C-Pulse® System

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

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

Disclosures

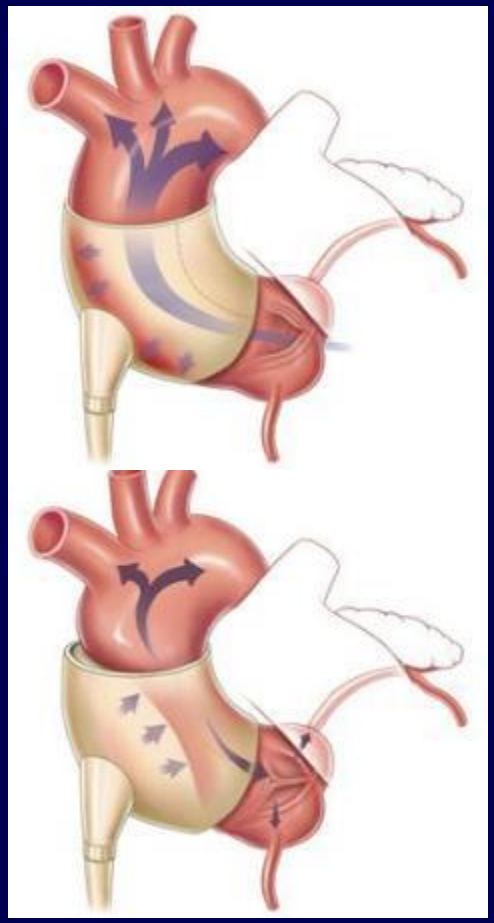
- No financial disclosures

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
- Preliminary indications of 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 Subjects (N=20)
Incision to Dressing Time (mins)	165.7 42.4 (19) 156.0 [98.0, 247.0]
Anatomical Approach	
Full Sternotomy	70.0% (14/20)
Right Anterior Thoracotomy	0% (0/20)
Partial Sternotomy	10.0% (2/20)
Left Anterior Thoracotomy	0% (0/20)
Transverse Sternotomy	0% (0/20)
Posterolateral Thoracotomy	0% (0/20)
Right Parasternal	20.0% (4/20)
Intermediate (PIL connect)	0% (0/20)
Left Parasternal	0% (0/20)
ECG Sensing Lead Location	
Epicardial RVOT	20.0% (4/20)
Epicardial Left Ventricle	75.0% (15/20)
Other	5.0% (1/20)
Time in ICU (days)	2.2 2.6 (19) 1.1 [0.6, 11.1]
Time in Hospital (days)	12.4 11.9 (20) 8.5 [4.0, 60.0]

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

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

