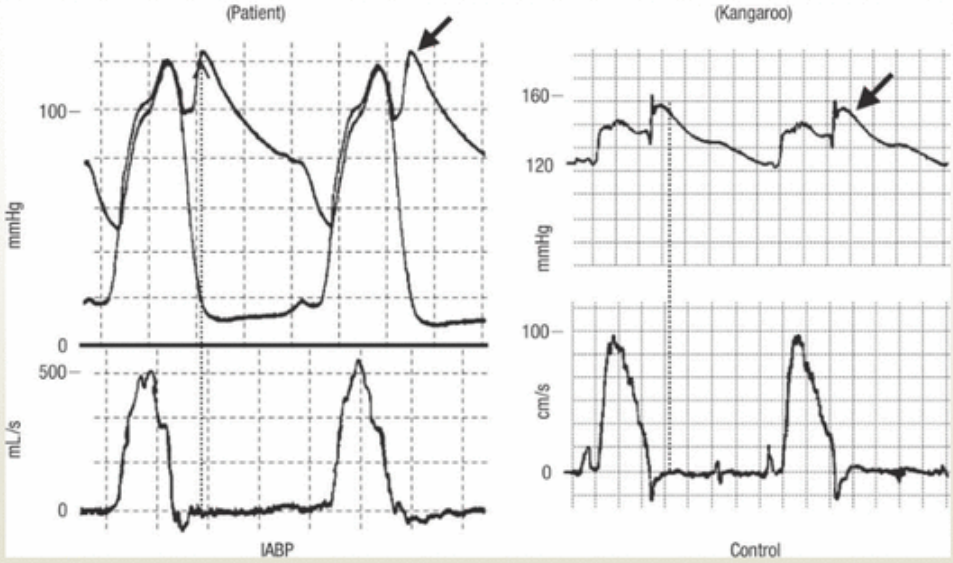
www.sunshineheart.com

Dimitrios Georgakopoulos, PhD
CSO, Sunshine Heart Inc.

Forward Looking Statement

- 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 on Form 10-K for the fiscal year ended December 31, 2014.
- 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.

Counterpulsation Mechanism Based On Physiologic Hemodynamics of Wave Travel in Arteries



McDonald's Blood Flow In Arteries. 6th Ed.

C Pulse Counterpulsation: 3D CT Clinical Example

Courtesy Dr. Daniel Bujnoch; Department of Cardiac Surgery, University of Erlangen, Germany 25

C-Pulse Design: Unique Placement on Ascending Aorta

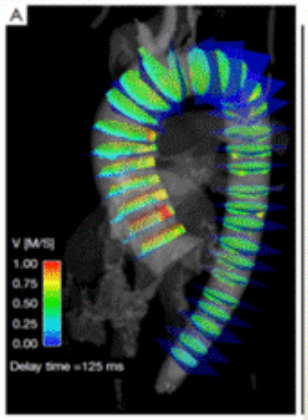
- **Proximal Aorta 70% of compliance in**

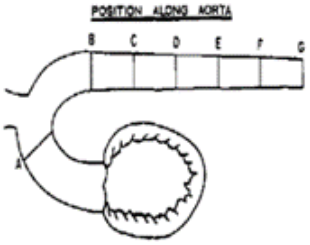
PROXIMITY TO AORTIC VALVE AND UNIDIRECTIONALITY AS PRIME FACTORS IN COUNTERPULSATION EFFECTIVENESS

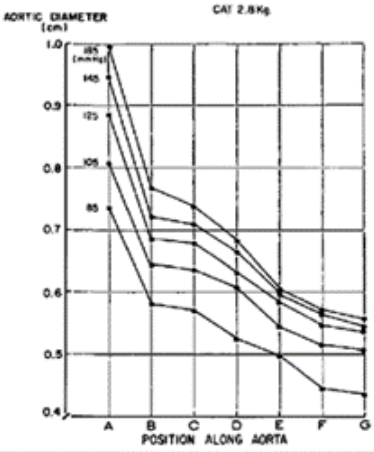
S. Furman, R. Whitman, J. Stewar, B. Parker, and M. McMullen

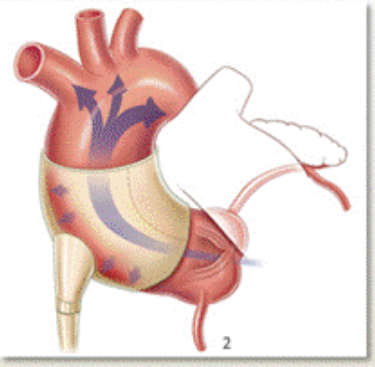
An aortic occlusive balloon of small volume distal to the volume displacing balloon projected virtually the total displacement toward the heart and increased arch and coronary blood flow.

Vol. XVII Trans. Amer. Soc. Artif. Int. Organs







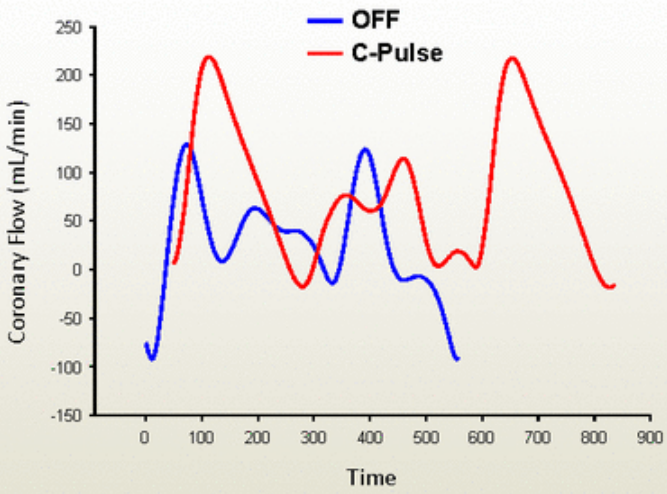


Arndt et al. Circ. Res. 28:1971

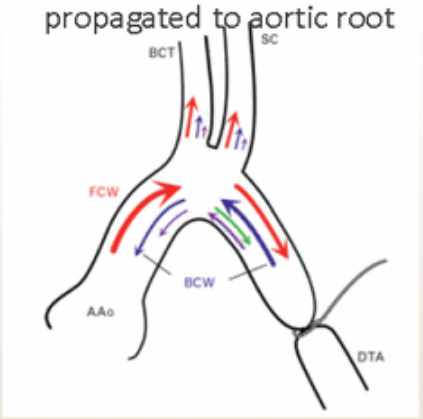
Counterpulsation and Myocardial Oxygen Consumption

- The heart is especially **vulnerable** to ischemia, because its O2 extraction ratio is 65% (vs. average of 25% for rest of body)
- Because the heart is near maximal O_2 extraction during increased demand, primarily accomplished by *increasing blood flow*

C-Pulse Effect on Coronary Hemodynamics in Normal Swine



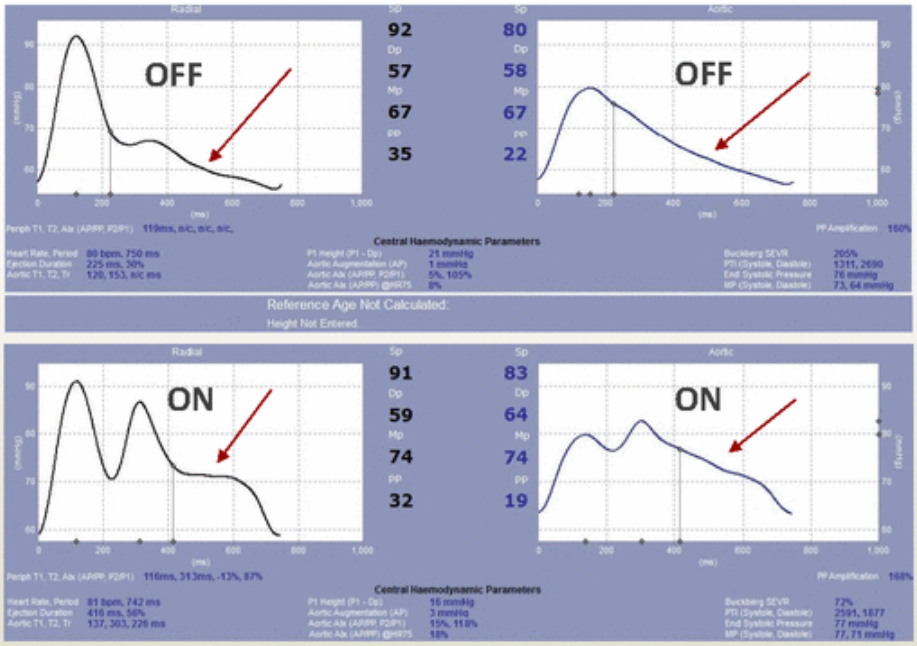
Backward waves from descending less efficiently propagated to aortic root



Mynard et al. J. Hypten. 33:2015

"If you wanted to design a perfect sound absorber, you could hardly do better than a set of tapering and branching tubes ...such as the arterial tree. (DA McDonald 1960)." 42

Boost Diastolic Pressure: Reservoir for Coronaries to Fill



43

Counterpulsation and Coronary Perfusion and Oxygen Utilization at Rest and Exertion

SUNSHINE HEART

Improvements in Myocardial Perfusion Observed in Patients Supported with the C-Pulse® Counterpulsation Device

Renzo Cecere[1], Marc Hickeson[2], Nadia Giannetti[3]
[1]McGill University Health Centre, Cardiac Surgery, Montreal, Canada; [2]McGill University Health Centre, Nuclear Medicine, Montreal, Canada; [3]McGill University Health Centre, Cardiology, Montreal, Canada

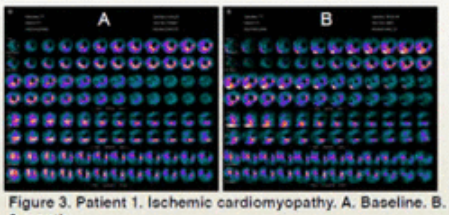


Figure 3. Patient 1. Ischemic cardiomyopathy. A. Baseline. B. 6-month.
MPI at baseline shows a perfusion defect involving the mid to distal anterolateral, anterior and anteroseptal walls, the apex and the distal inferior and inferolateral walls with partial reversibility in the distal inferior and inferolateral walls at rest. At 6-months post-implant, there is improvement in perfusion in the distal inferior and inferolateral walls.

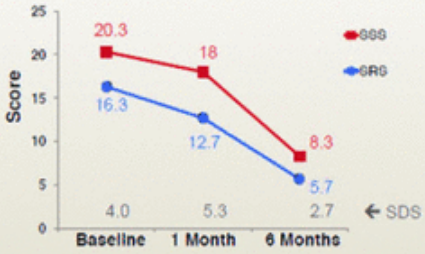


Figure 2. SPECT myocardial perfusion imaging (MPI) Stress-Rest scoring

What About Other Concept of Counterpulsation: Reduce Cardiac Afterload?

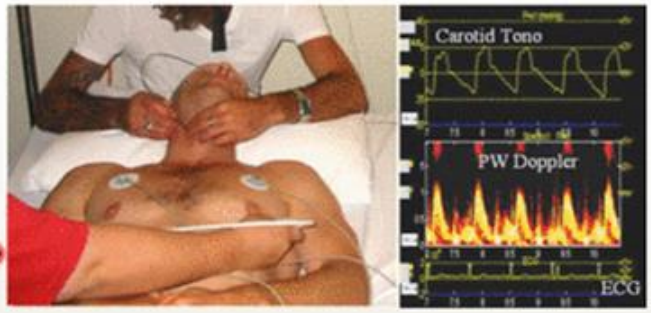
Wave Travel and Reflection Animation

SUNSHINE HEART

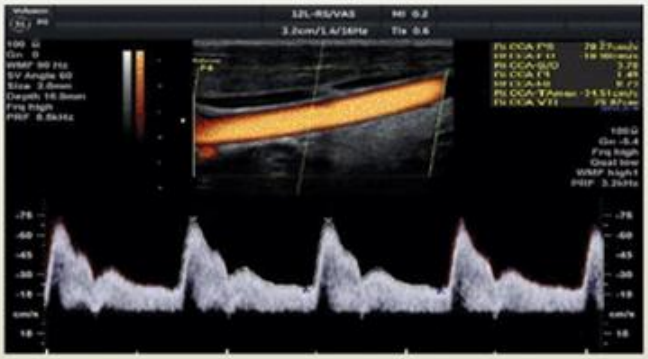
Play Video

Courtesy AtCor Medical (www.atcormedical.com)

LVOT



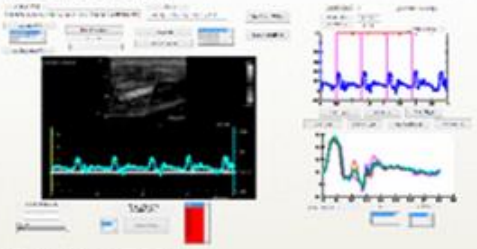
CCA



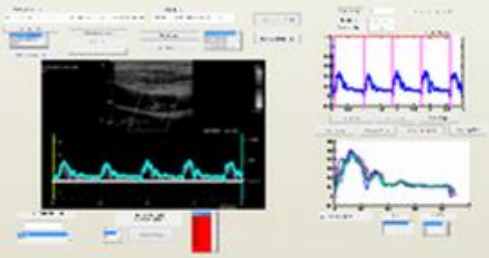
Ultrasound data – Ascending Aorta and Carotid Artery

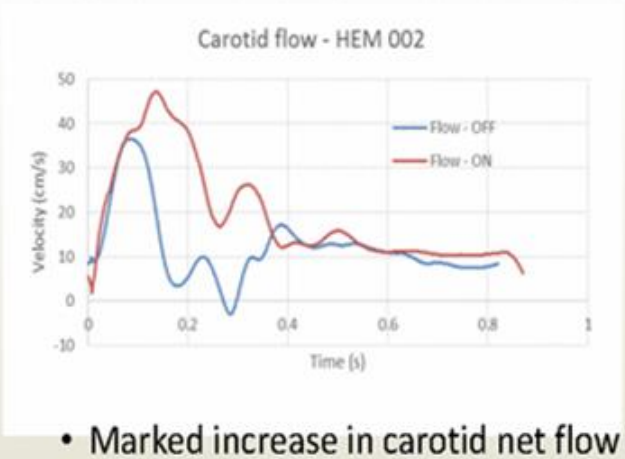
SUNSHINE HEART

Device OFF



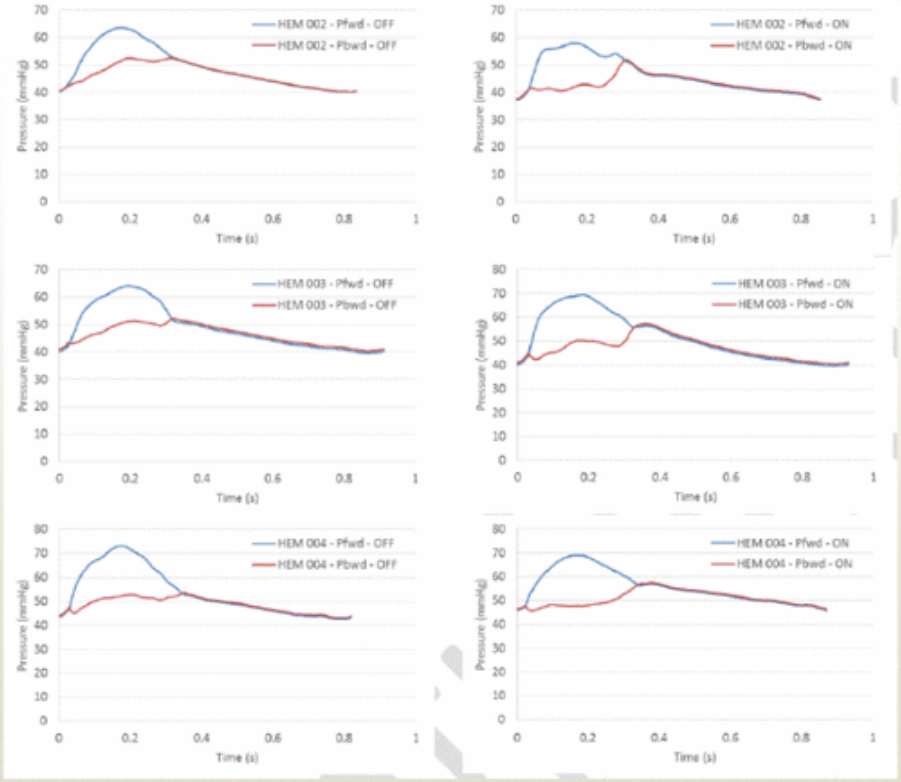
Device ON



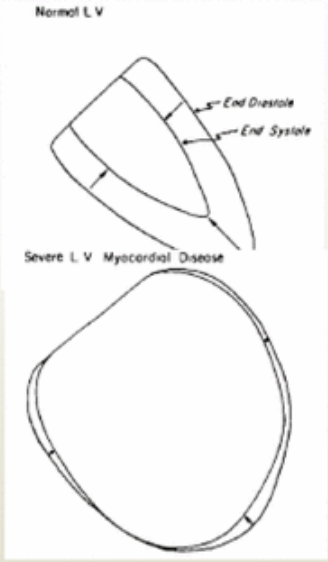


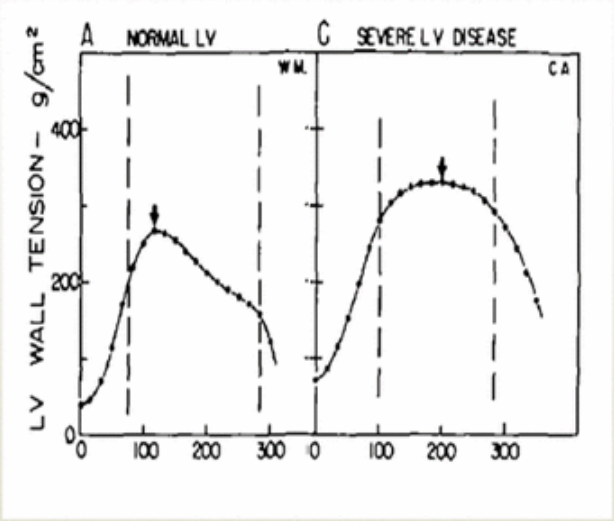
- Marked increase in carotid net flow (+57%)
- Increased flow in diastole
- Avg 30% increase in carotid flow

Forward and Backward Waves in Patients with C-Pulse: Ascending Aorta



Wall Stress Peaks Late Systole in HF

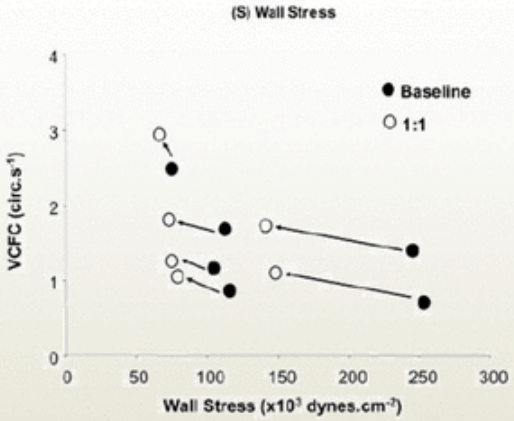


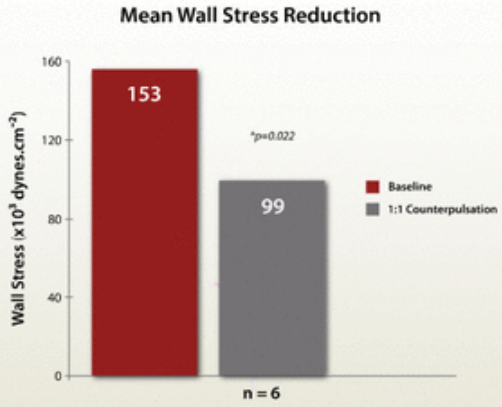


Noordergraaf, A. Circulatory System Dynamics. Lea and Febiger (1976).

12

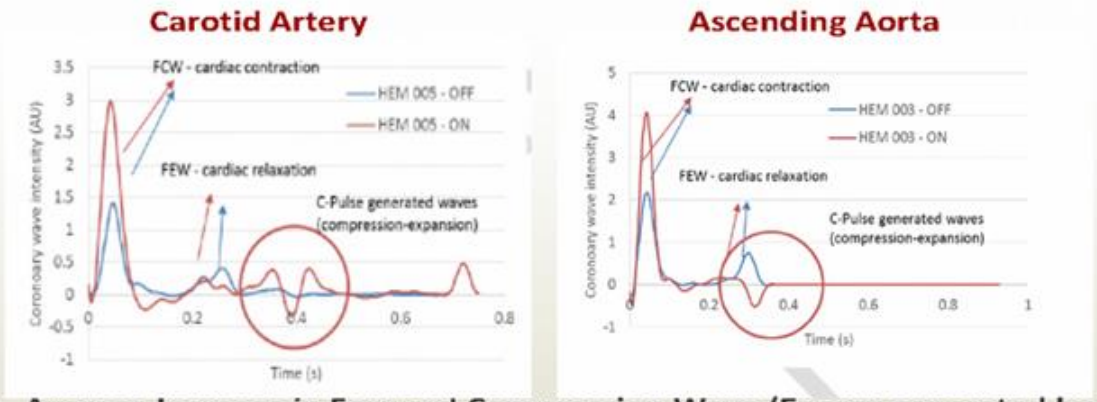
C-Pulse Reduces Wall Stress and Increases Shortening Velocity





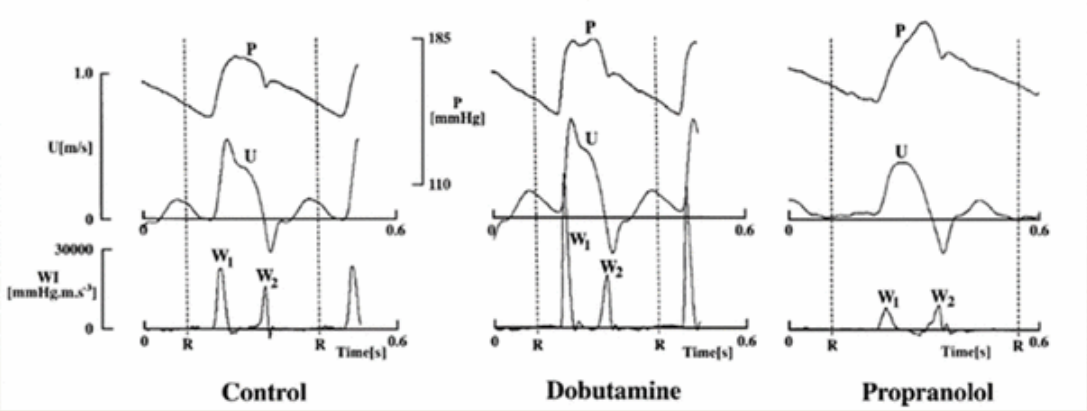
Leggett et al. Circ. 112:I-26. 2005

C- Pulse: Wave Intensity Analysis in Carotid and Aorta (N=3)

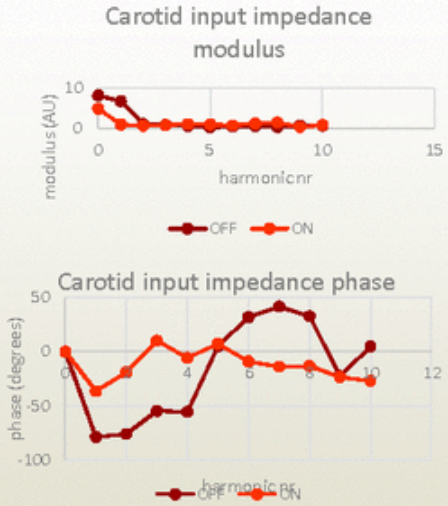


- **Average Increase in Forward Compression Wave (Energy generated by LV): 65%**
- **Similar to positive inotrope with improved energetics profile**

C-Pulse Hemodynamically Similar to Positive Inotrope



HEM 002 – Pressure and Flow – carotid artery



- Marked decrease in carotid bed resistance
- Marked decrease in impedance
- Impedance ~ reduced reflections

Avg. Reduction in DC resistance: 30%

Clinical Importance of Wave Reflections and Late Systolic Load

SUNSHINE HEART

Epidemiology/Population

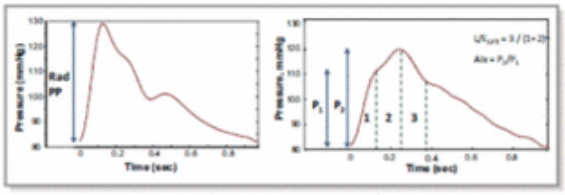
Reflection Magnitude as a Predictor of Mortality
The Multi-Ethnic Study of Atherosclerosis

Payman Zamani, David R. Jacobs Jr, Patrick Segers, Daniel A. Duprez, Lyndia Brumback, Richard A. Kronmal, Scott M. Lilly, Raymond R. Townsend, Matthew Budoff, Joao A. Lima, Peter Hannan, Julio A. Chirinos *Hypertension 2014; 64: 958-964*

Late Systolic Central Hypertension as a Predictor of Incident Heart Failure: The Multi-Ethnic Study of Atherosclerosis

Julio A. Chirinos, MD, PhD; Patrick Segers, PhD; Daniel A. Duprez, MD, PhD; Lyndia Brumback, PhD; David A. Bluemke, MD; Payman Zamani, MD; Richard Kronmal, PhD; Dhananjay Vaidya, MBBS, PhD; Pamela Ouyang, MD; Raymond R. Townsend, MD; David R. Jacobs, Jr, PhD

(*J Am Heart Assoc.* 2015



Hemodynamic Effects of Unloading with C-Pulse On Central Pressure and Wave Reflections

SUNSHINE HEART

Control/Tracking Number: 2015-SS-A-15860-AHA
Activity: Abstract
Current Date/Time: 6/10/2015 2:10:27 PM

Arterial and Cardiac Hemodynamics in Advanced HF Patients Implanted with the C-Pulse Counterpulsation Device: Implications for Myocardial Recovery

Author Block: J. Eduardo Rame, Hosp of the Univ of Pennsulvania, Philadelphia, PA; Dimitrios Georgakopoulos, David Pomfret, Sunshine Heart Inc, Eden Prairie, MN; Pavan Atluri, Hosp of the Univ of Pennsulvania, Philadelphia, PA; Phi Wiegn, VA North Texas Health Care System: Dallas VA Medical Ctr, Dallas, TX; Patrick Segers, Ghent Univ, Gent, Belgium; William T Abraham, The Ohio State Univ, Columbus, OH

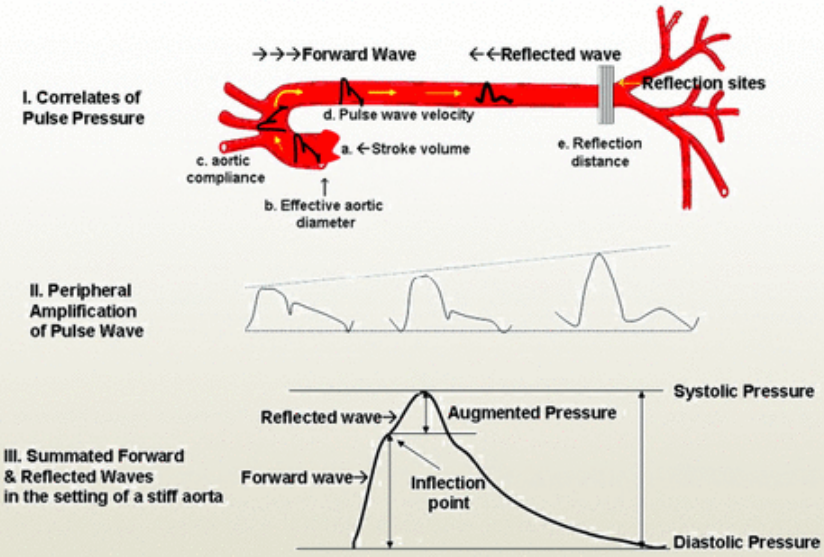
(N=6)	OFF	ON
Max Aortic BP (mmHg)	EMBARGOED	
Diastolic BP (mmHg)		
P1 (mmHg)		
Time to P2 (ms)		
SEVR		
Aix (P2/P1)		

Mean±SD. Paired t-test. † p<0.01; * p=0.01; ‡ p<0.05

31

To be presented AHA 2015!

Wave Reflections Primarily Arise from Periphery: How Does C-Pulse Affect Peripheral Arteries?



SUNSHINE HEART

HOW DOES A CUFF IN ASCENDING AORTA INFLUENCE PERIPHERAL VESSELS?

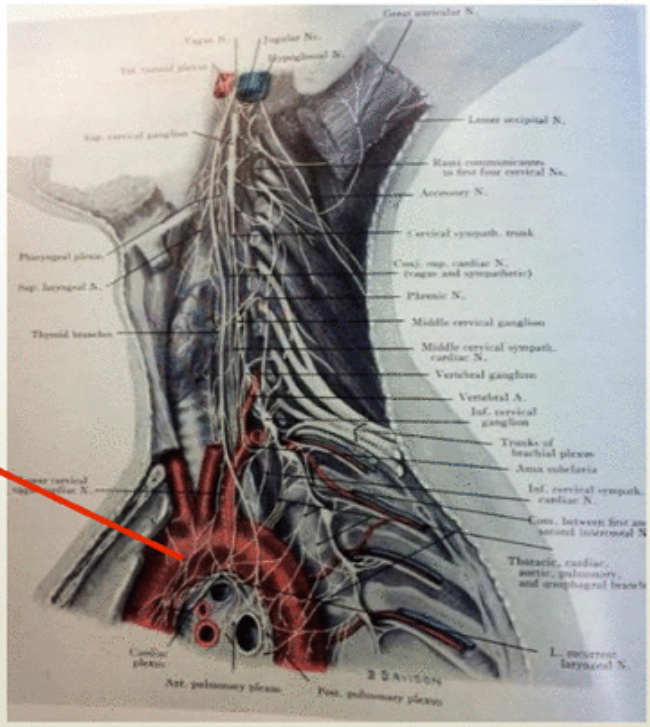
Large Unloading Effects Partly Due to Neural Reflexes?

SUNSHINE HEART

Direct and reflex vascular effects of intra-aortic balloon counterpulsation in dogs

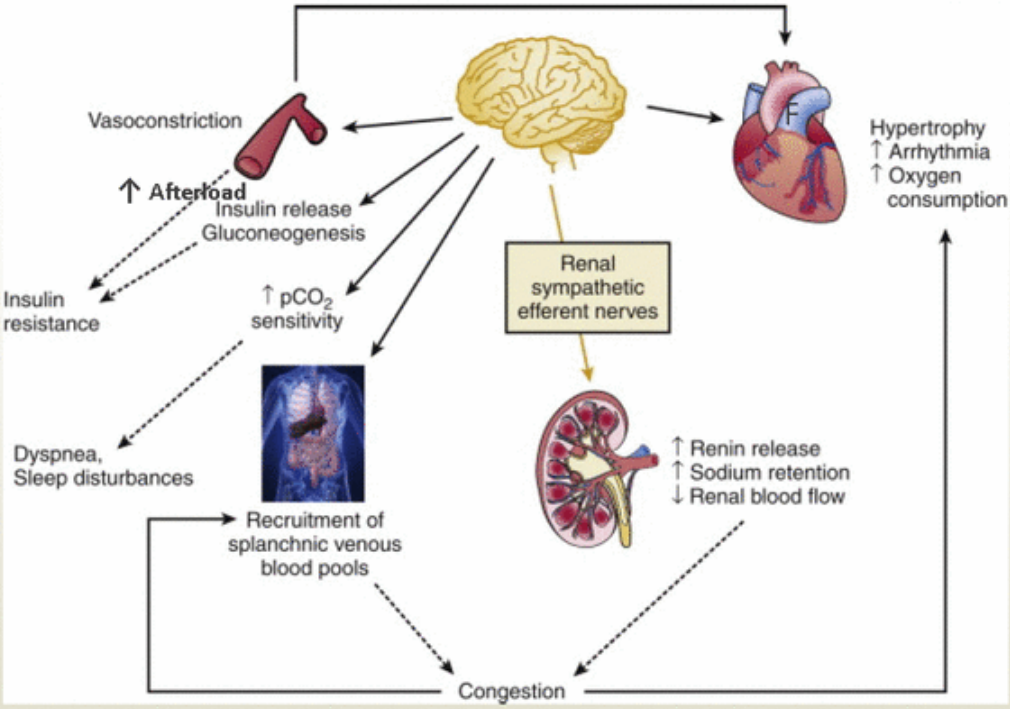
Am. J. Physiol. 221(3); 1971

C-Pulse balloon placement even more optimal location to activate reflexes



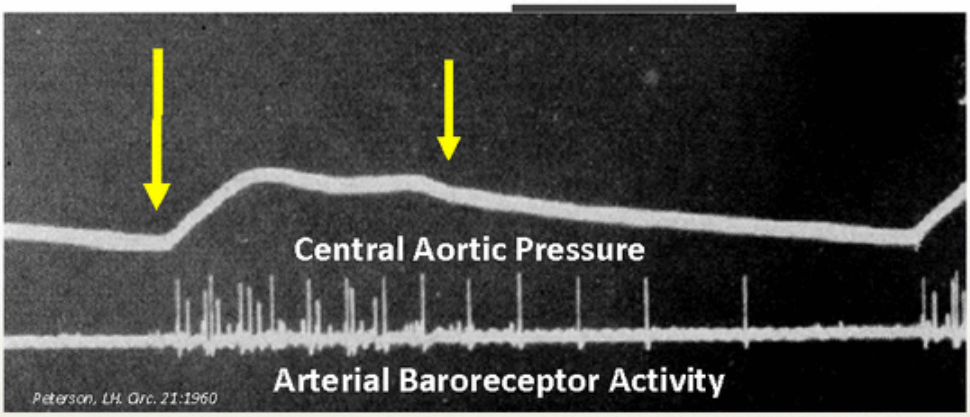
Mitchell GAG. Anatomy Autonomic Nervous System. 1953

Systemic Effects of Neural Reflex Modulation of Sympathetic Nervous System



Black, HR. Braunwald's Hypertension; 2012.

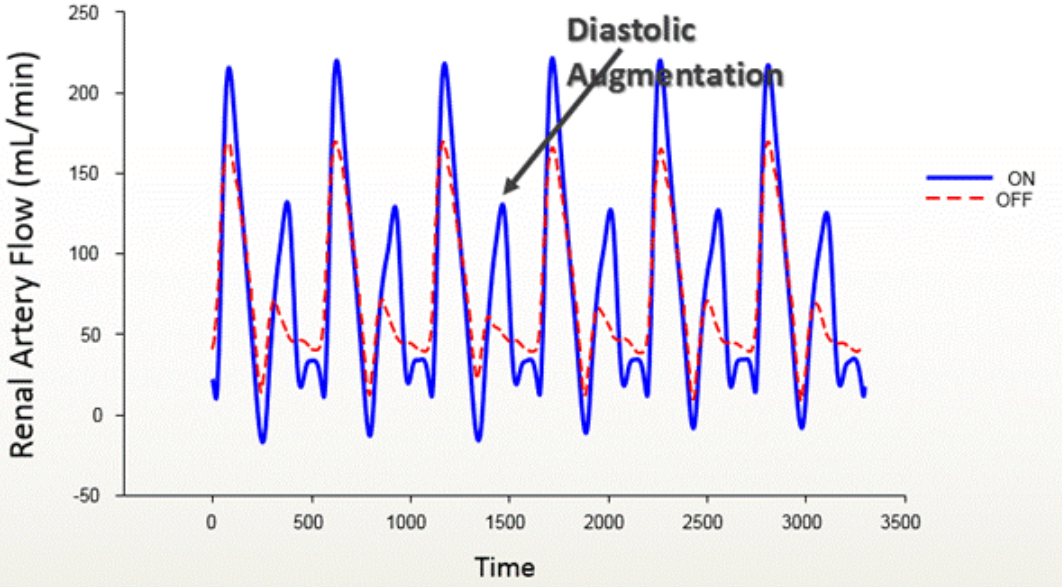
C-Pulse



Bronk and Stella. J Cell. Comp. Physiol. (1): 1932

Counterpulsation Timed to Most Sensitive Phases of Cardiac Cycle for Baroreceptor Stimulation

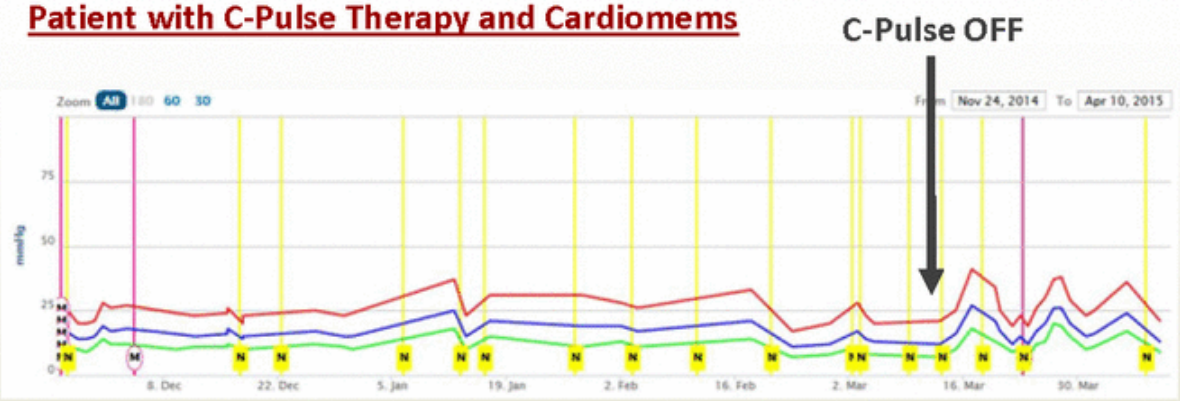
C-Pulse Effects on Renal Blood Flow: Normal Swine



47

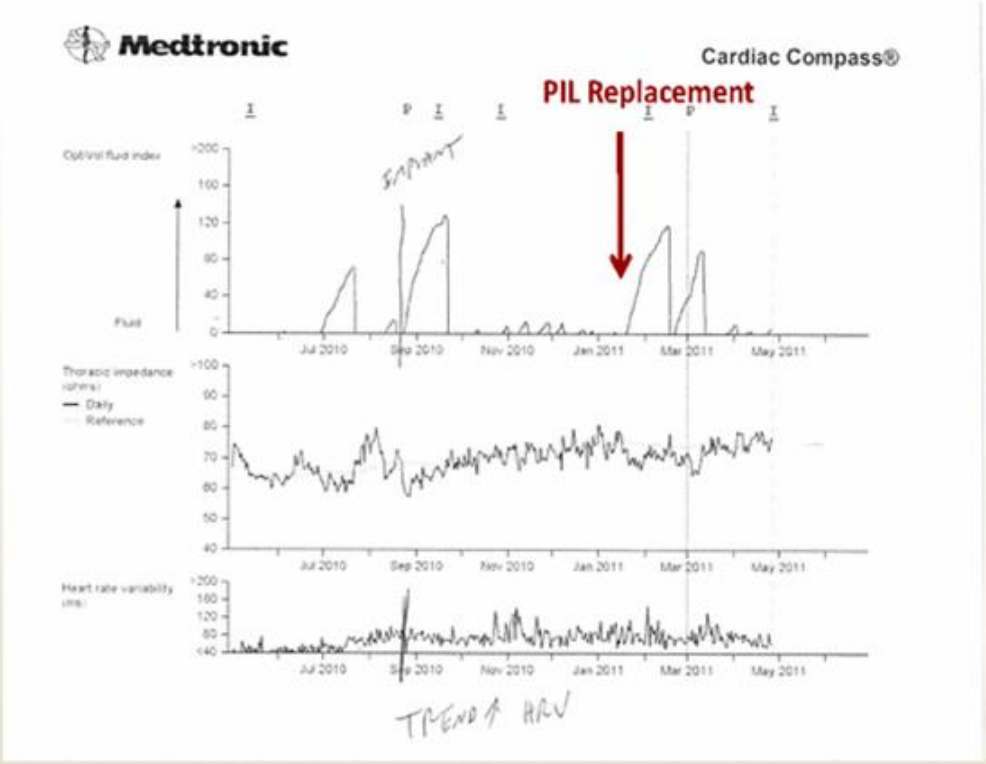
C-Pulse and Volume Management

Patient with C-Pulse Therapy and Cardiomems

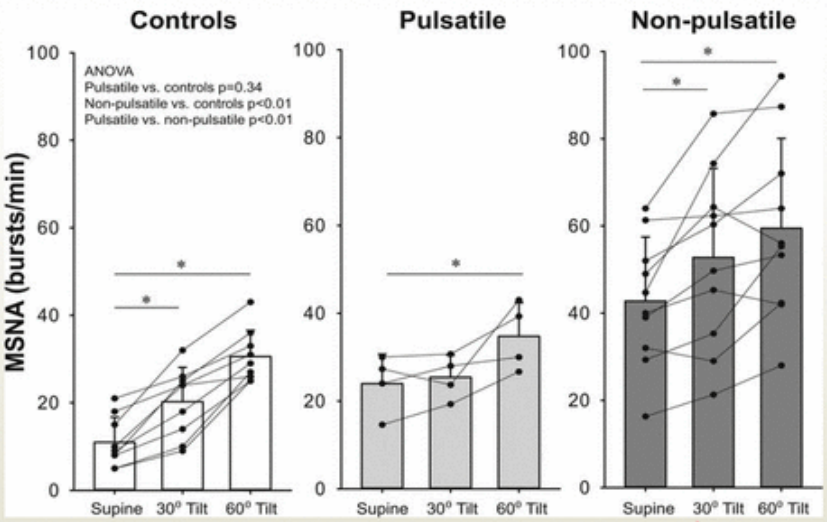


Submitted to HFSA 2015

C-Pulse and Heart Rate Variability: Clinical Case



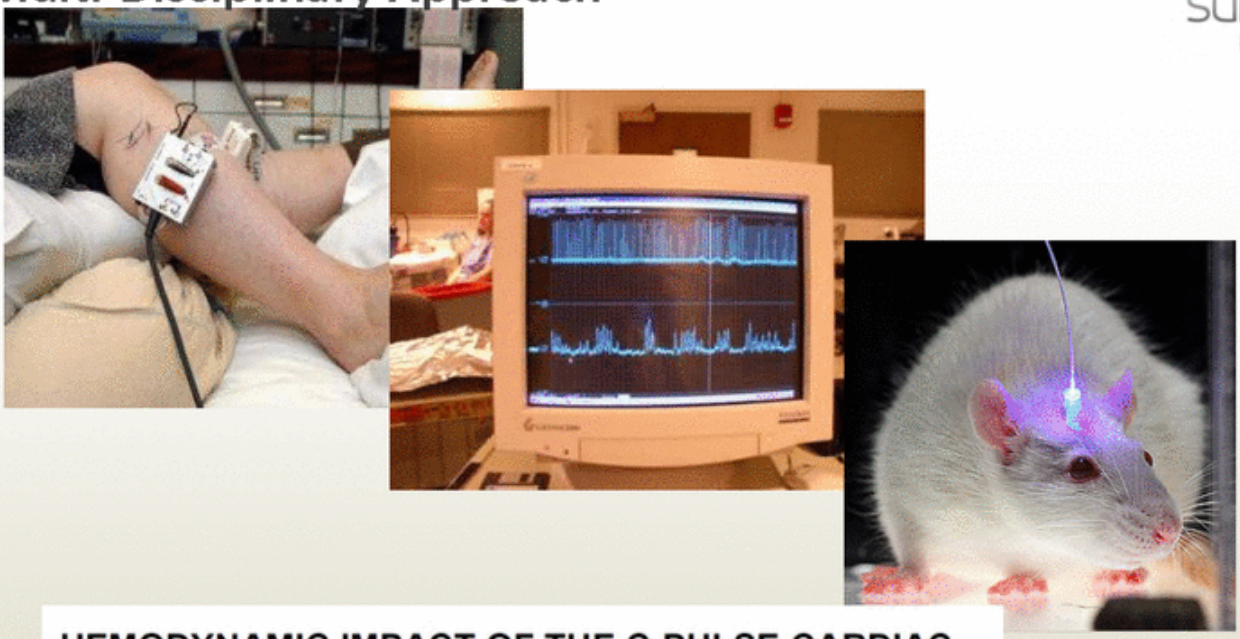
Pulsatility and Sympathetic Nervous System: Insights from LVAD Patients



Markham D W et al. Circ Heart Fail. 2013;6:293-299

Individual and mean muscle sympathetic nerve activity (MSNA) burst frequencies in healthy controls and patients with pulsatile and non-pulsatile left ventricular assist devices in the supine position and during upright tilt.

C-Pulse and Studies to Assess Neuromodulation Effects: Multi-Disciplinary Approach



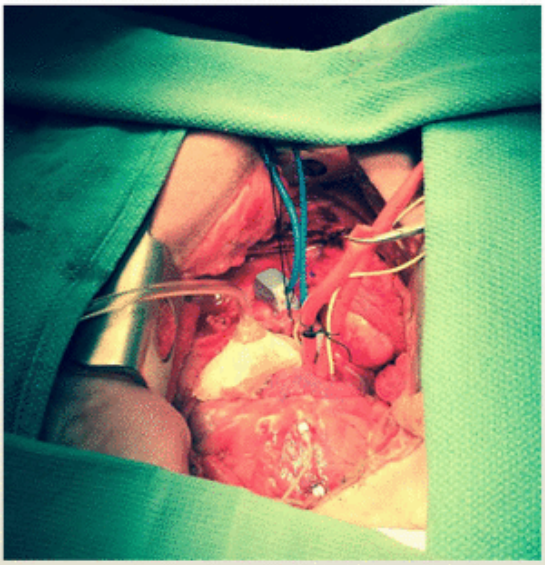
HEMODYNAMIC IMPACT OF THE C-PULSE CARDIAC SUPPORT DEVICE: A 1D ARTERIAL MODEL STUDY

D. Campos Arias[1], T. Rodriguez, N. Stergiopulos[2], P. Segers[3]

[1]Cujae, Research Group of Biomechanics and Biomaterials, Cuba, 2 LHTC, EPFL, Lausanne, Switzerland; [3] IBiTech-bioMMeda, iMinds Medical IT, Ghent University, , Belgium

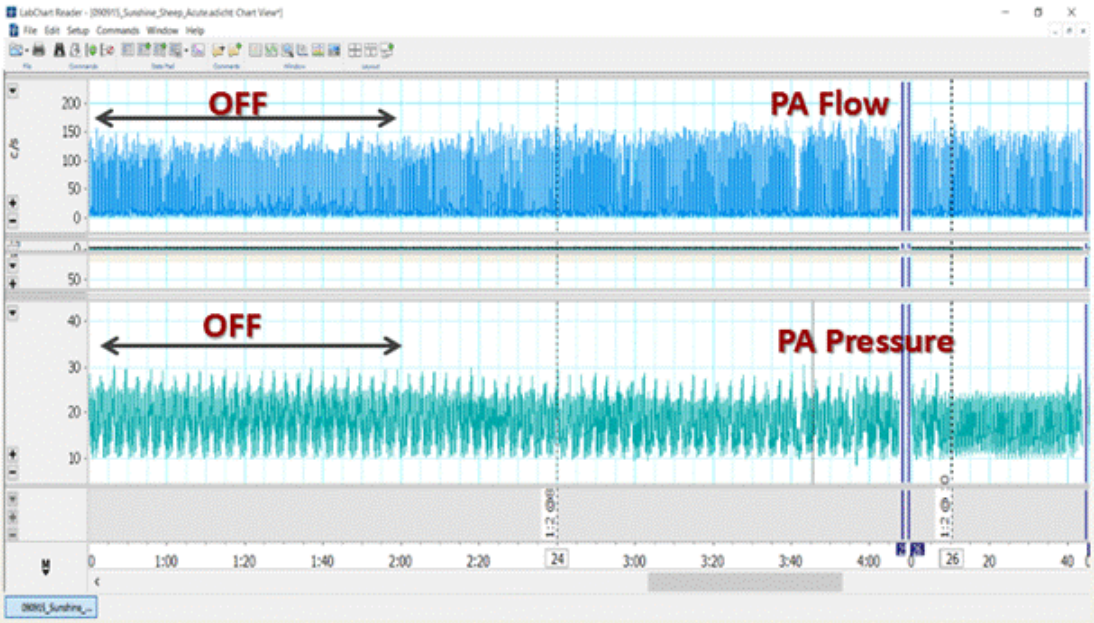
Animal Studies: Pulmonary Artery Counterpulsation

SUNSHINE HEART

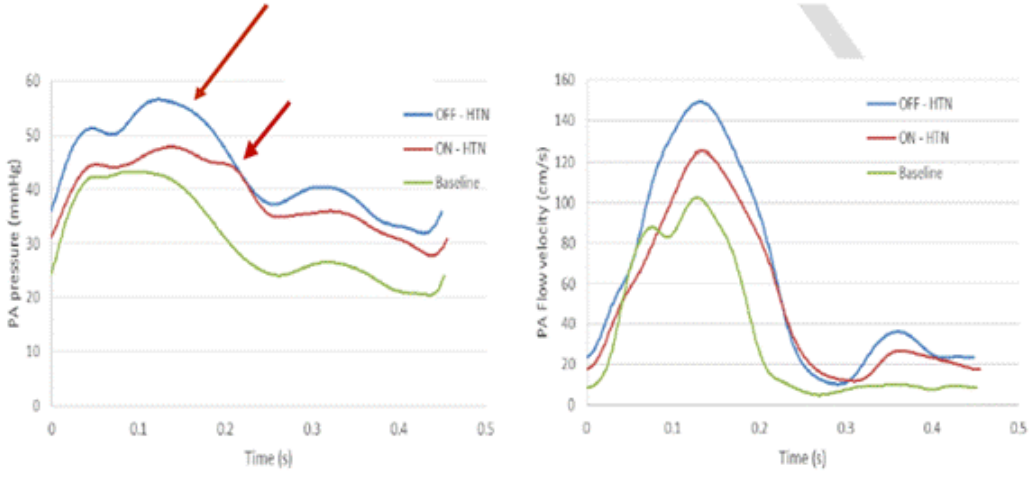


- Pulmonary HTN
- RV Failure Secondary to LVAD
- Congenital Defects (Tetralogy of Falot)

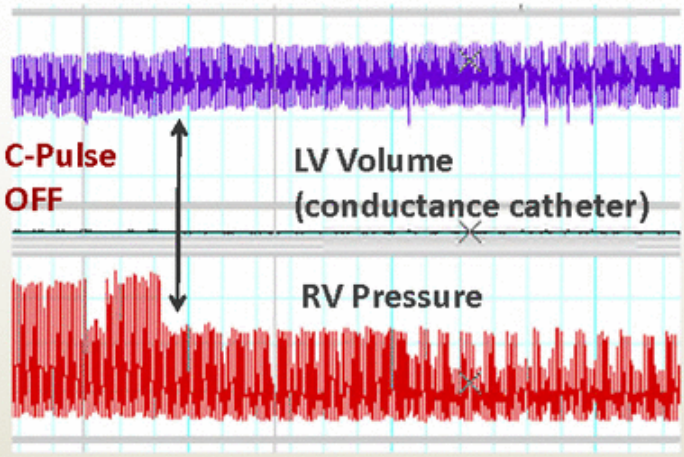
C-Pulse Counterpulsation on Pulmonary Artery



Pulmonary Pressure and Flow in PA HTN: C Pulse Acutely Reverses Elevated PA Pressure

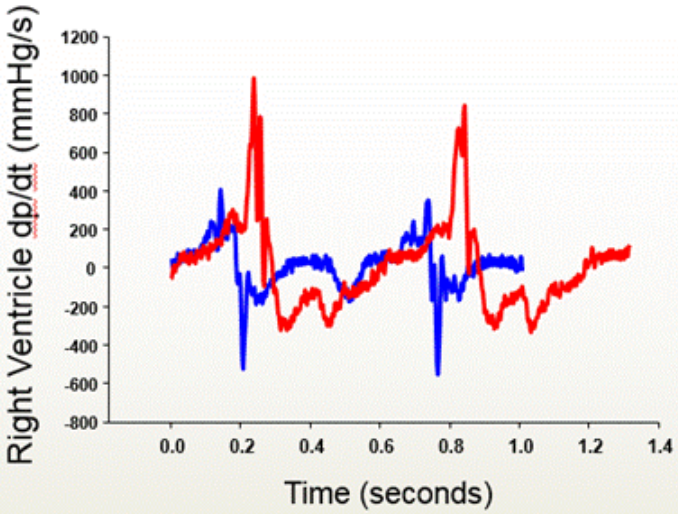


C-Pulse Unloads RV during Right Heart Failure and Simultaneously Reduces LV Dilation



- C-Pulse restores RV function in setting of pulmonary hypertension and acute RV failure
- Reduces dilation of LV during right heart failure

Counterpulsation on PA Improves RV Function In Acute Right Heart Failure due to Embolism



Summary

- C pulse provides based on traditional concepts of counterpulsation: increase coronary perfusion and afterload reduction.
- Advanced hemodynamic analysis from patients indicates afterload reduction in late systole not onset of ejection related to balloon deflation.
- Late systolic reduction associated with marked vasodilation in carotid artery and distal arterioles. What is mechanism????
- Hypothesis of mechanical stimulation of aortic and carotid baroreceptors. Stimulation due to nature of counterpulsation timed during cardiac cycle mimics physiologic stimulation pattern
- Chronic neuromodulation and enhanced coronary perfusion may provide substrate for chronic remodeling and myocardial recovery.

EU – CE marked / US - Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

SUNSHINE HEART

Thank You!

www.sunshineheart.com

FRM-04558-B

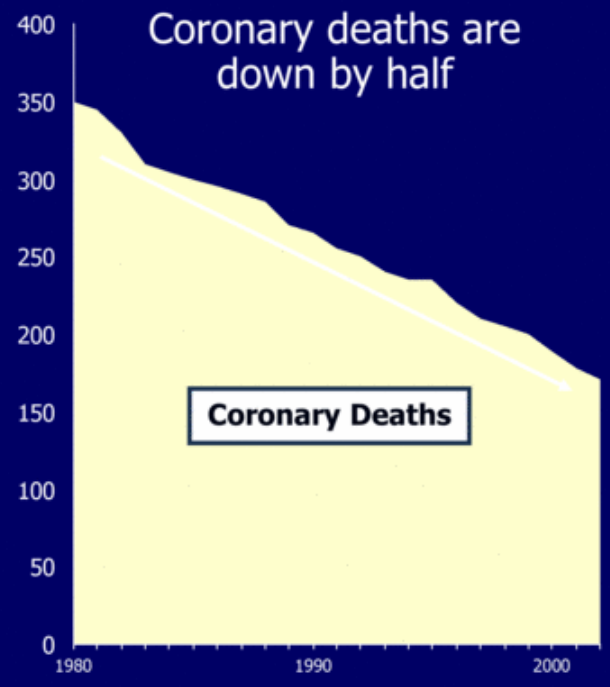
MANAGEMENT OF ADVANCED HEART FAILURE TODAY

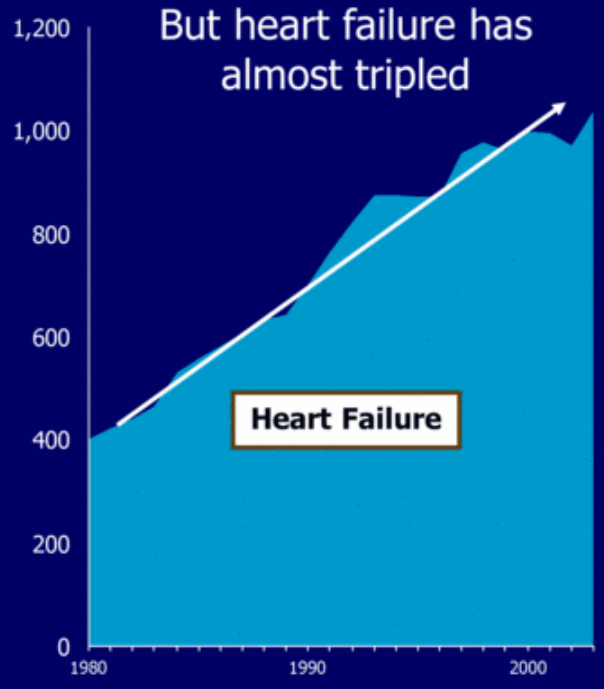
Leslie W. Miller, MD
Director of Heart Failure
Morgan Heart Institute

Forward Looking Statement

- 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 on Form 10-K for the fiscal year ended December 31, 2014.
- 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.

Heart Failure versus Coronary Deaths





Consequence of our Success
Need new technologies for chronic disease management

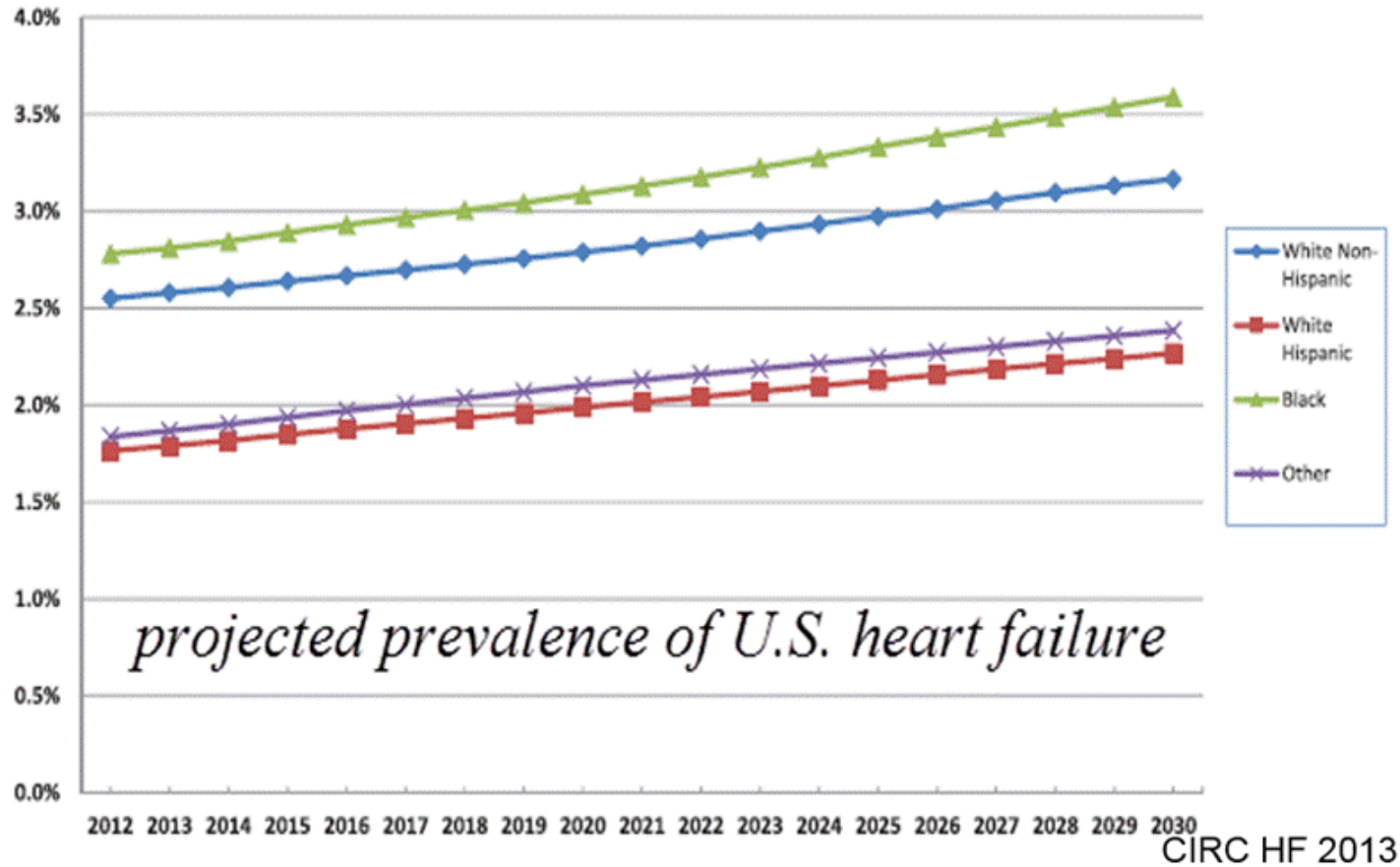
Source: National Hospital Discharge Survey, CDC/NCHS and NHLBI.

Heart Failure Facts

- **Only form of CV disease increasing in Mortality**
- **> 7 million patients in U.S.; > 50% Systolic HF**
- **> 800,000 New cases/year*; One every 9 deaths***
- Increase is due to advances-AMI*, PCI, ICDs
- Epidemic of Obesity, Diabetes, HTN
- **Prevalence: 7-10% people > 65 yrs of age (M=F)**
- **Population > 65 yr-double the incidence by 2030**
- **NUMBER Patients increase by 2025 to > 10 M**

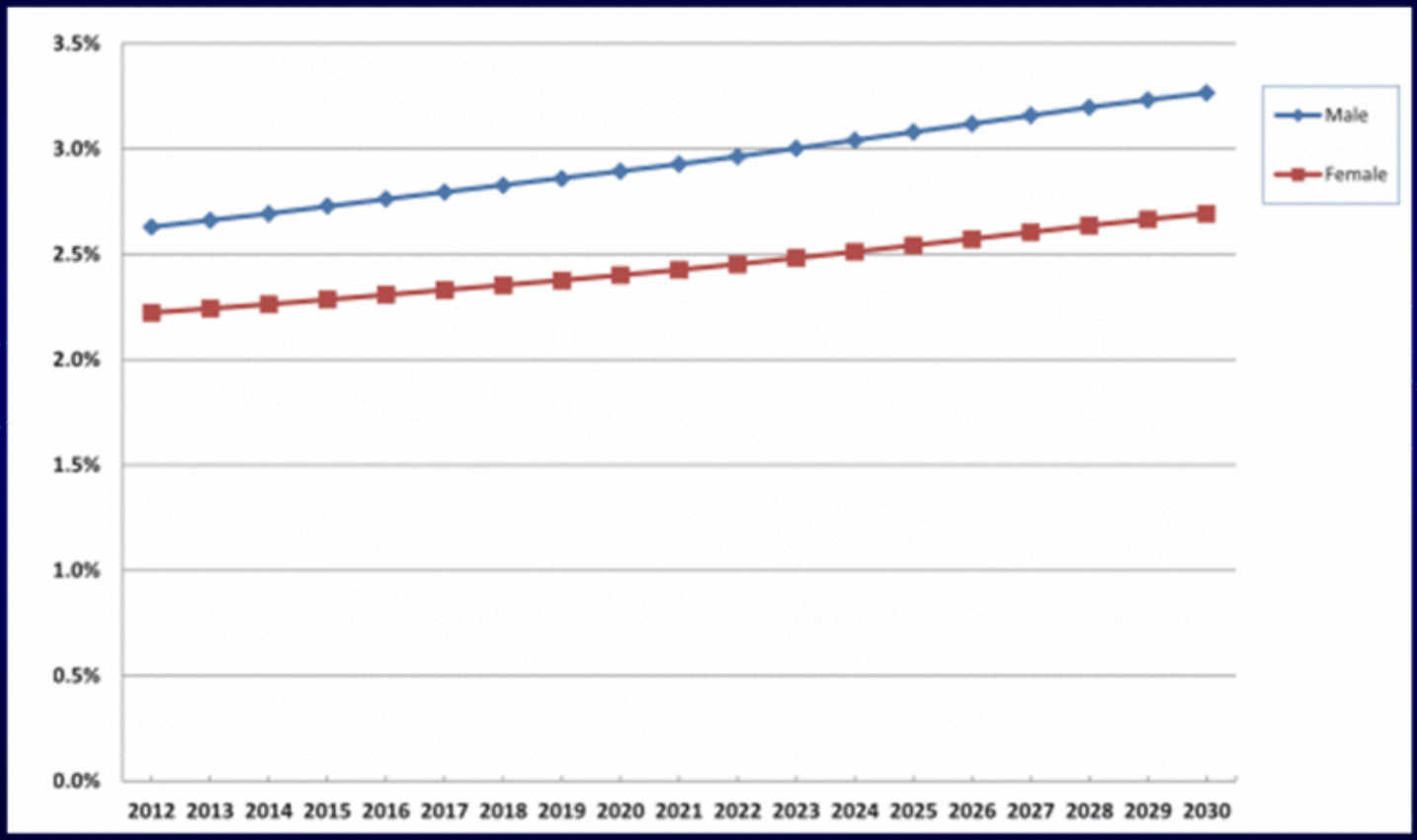
AHA Policy Statement

Forecasting the Impact of Heart Failure in the United States



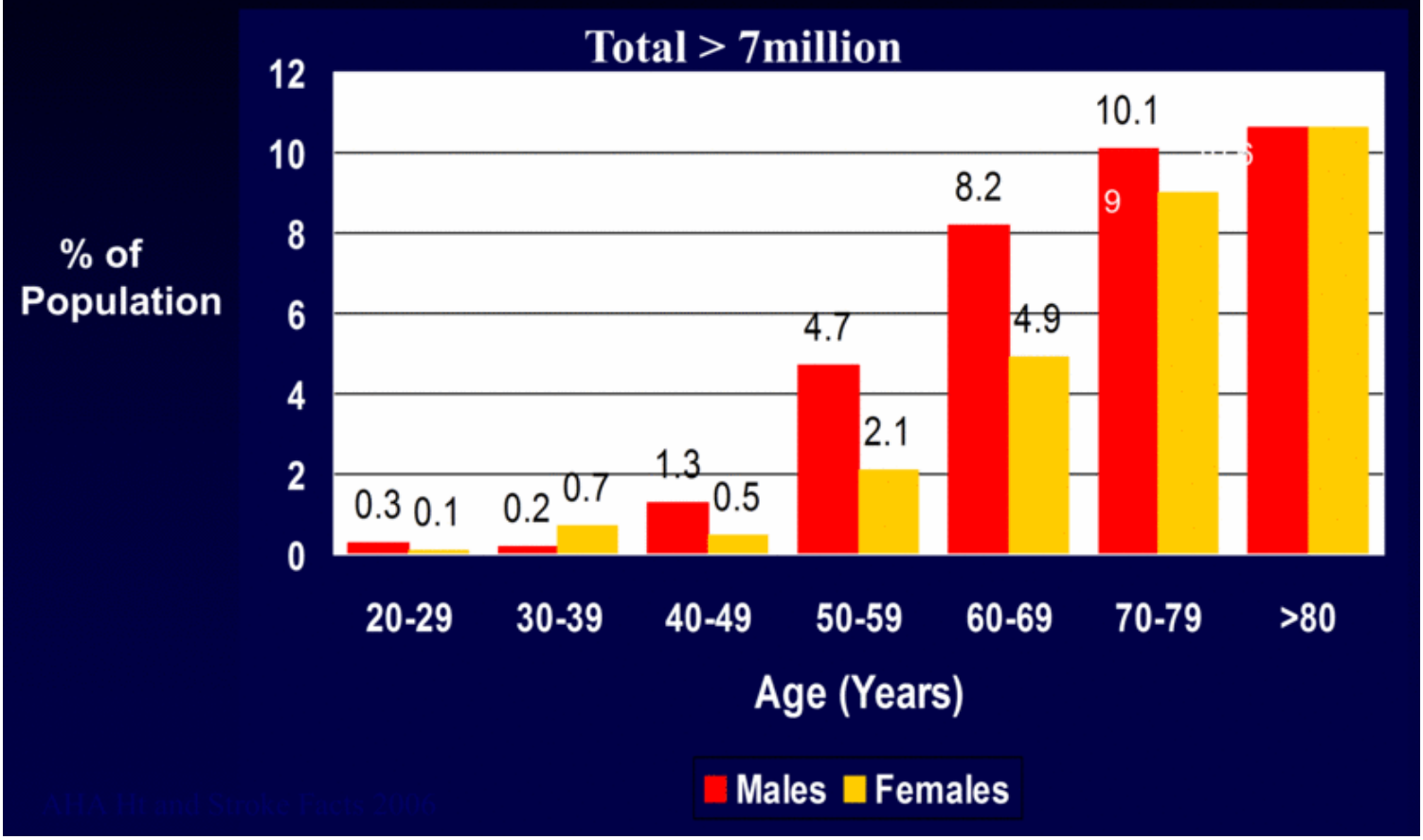
CIRC HF 2013

MORTALITY BY GENDER WITH HEART FAILURE



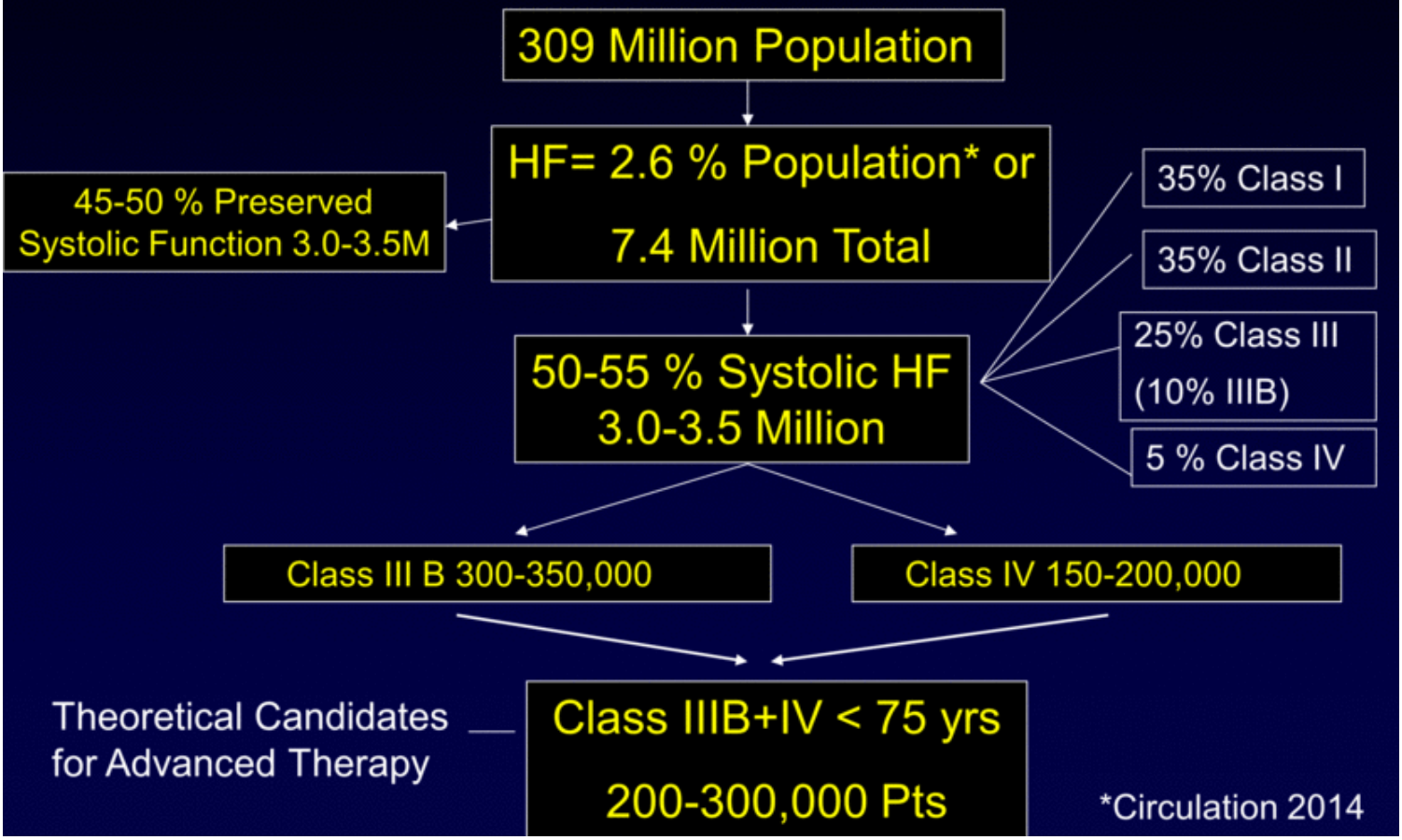
* Heidenreich Circ HF 2013-AHA Forecast

HEART FAILURE
Estimated Prevalence by Age & Gender



AHA Ht and Stroke Facts 2006

Current Estimate of Advanced HF Pts



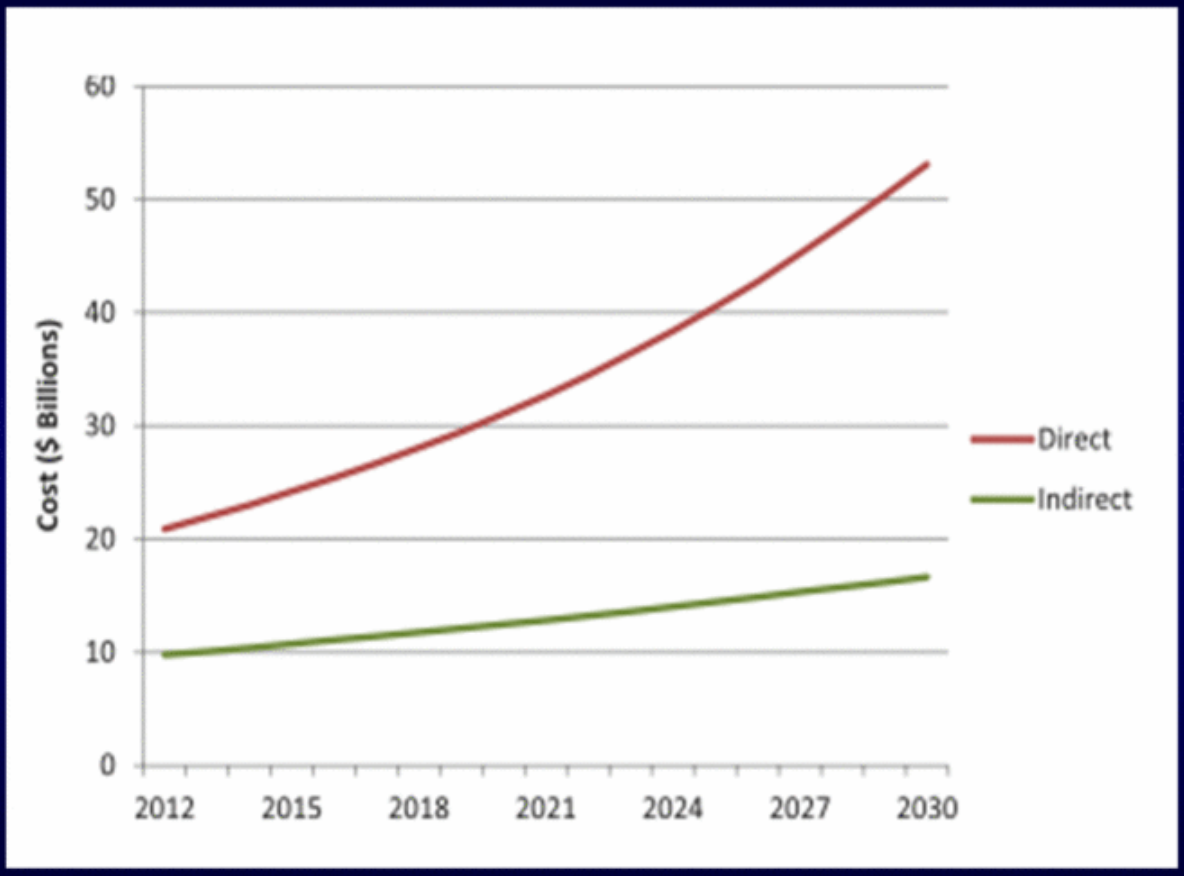
*Circulation 2014

Heart Failure Facts

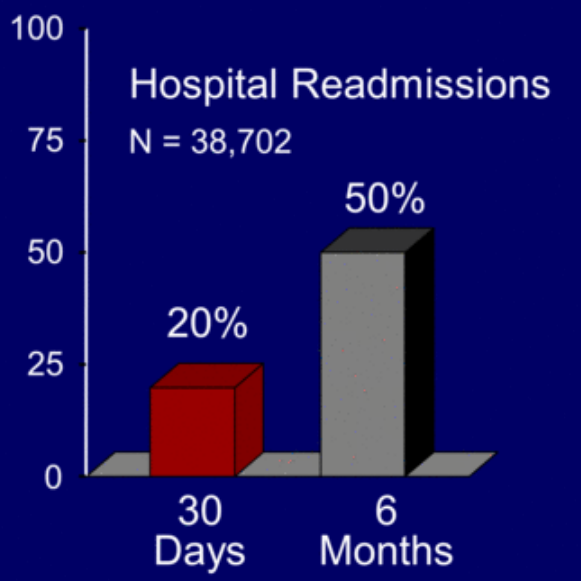
- Mortality > 60% at 5 yrs, worse by Class
- > 1 Million Hospitalizations/Yr (3 M as #2,3 Dx)
- More Hosp days care HF than any other Dx
- # 1 cause of readmission 30 days: 20-30%
- Loss of work impact > $8 Billion
- COST NOW: $31 B ; COST 2030: $ 70 Billion*
- Mandate to find new more cost effective therapies

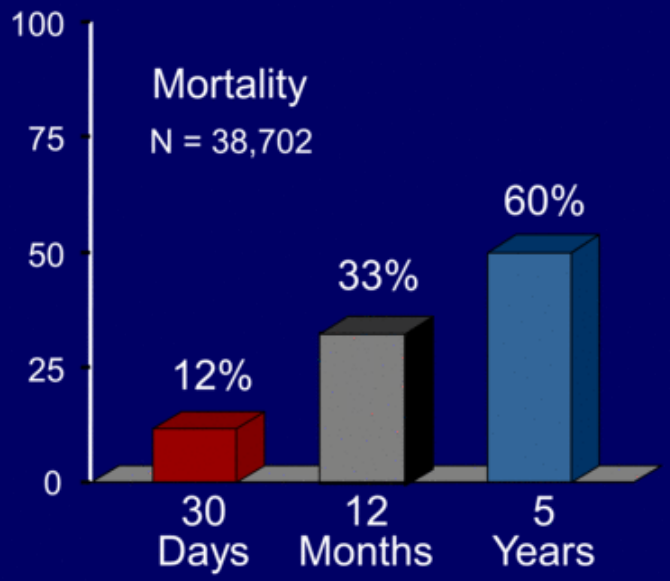
* Heidenreich Circ HF 2013-AHA Forecast

PROJECTED INCREASE IN TOTAL COST OF HF CARE



Outcomes in Patients Hospitalized with Heart Failure

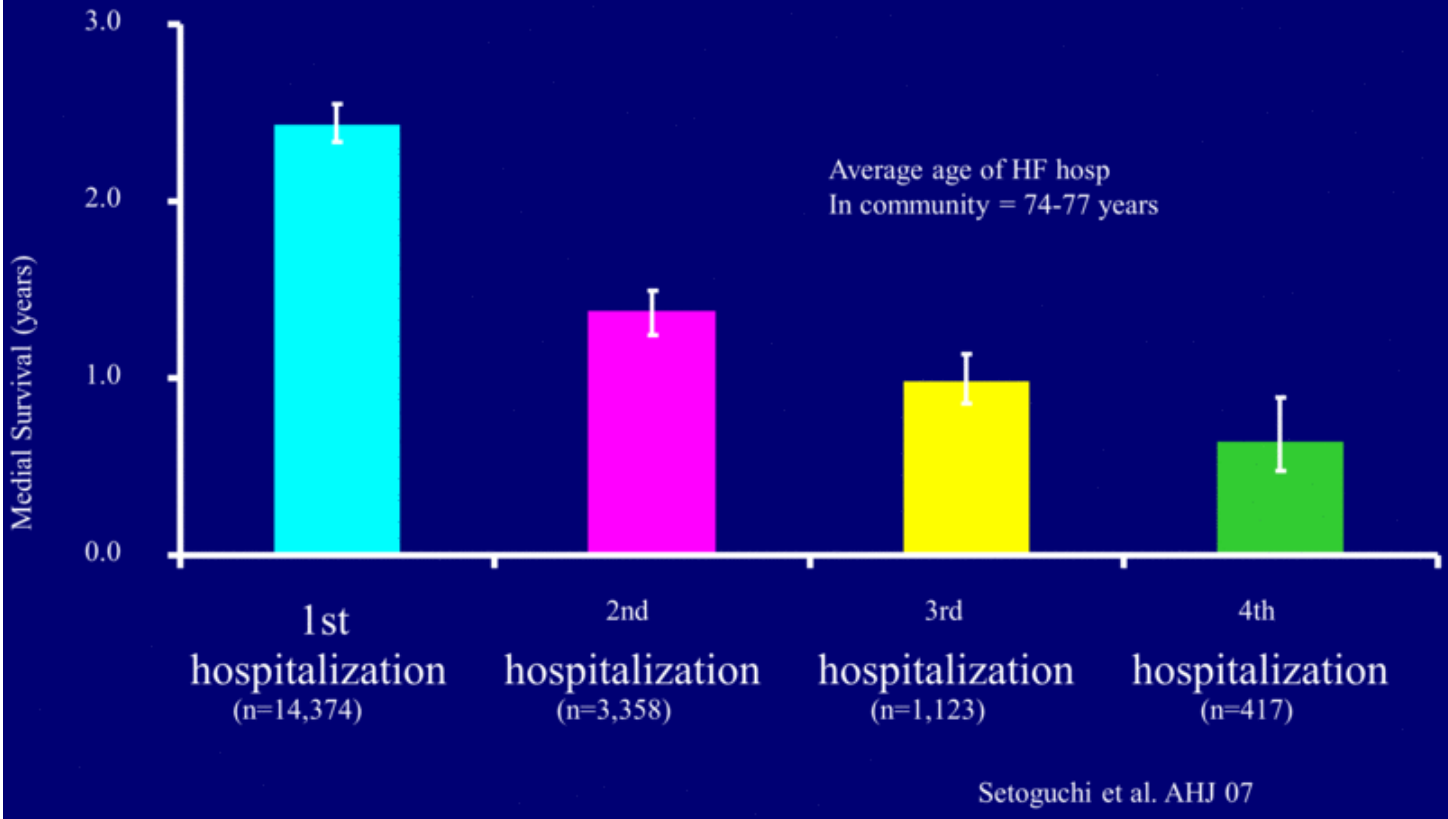




Median length of hospital stay: 6 days

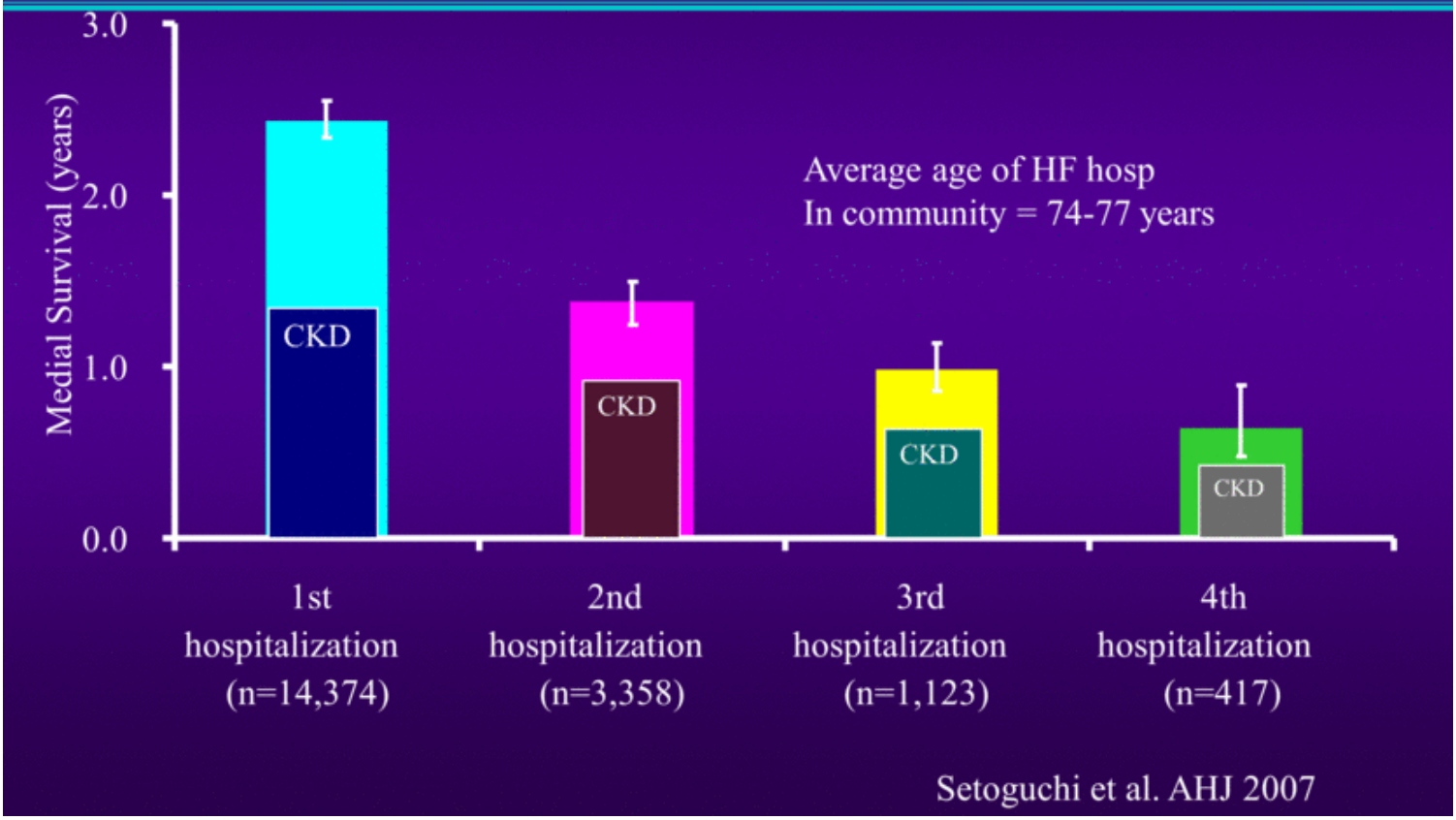
References: Aghababian RV. *Rev Cardiovasc Med.* 2002;3(suppl 4):S3-S9.
Jong P et al. *Arch Intern Med.* 2002;162:1689-1694.

Median Survival Decreases Progressively after Each Hospitalization



Setoguchi et al. AHJ 07

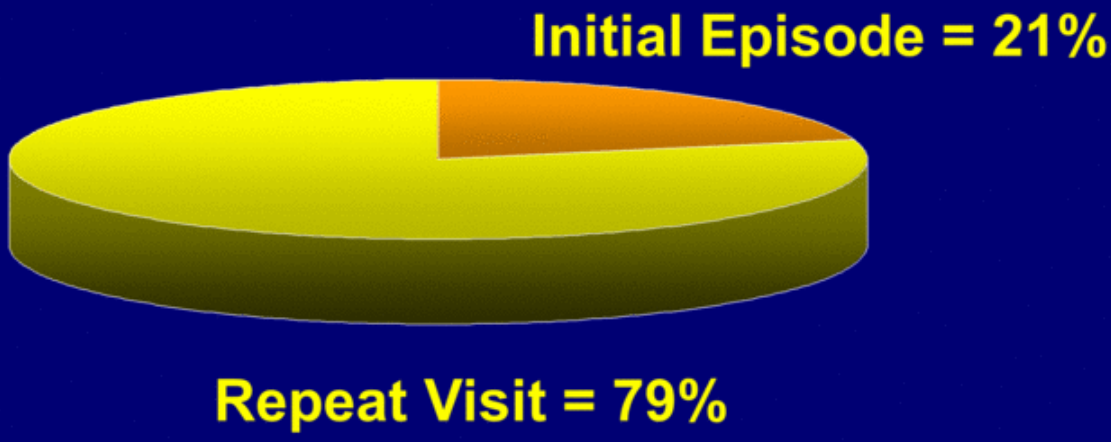
Median Survival Decreases Progressively after Each Hospitalization Impact of Chronic Kidney Disease (CKD)



Setoguchi et al. AHJ 2007

Hospital Visits for Congestive Heart Failure

Emergency Department Presentations



Aghababian RV. *Rev Cardiovasc Med.* 2008;3(suppl 4):S3–S9.

Failed In-Hospital Trials-ADHF

- DOSE-Diuretic dosing: IV infusion vs Bolus
- ASCEND- BNP vs Std Care
- DAD-HF: low dose Dopamine, high/low lasix
- PROTECT: Rolofyline vs std care
- CARRESS: Ultrafiltration
- RELAX: Seralaxin vs placebo
- ASTRONAUT: Aliskerin
- SMAC-HF: Hypertonic saline

Givertz et al J Card Fail 2013

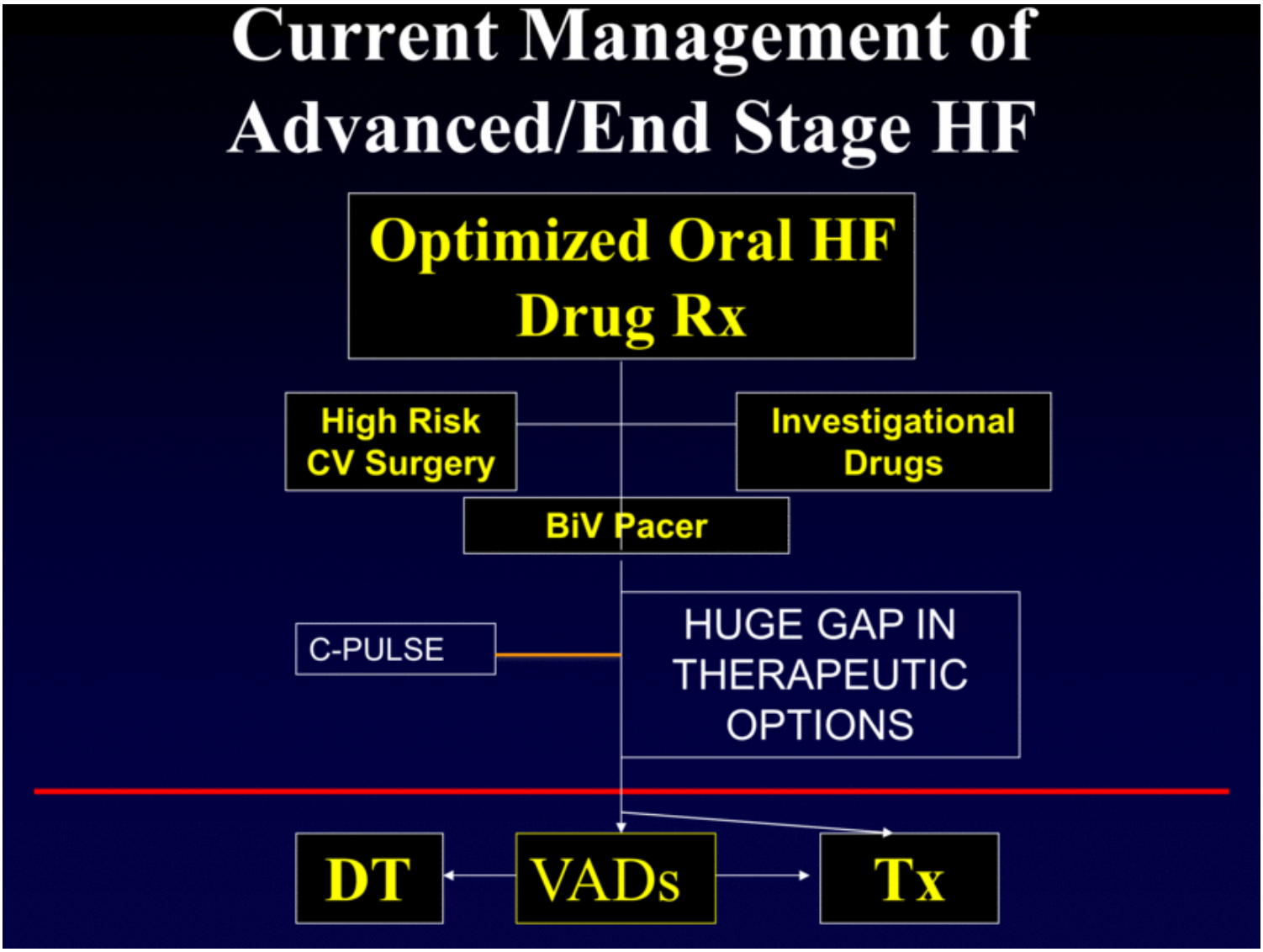
Failed New Therapies for Heart Failure

- Intravenous Inotropes-Milrinone (OPTIME)
- Calcium Sensitizer Inotrope-Levosimendan (LIDO)
- Endothelin Receptor Antagonists (RITZ)
- BNP metabolism Neprolysin inhibitor (OVERTURE)
- Calcium Channel Blockers (PRAISE)
- TNF antibodies (RENAISSANCE)
- Brain Natriuretic Peptide (FUSION 3)
- Vasopressin Antagonist (Tolvaptan)
- Adenosine Receptor Antagonist (PROTECT)
- Angiotensin Receptor Block (Irbesartan) (I-PRESERVE)

New Drugs for Heart Failure

- Entresto : New combined ARB and BNP inhibitor VS ACEI
- PARADIGM Study*: 8,000 patients
- Reduced Mortality by 20%
- Reduced Hospitalization by 20%
- Only 1 % were Class IV
- Corlanor: Designed to slow HF; only blocks ion channel
- No effect on Mortality
- Reduced Hospitalization by 23%
- Add on drug, Beta Blocker intolerant
- Only 1 % Class IV; 1% African Am

Current Management of Advanced/End Stage HF

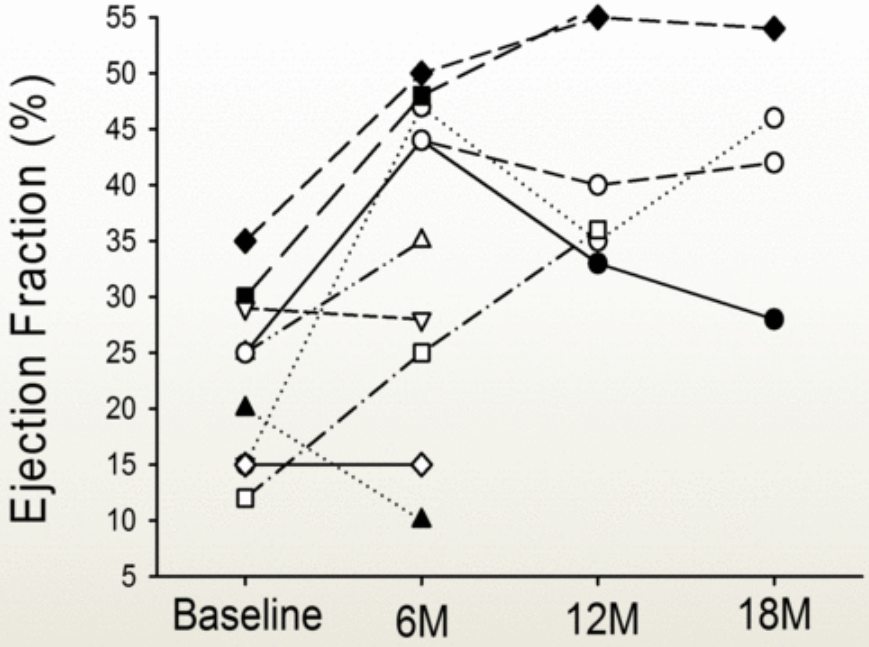


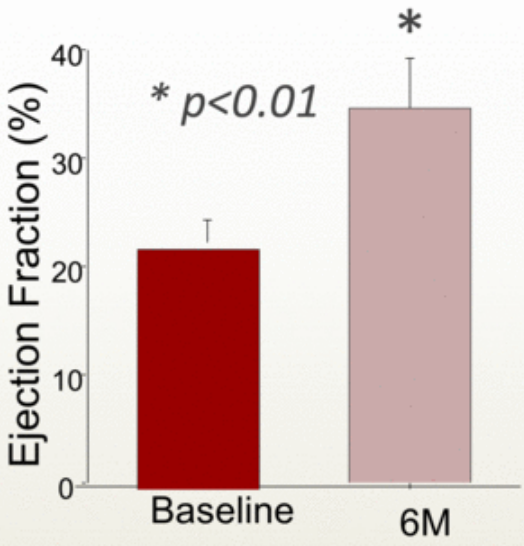
WHY SUNSHINE HEART COUNTER-HF™

- **Huge Gap in Therapeutic Options between optimized Medical Therapy/CRT → Ht Tx or large LVAD**
- **Implant is much less invasive compared to Tx/LVAD**
- **Multiple Mechanisms of benefit**
- **Device can be safely stopped-Relieve Anxiety of Risk**
- **Patient can SHOWER with drive line detached-QOL**
- **Modular design allows easy repair of drive line**
- **Moving to eliminating drive line**

Caution: C-Pulse ® is an investigational device. The device is limited by federal (United States) law to investigational use only.

OPTIONS HF
Improvement in Ejection Fraction

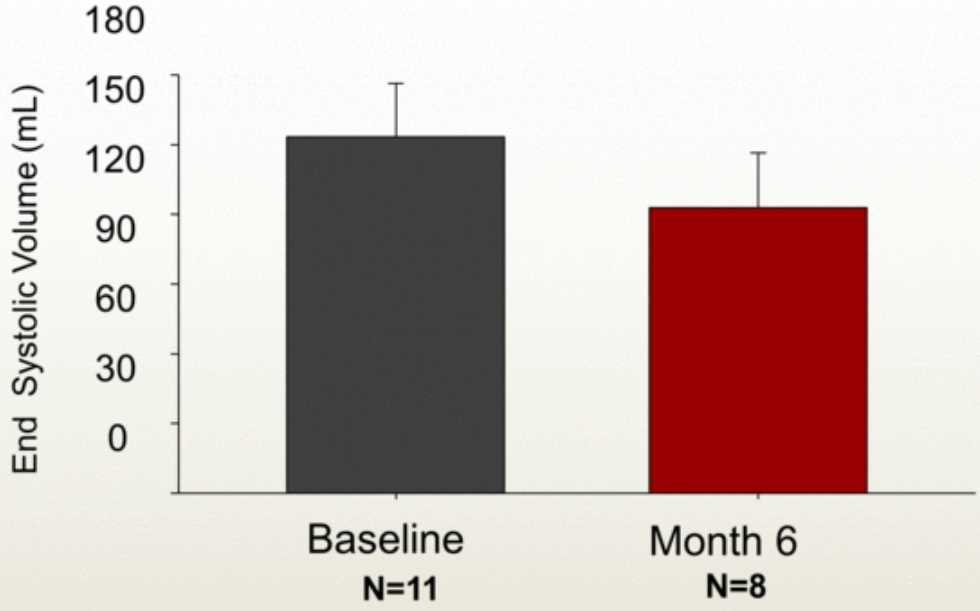




C- Pulse OPTIONS-HF Structural Remodeling

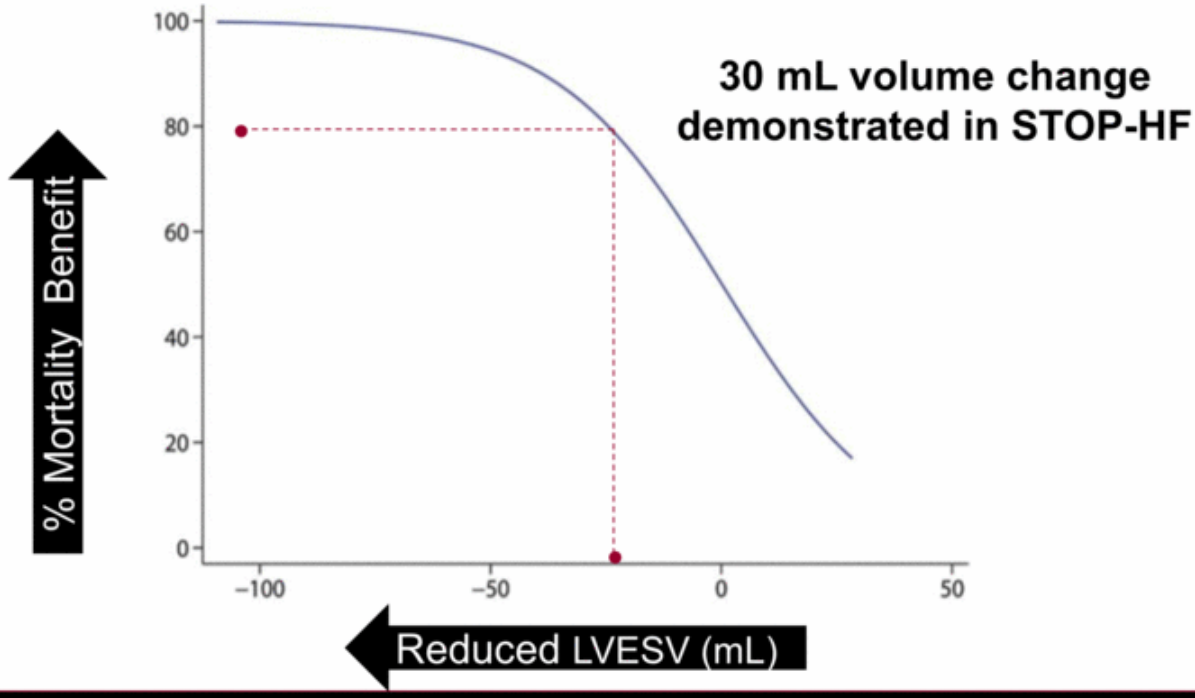
SUNSHINE HEART

End Systolic Volume



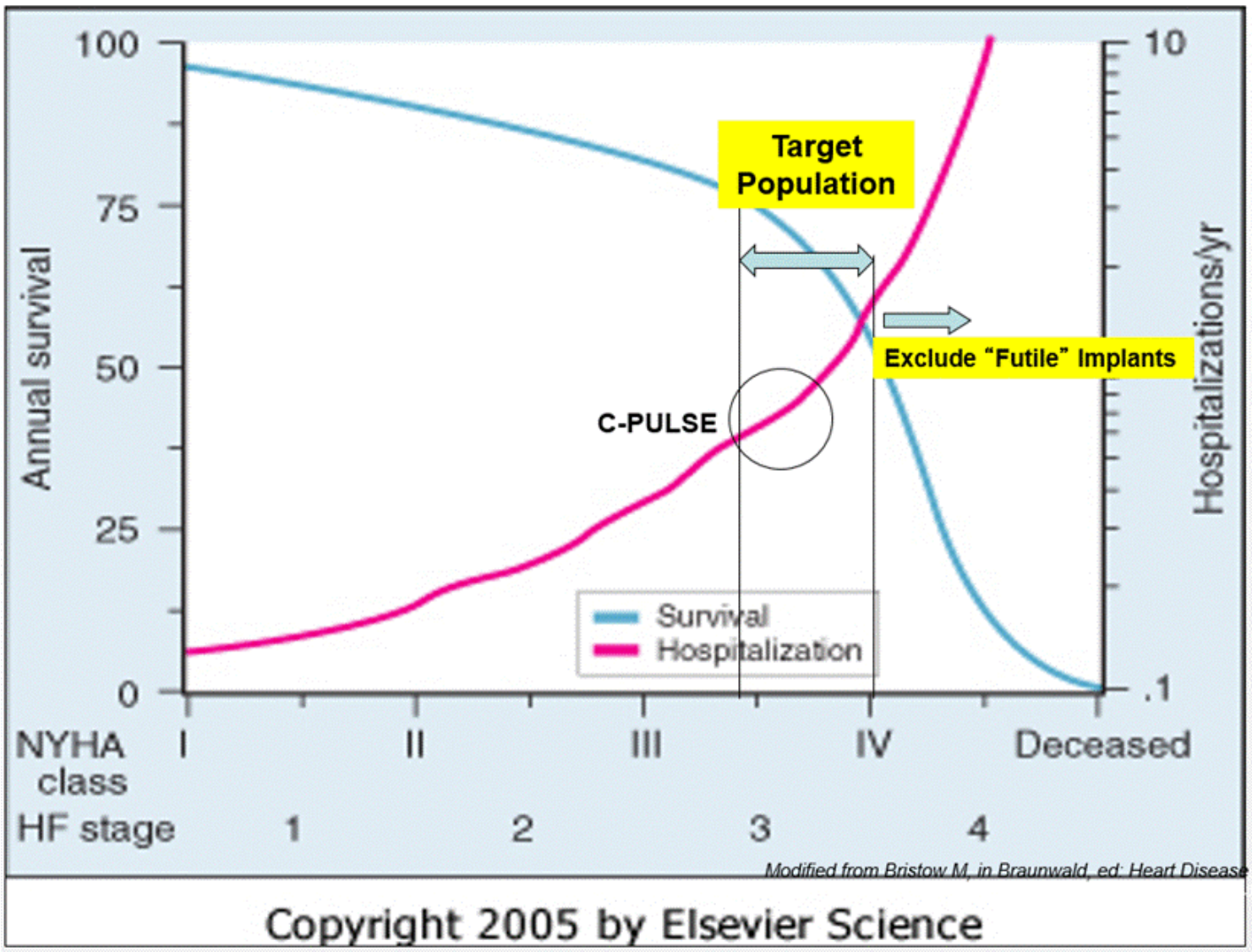
Sunshine Heart data on file

LVESV is Correlated with Mortality
Meta Analysis of 30 trials*



Studies indicate that a 30 mL LVESV change correlates with~80% improvement in mortality.

*Kramer DG. JACC 2010; 56(5)

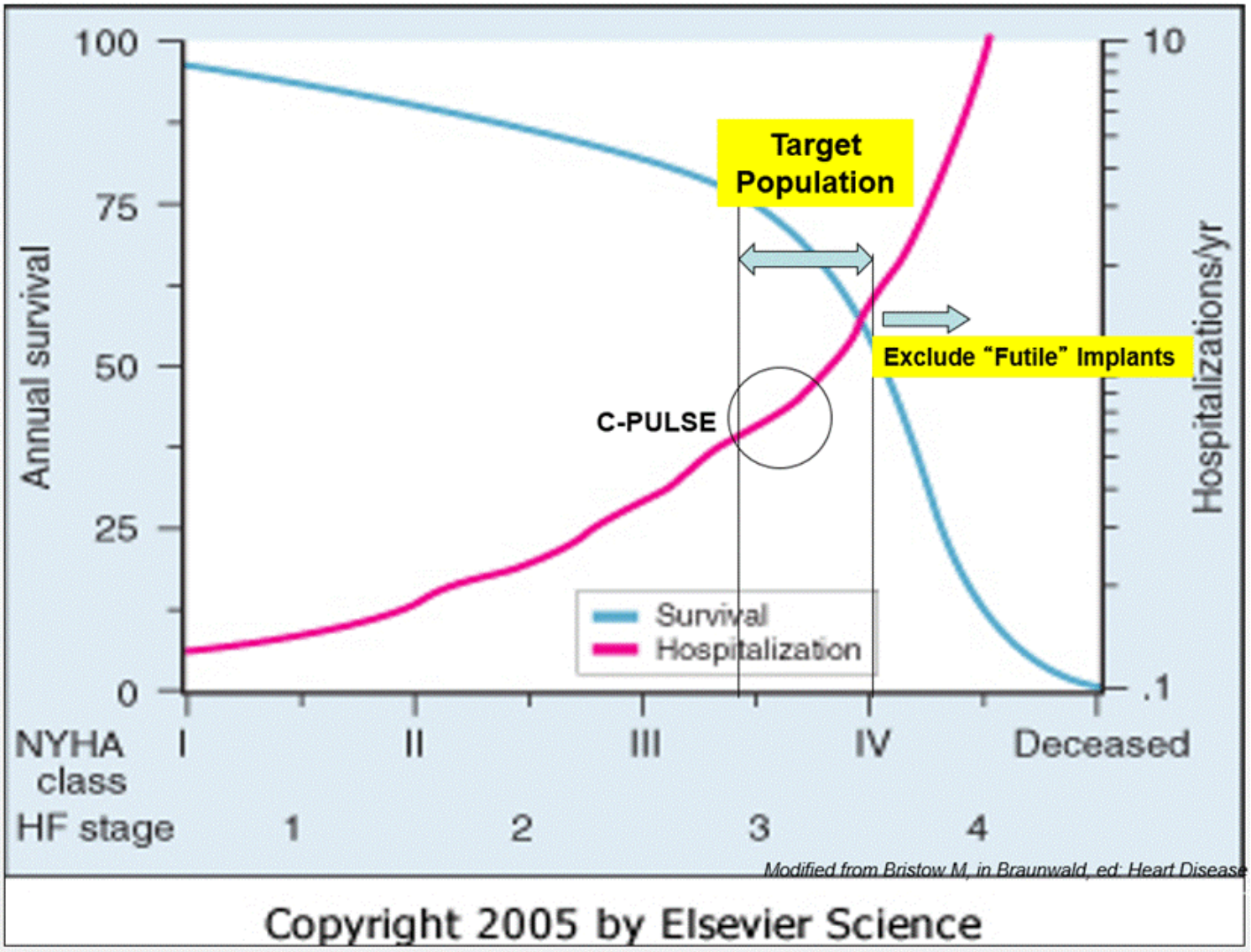


CURRENT LVAD PROBLEMS

- **Significant advances in technology**
- **Cost is >$150,000 just for index hospitalization**
- **READMISSION rate: Avg 2.6 admits first year**
- **GI Bleeding-main cause of readmission**
- **Stroke: 8-10%**
- **Device Thrombosis/Replacement**
- **Infection**

RECOVERY

- Holy Grail of any form of mechanical support
- Sufficient improvement to remove the device
- Limited success with today's chronic LVADs- 5-10%
- Explant and failure requires large Reoperation procedure
- If improvements seen in the short follow up with C-Pulse
- Persist or improve more, could lead to increased Recovery
- Goal is significant sustained improvement
- If HF returns, limited procedure to reinitiate therapy



Modified from Bristow M, in Braunwald, ed: Heart Disease

SUMMARY

- Growth in Heart Failure is “At a Tipping Point”
- Rapid increase in those still symptomatic on Optimal MM
- Once hospitalized for HF, dramatic decline in Survival
- Cost of this expansion (hospitalizations) is not sustainable
- Clear need for effective new alternative to current Rx
- Pilot data from C-Pulse is very encouraging
- Sustainable Recovery would have enormous impact
- Design makes it much more attractive to patient
- COUNTER trial should enroll well

STANDARDIZED CONSENT C-PULSE

- Trial enrollment is a critical component of success
- Enrollment varies between sites
- Significant Variability Consent Presentation
- New Approach: Create Scripted, Video-Taped Presentation of study and details-
- Allows uniform and "ideal" presentation as many times as patient needs and subsequent questions addressed
- FDA, Sponsor, PI, and Patient ALL Advantaged

Caution: C-Pulse ® is an investigational device. The device is limited by federal (United States) law to investigational use only.

SUNSHINE HEART

Progress of the Fully Implantable System

TCT Conference, Oct 13, 2015 San Francisco

www.sunshineheart.com

Forward Looking Statement

- 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 on Form 10-K for the fiscal year ended December 31, 2014.
- 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.

C-Pulse II Overview:

C-Pulse II - Fully Implantable System

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

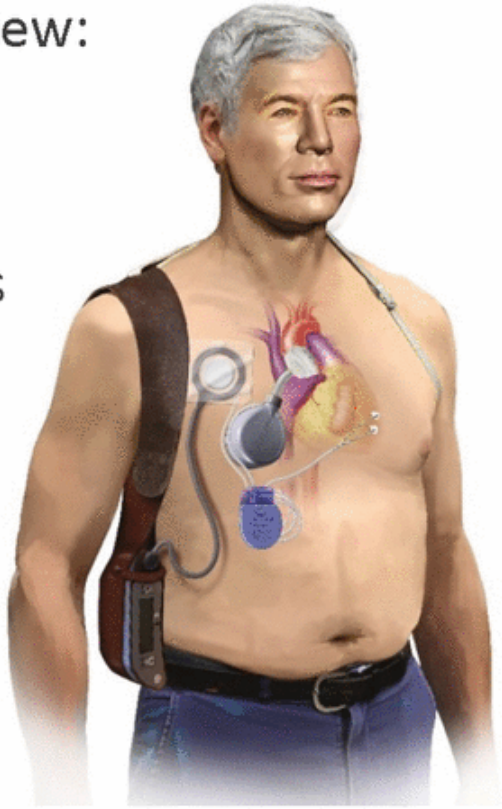
1. **Non-blood contacting**
2. **Non-obligatory**

C-Pulse II Overview:

C-Pulse II - 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***

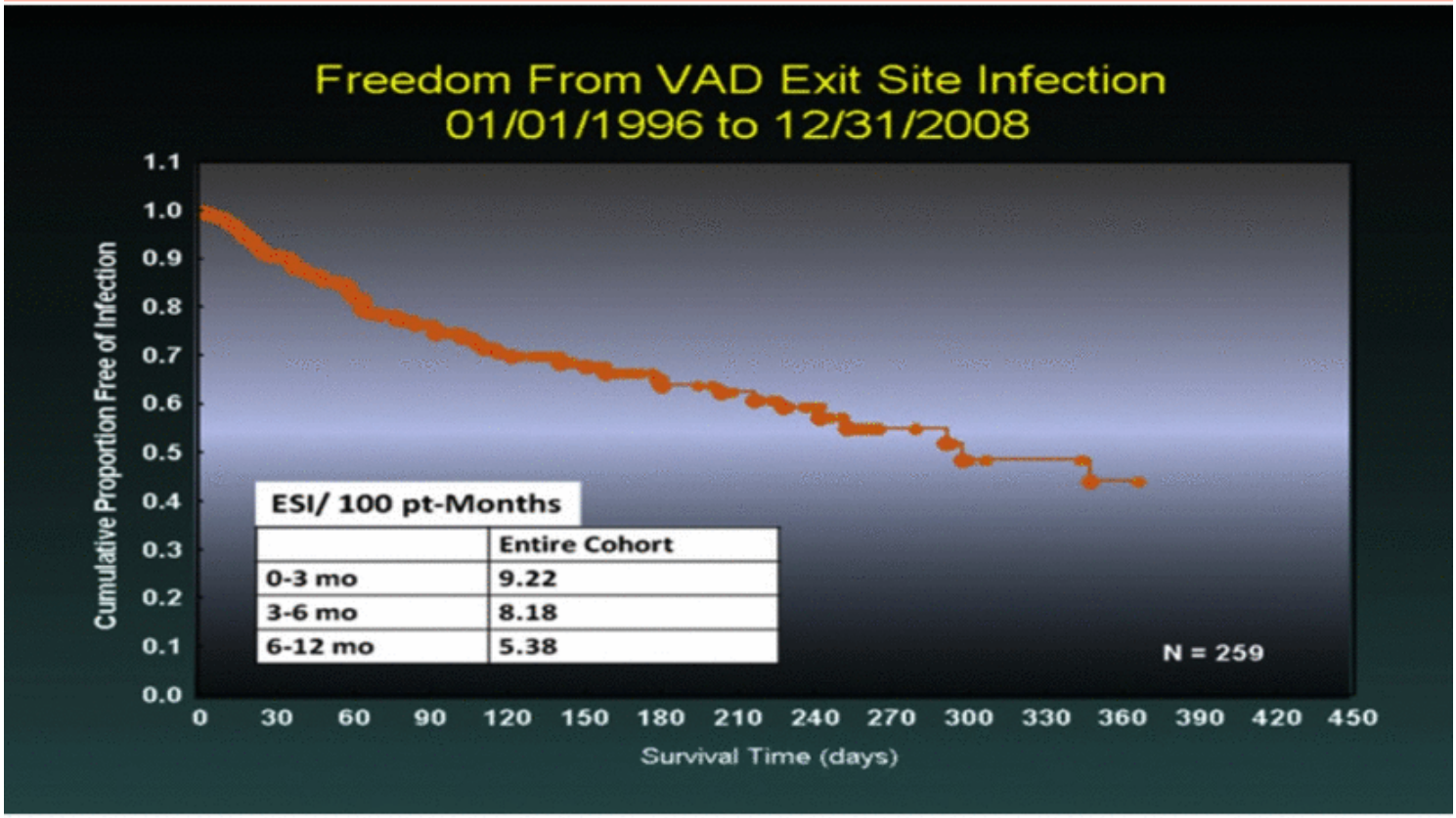


C-Pulse II Overview:

C-Pulse II - Fully Implantable System

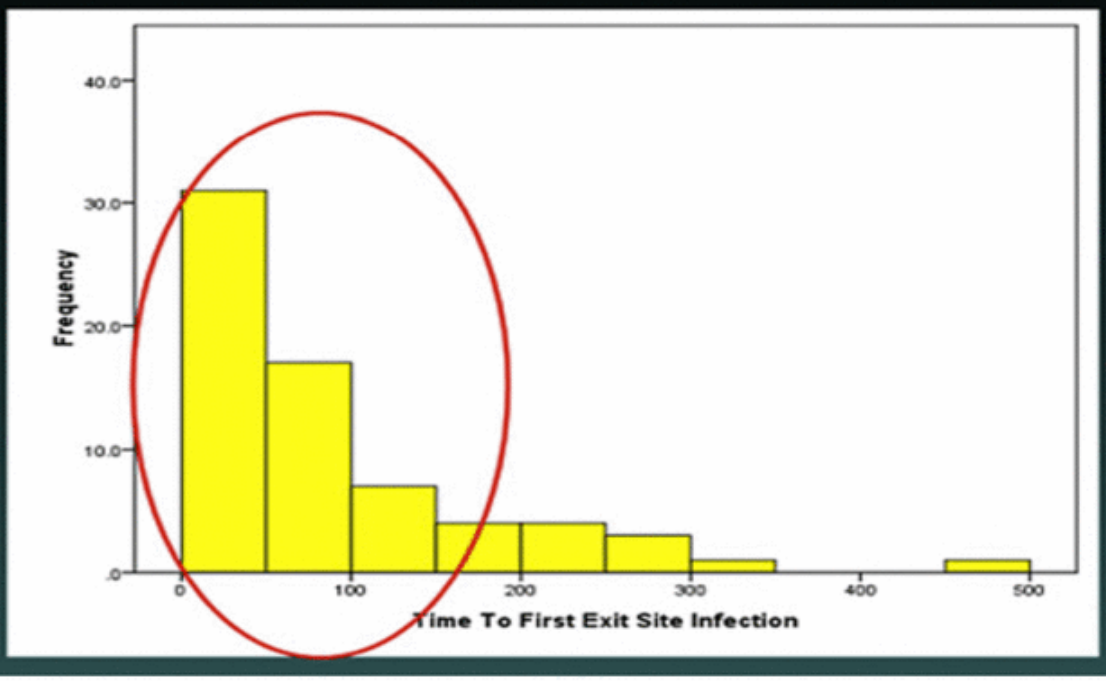
Internal electro-hydraulic converter and TETS eliminate the percutaneous drive line and associated infection risks.

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



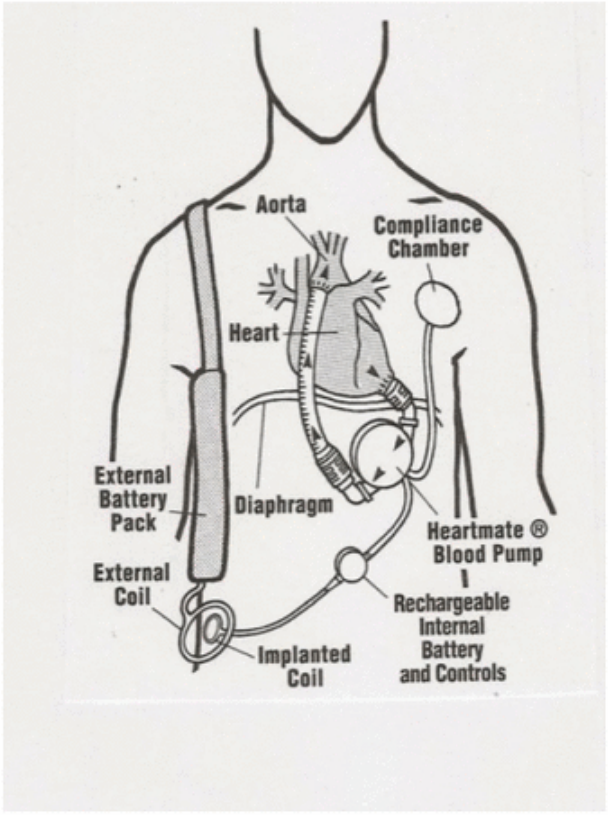
Pramod Bonde *et al.* Yale University

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



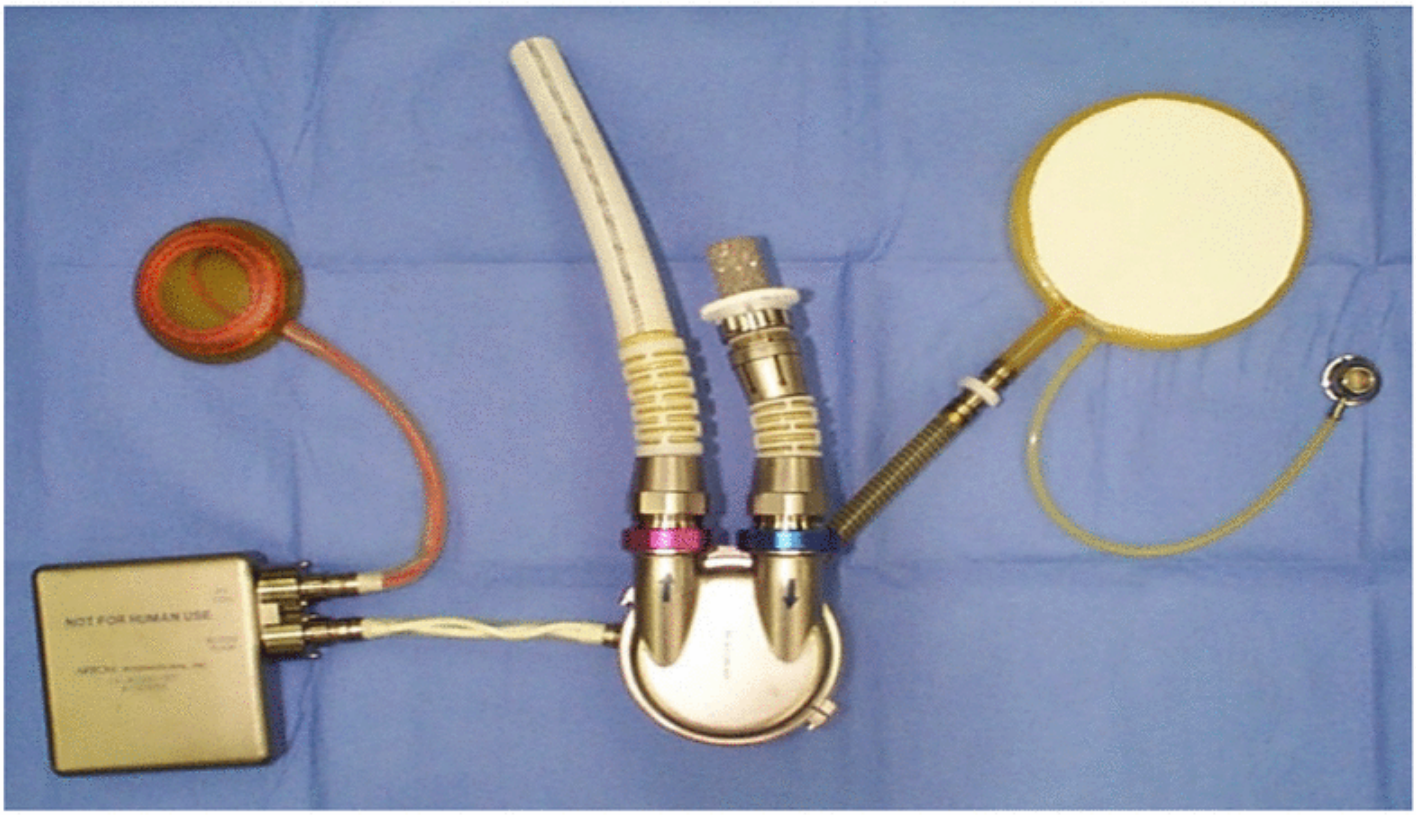
Pramod Bonde *et al.* Yale University

Eliminating the driveline is *not* a new idea…

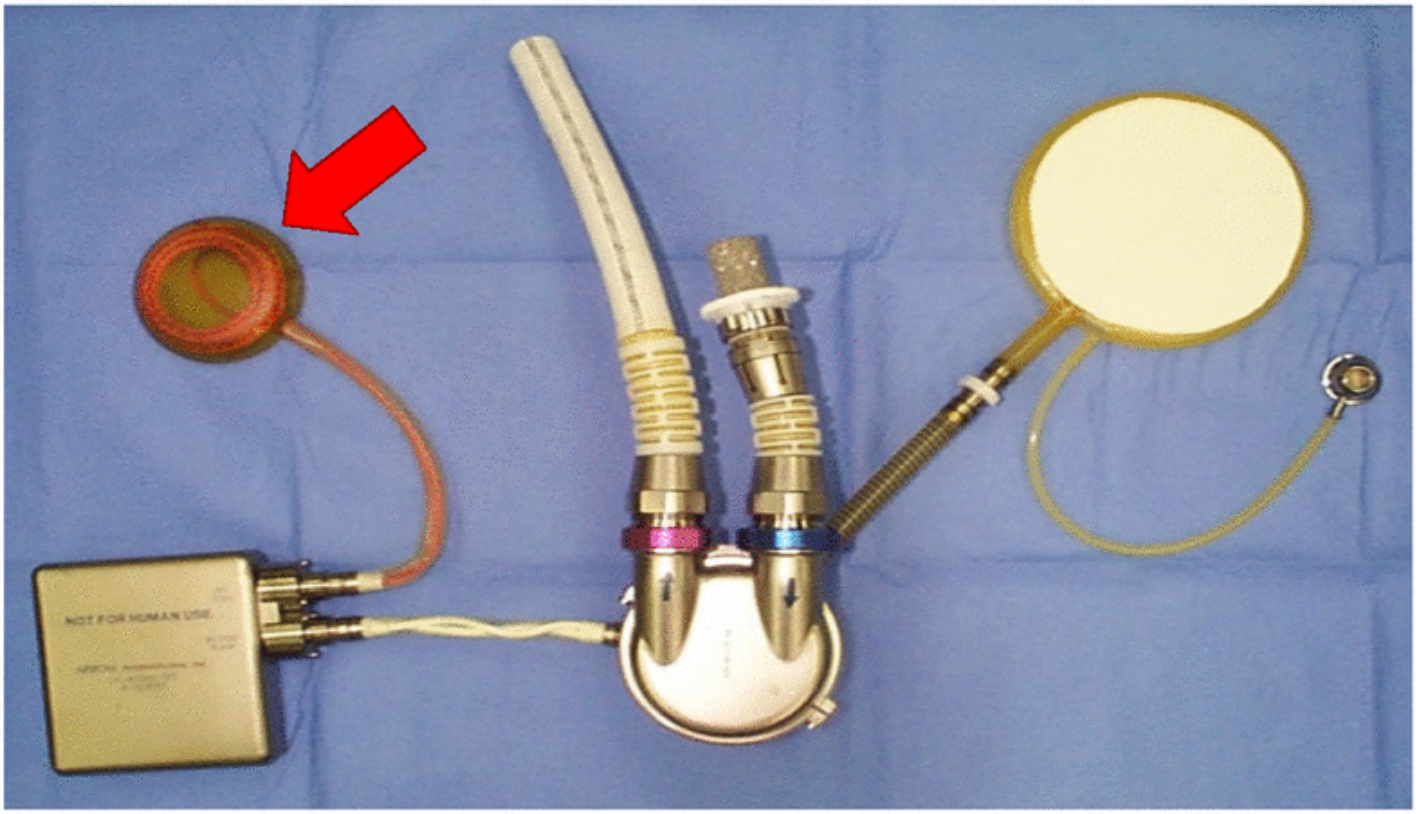


Circa 1985

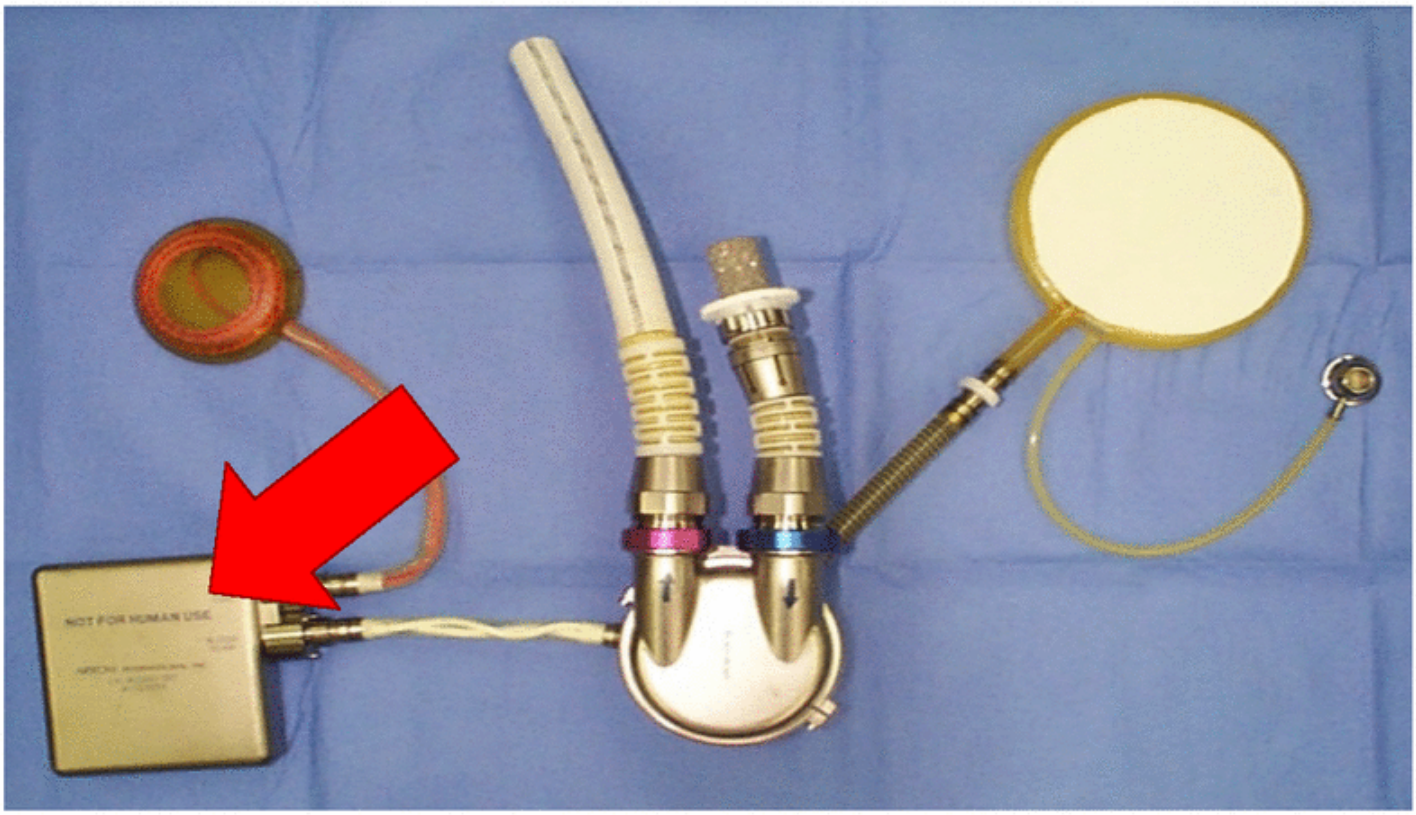
Arrow LionHeart LVAD



Arrow LionHeart LVAD



Arrow LionHeart LVAD



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

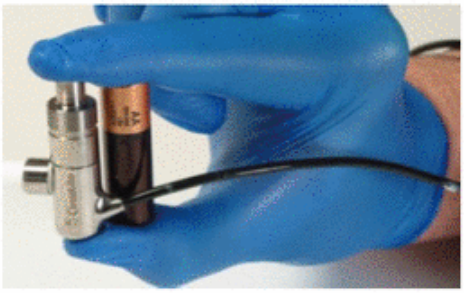
Penn State Arrow Lionheart

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

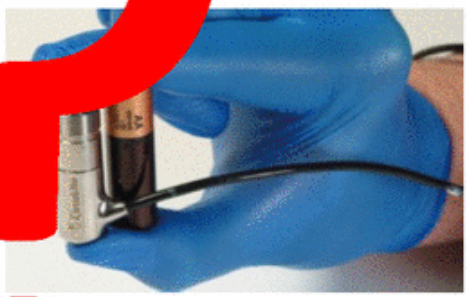
Where will clinical implementation of TETS technology first find traction?


HEART
Assist 5



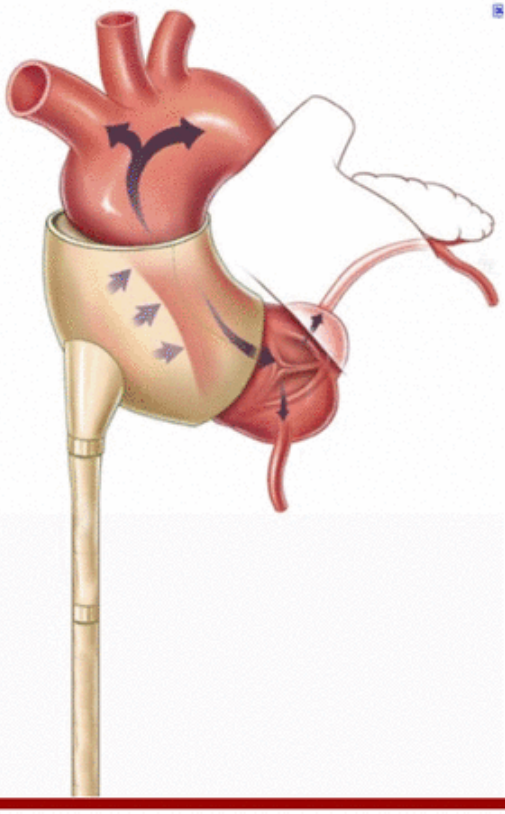

Berlin Heart


HEART
Assist 5

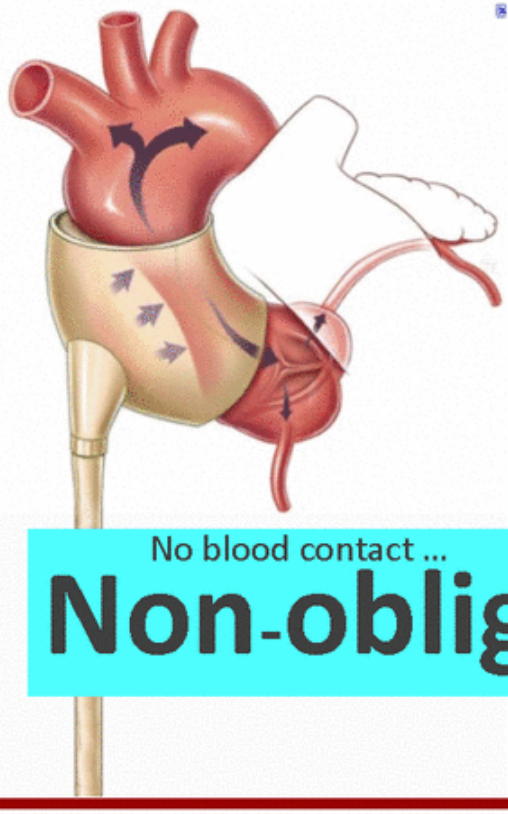


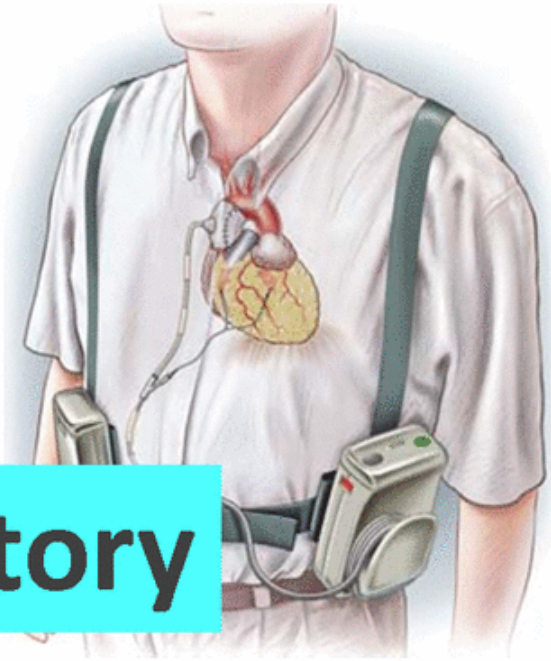

Berlin Heart

SUNSHINE HEART C-pulse extra-aortic balloon cuff



SUNSHINE HEART C-pulse extra-aortic balloon cuff

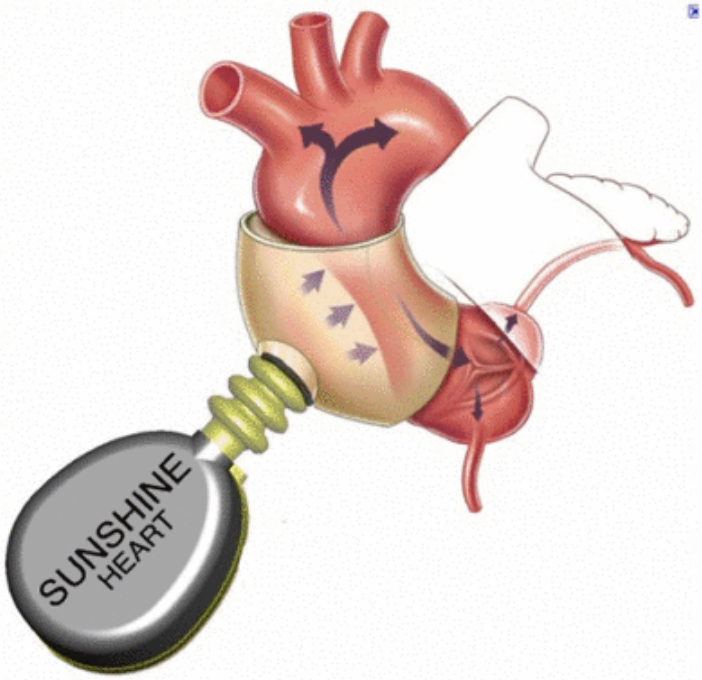


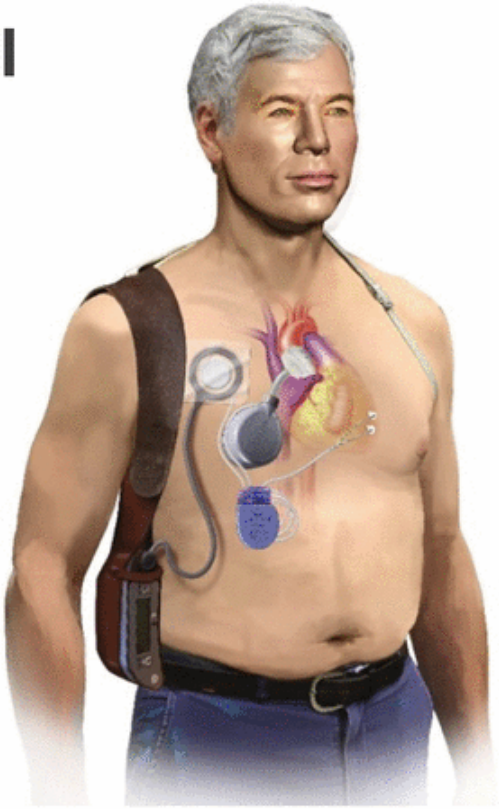


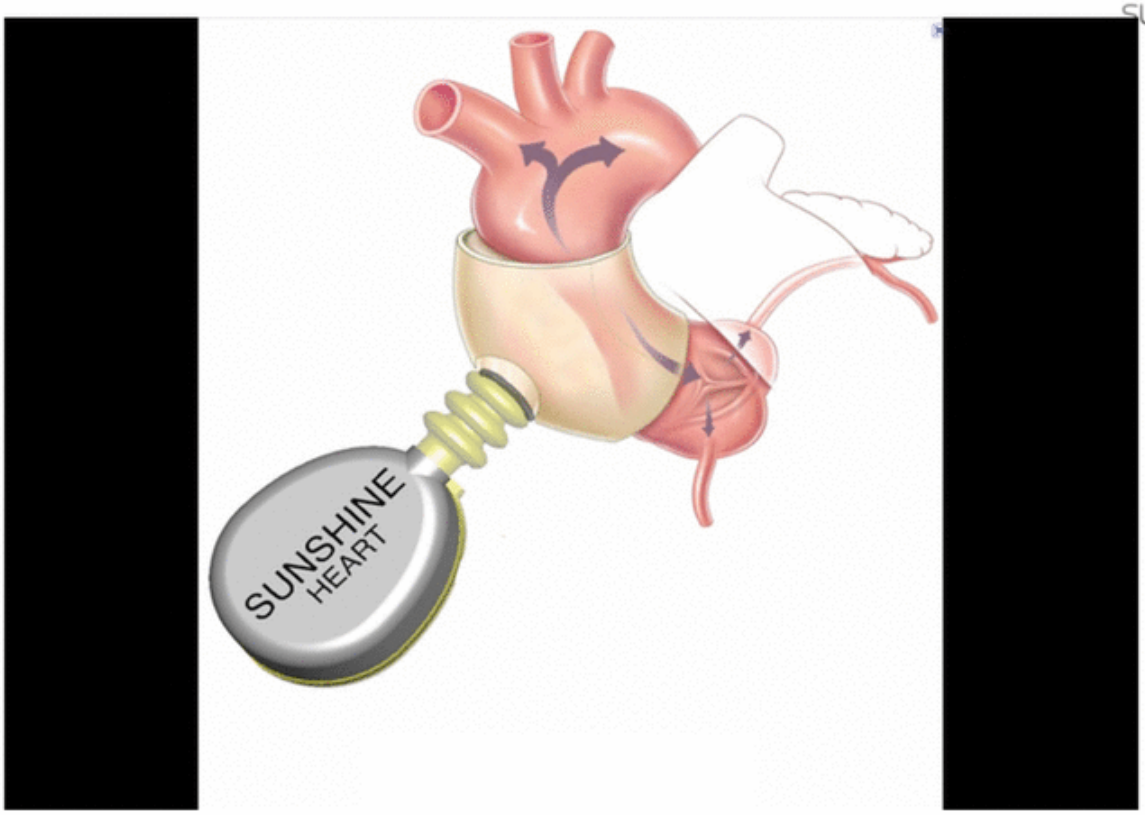
No blood contact ...

Non-obligatory

SUNSHINE HEART C-pulse II

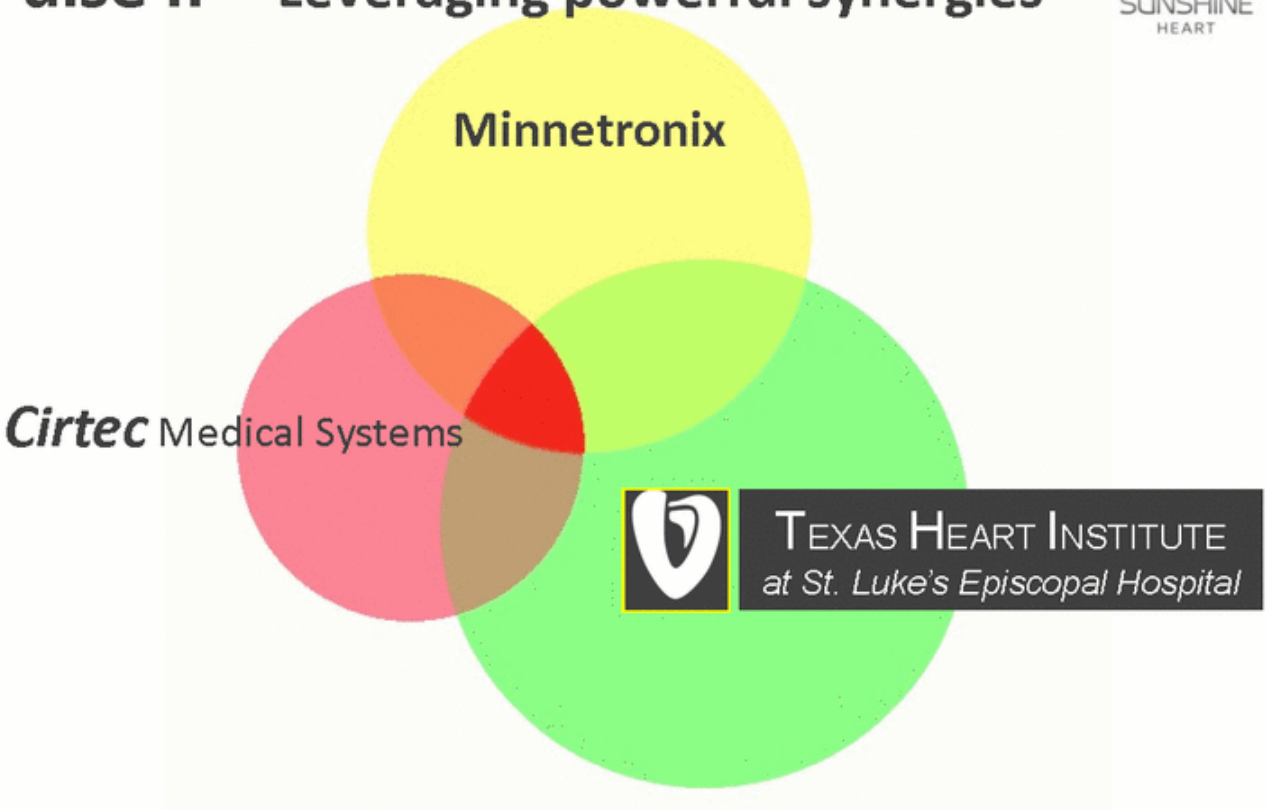





SUNSHINE
HEART

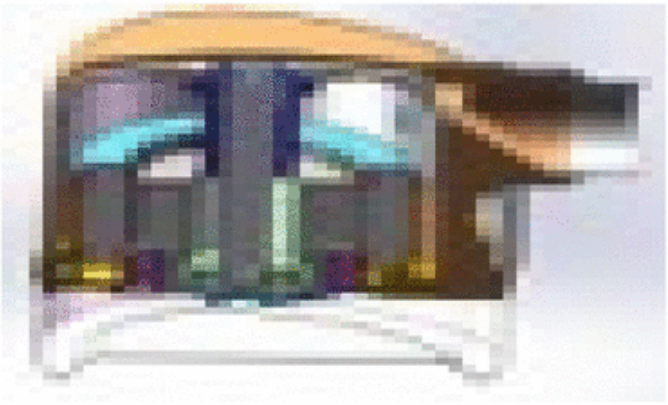
Electrohydraulic pump…

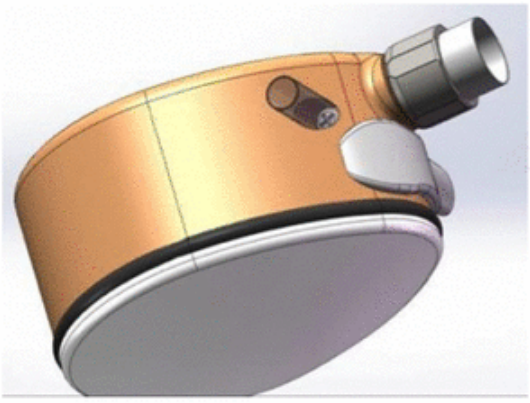
C-Pulse II – Leveraging powerful synergies



Electrohydraulic pump- *Cirtec* Medical Systems

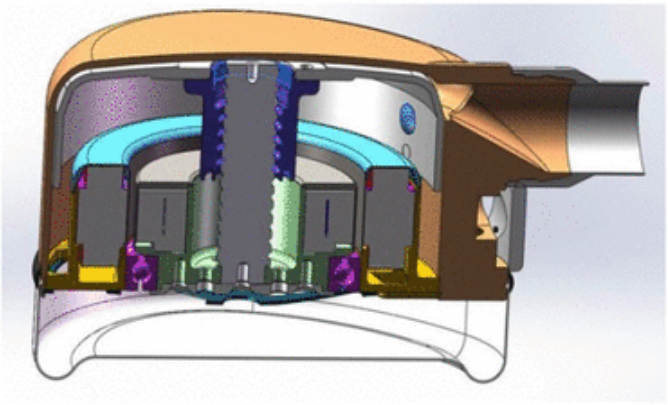
- Rapidly inflates and deflates extra-aortic balloon cuff (reproduces C-I physiology)
- EKG synchronized to provide counter-pulsation
- Balloon passively empties in the event of pump or power failure (essential)
- Leverages the incompressibility of silicone oil
- Compliance reservoir incorporated into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

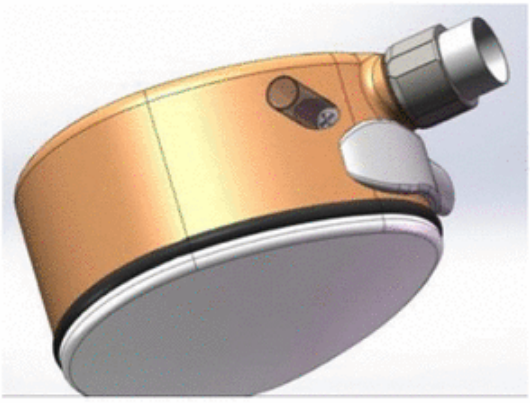




Electrohydraulic pump- *Cirtec* Medical Systems

- Rapidly inflates and deflates 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





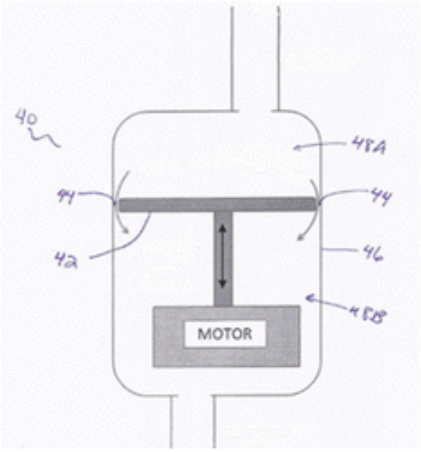
C-Pulse II – Important IP progress

SUNSHINE HEART

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.



C-Pulse II – Important IP progress

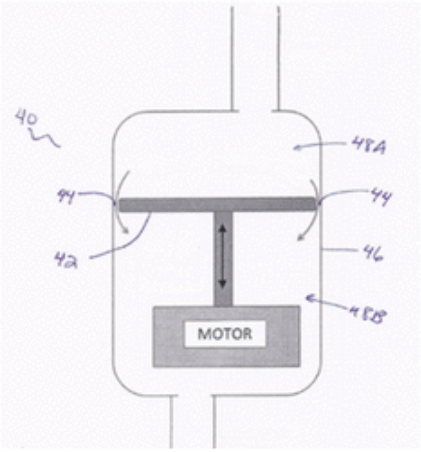
SUNSHINE HEART

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.

So no need for an implantable battery



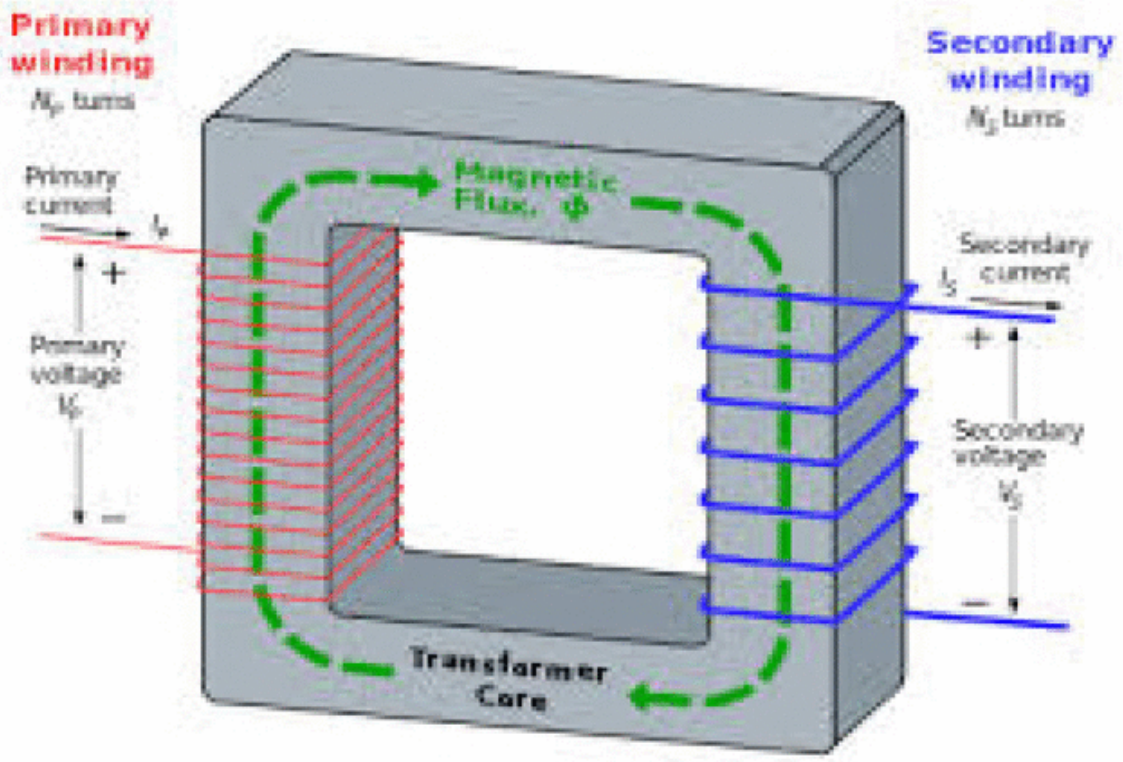
How are we going to power it?

Trans-cutaneous Energy Transfer System (TETS)

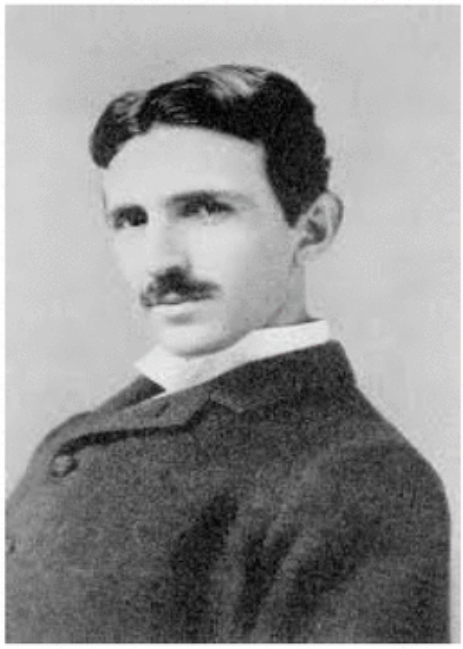
- DC battery pack outside the body
- DC current is put through an oscillator to make AC
- AC current energizes external coil (1°) to generate an oscillating magnetic field
- Oscillating magnetic field goes through the skin
- Oscillating magnetic field is picked up by a tuned internal coil (2°) resulting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

Standard transformer

Inductive coupling through an air-gap



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
- Newer iterations avoid previous challenges associated with thermal injury to the skin

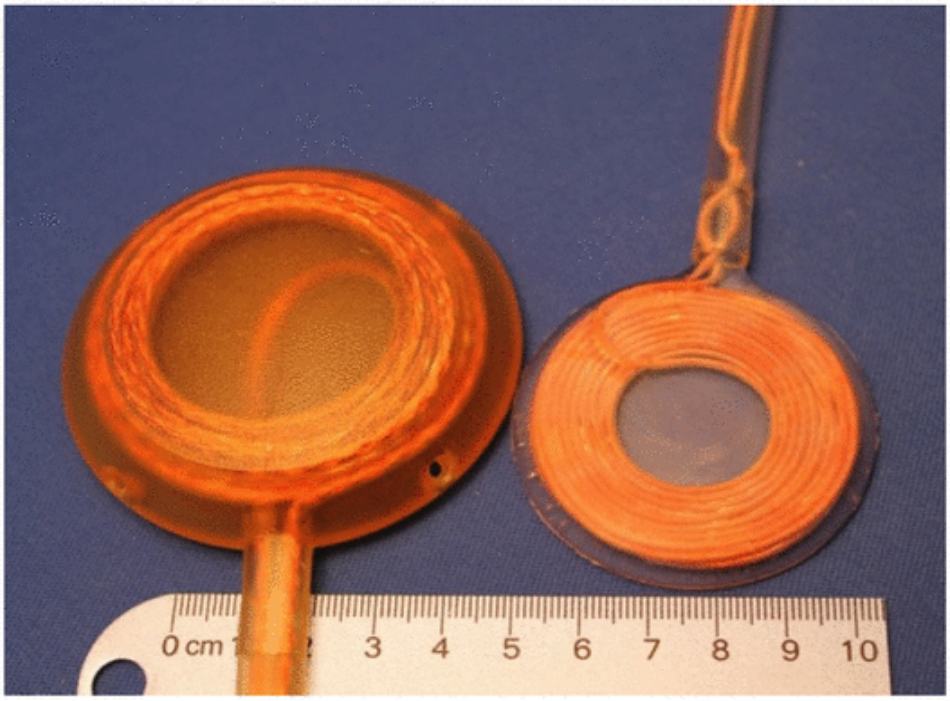
Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

Minnetronix

SUNSHINE HEART

Improvement in TETS component geometry and function




SUNSHINE
HEART
SUNSHINE
HEART
Where are we going to test it?


TEXAS HEART INSTITUTE
at St. Luke's Episcopal Hospital

THI Cardiovascular Research Lab ICU

nonclinical and preclinical safety testing are required by the global regulations prior to human trials

Surgical Implant and system integration

- THI's Cardiovascular Research Lab
- One of the premiere large animal cardiovascular research lab in the world
- Domain dominance in development and implementation of heart failure technology
- Successful acute system implantation (first generation)

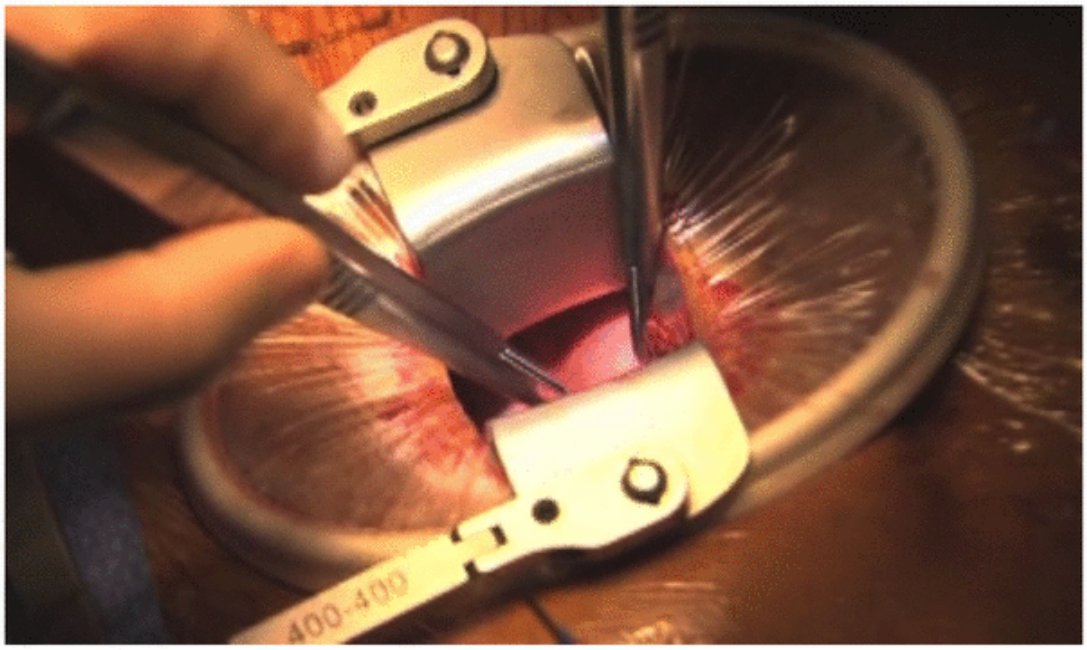
Minimally Invasive Implantation

SUNSHINE HEART

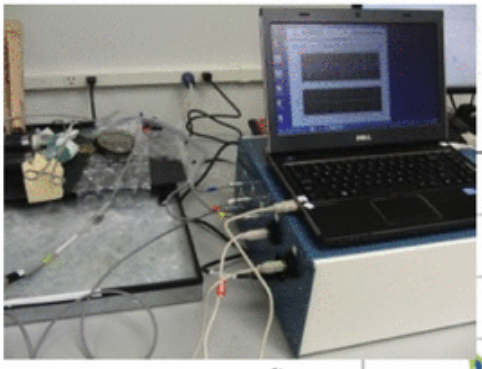
Small incision

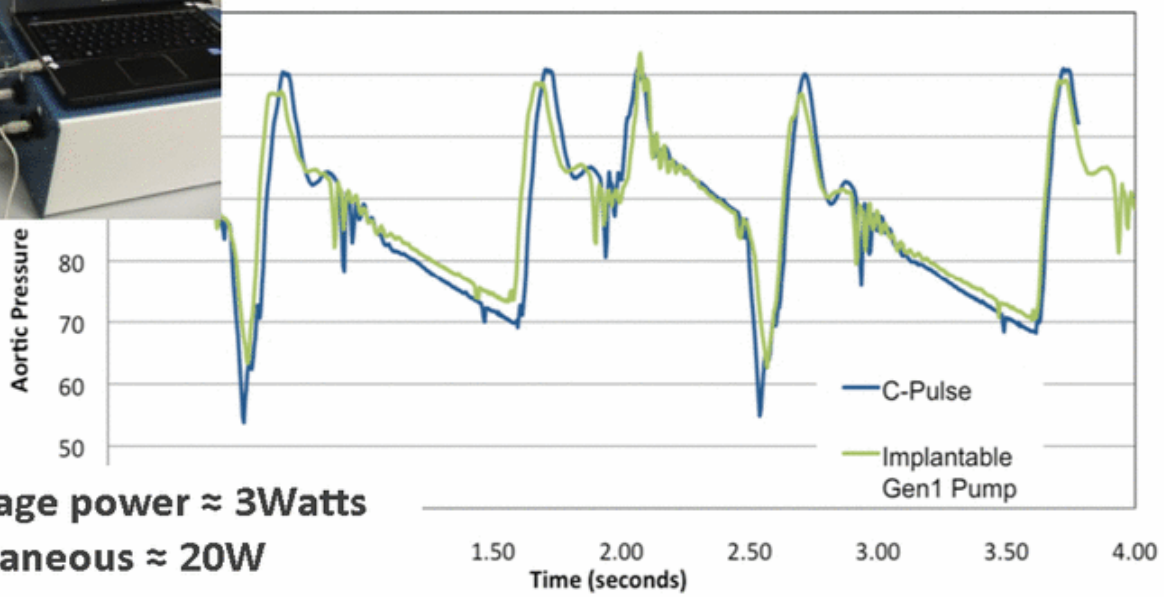
Sternal-sparing

No cardiopulmonary bypass



Recent Progress -Bench-Top Tests, CPII versus CPI





Typical Average power ≈ 3Watts

Peak Instantaneous ≈ 20W

Recent Acute animals (x2)

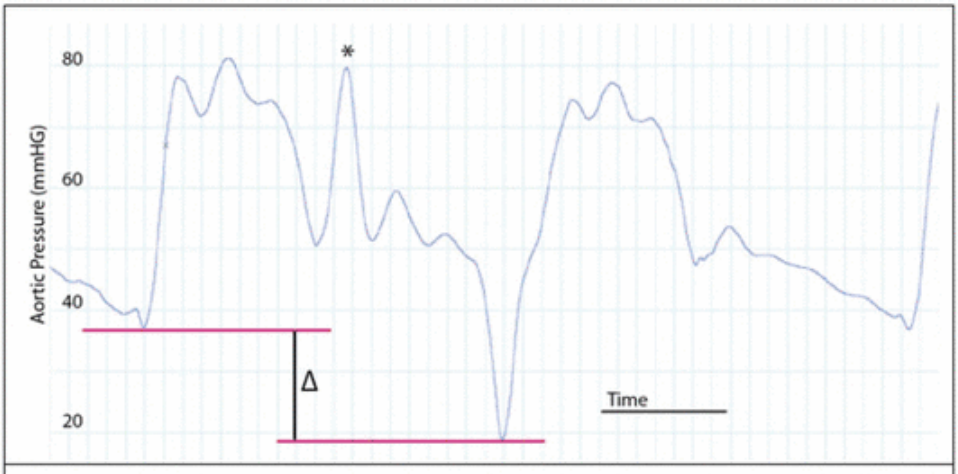
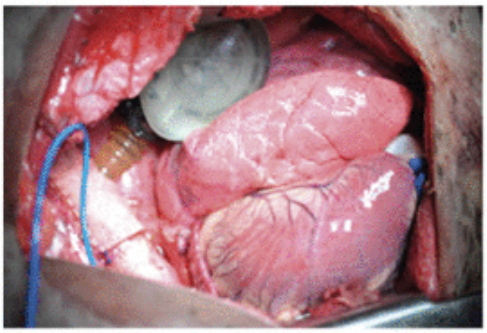
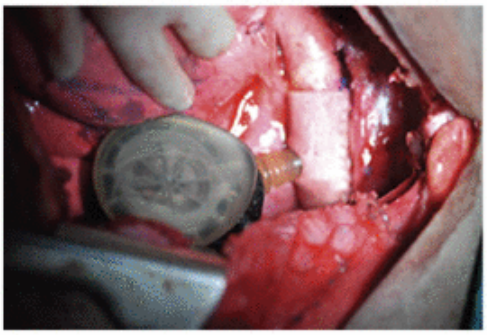
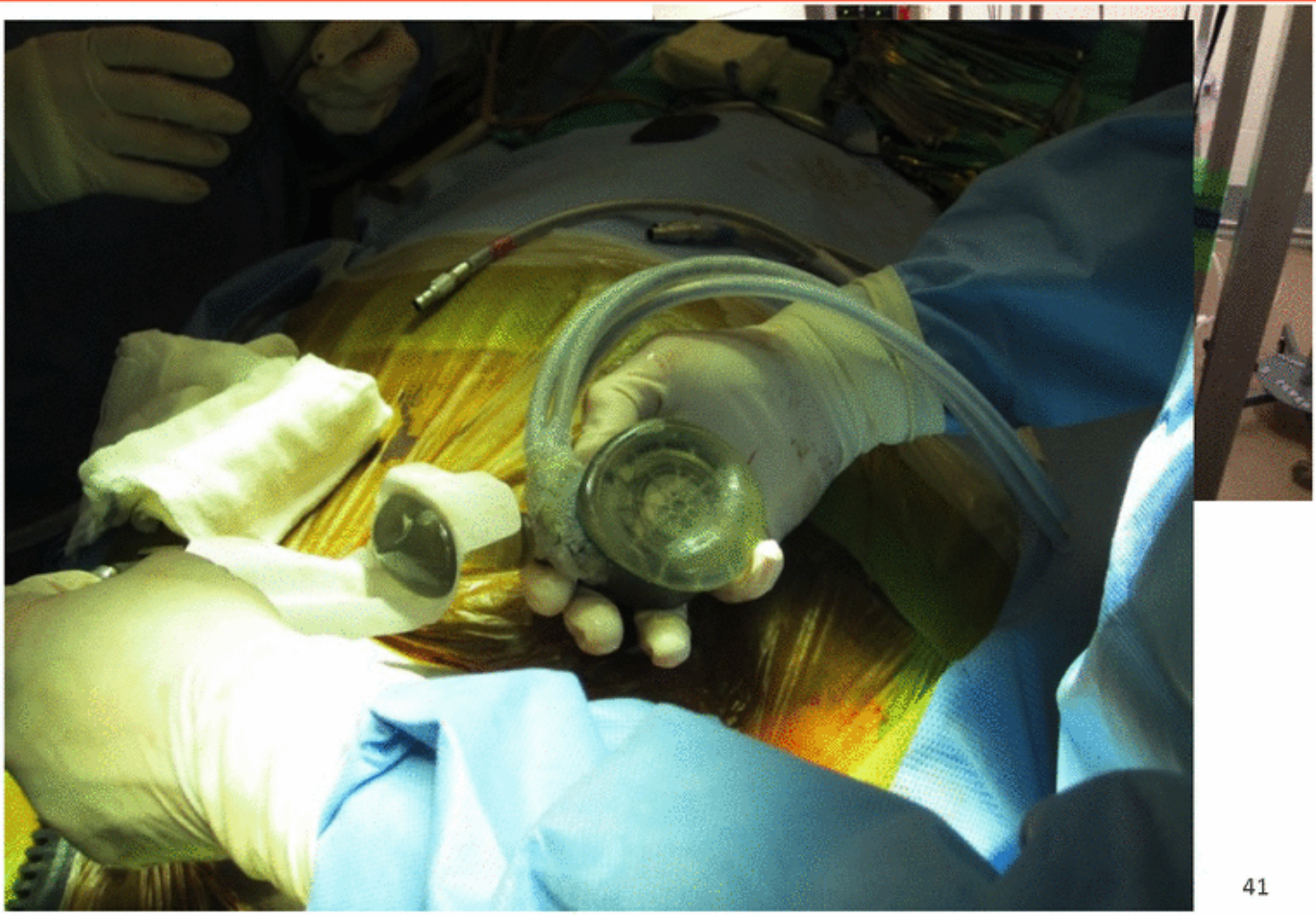
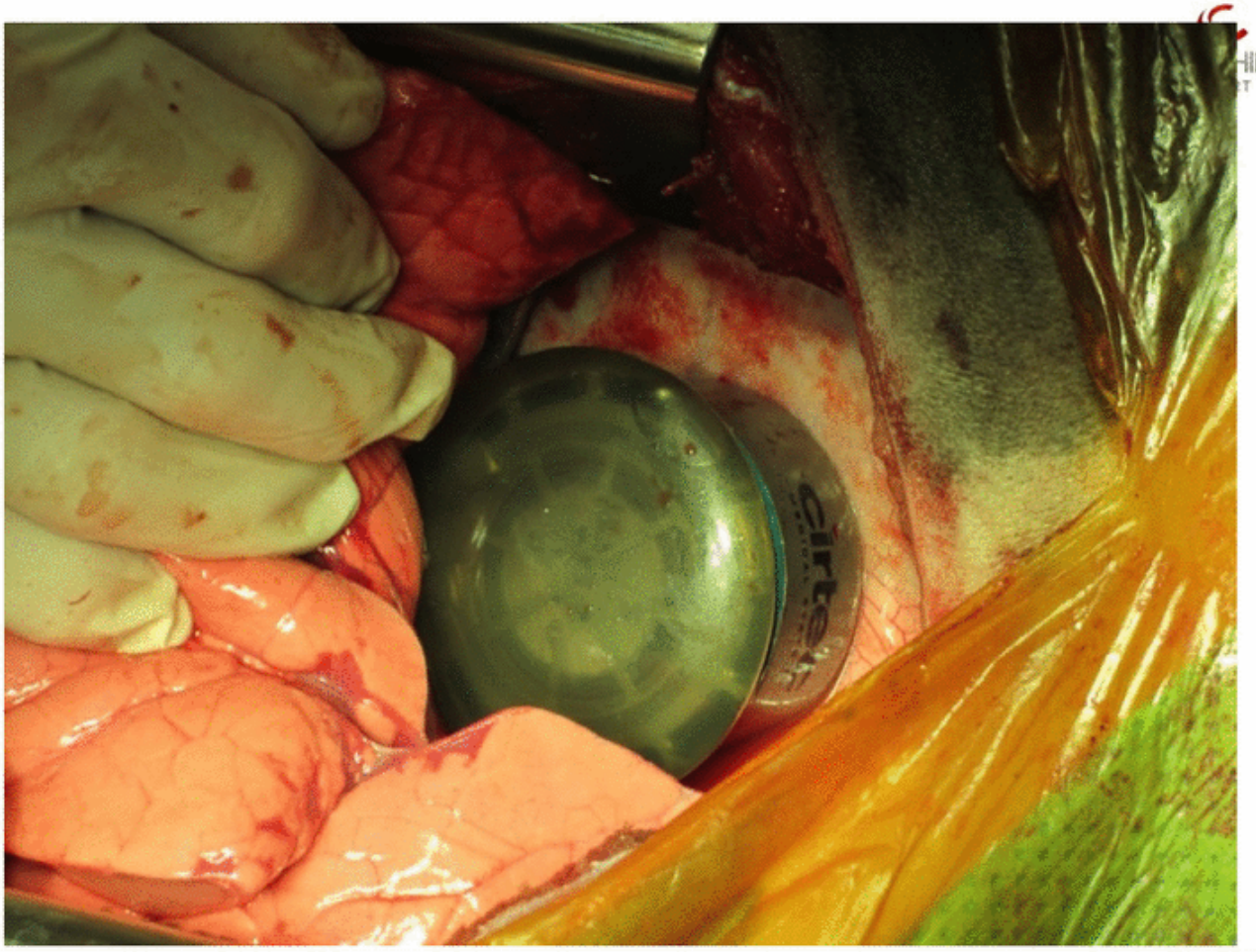


Figure 11. Hemodynamic performance of the CP2-Gen1 assembly operating in 1:2 mode during an acute bovine trial. Trace shows clear diastolic augmentation (*) and subsequent reduction in end diastolic pressure (Δ) of >15mmHg compared to the adjacent non-counterpulsated cycle.





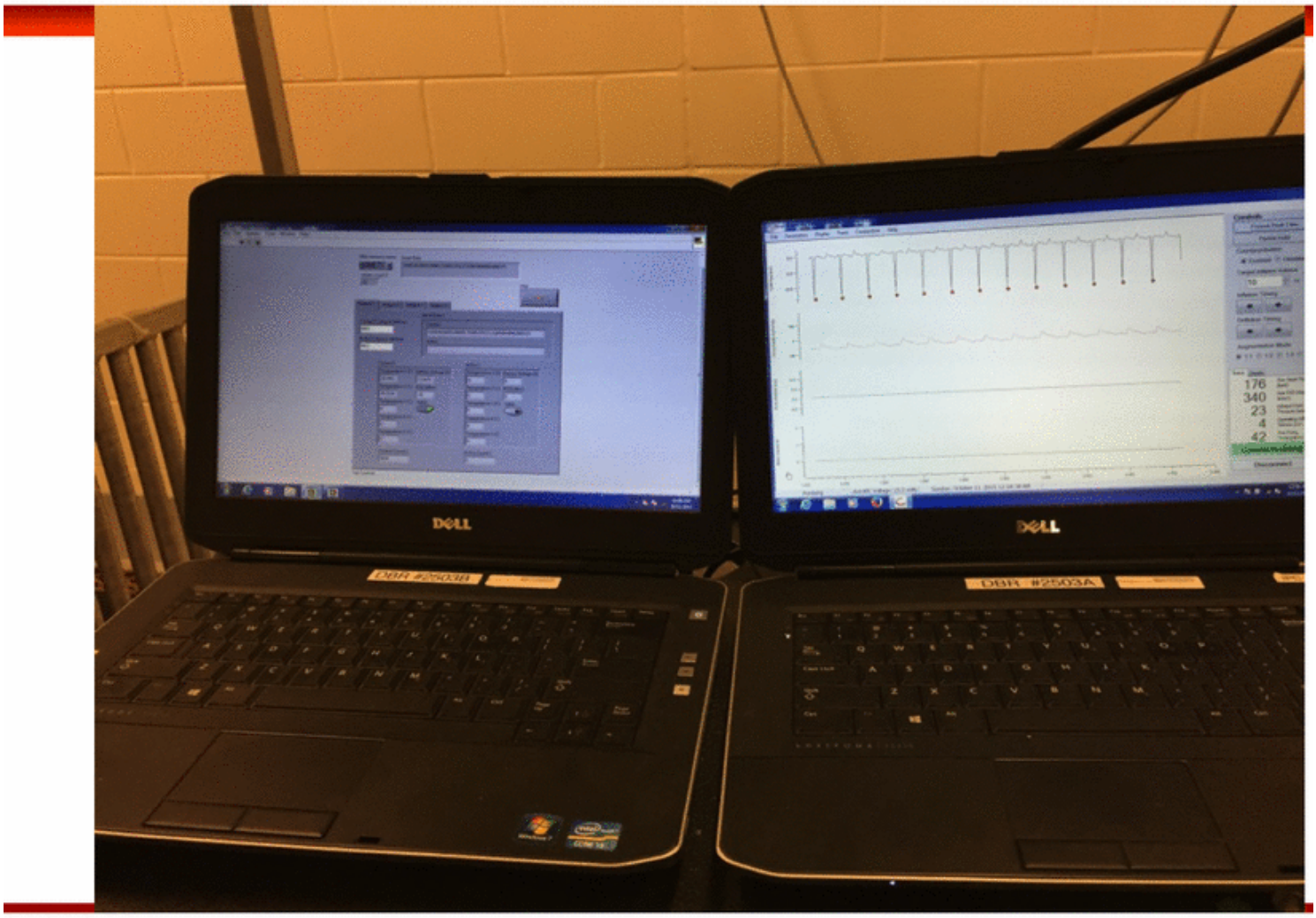





"But still try for who knows what is possible!"
Michael Faraday
FARADAY
B-1962


B-1950
EINSTEIN


B-1950
EINSTEIN
4


DELL
DELL

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 preclinical testing suggests the design is performing as intended and within established safety parameters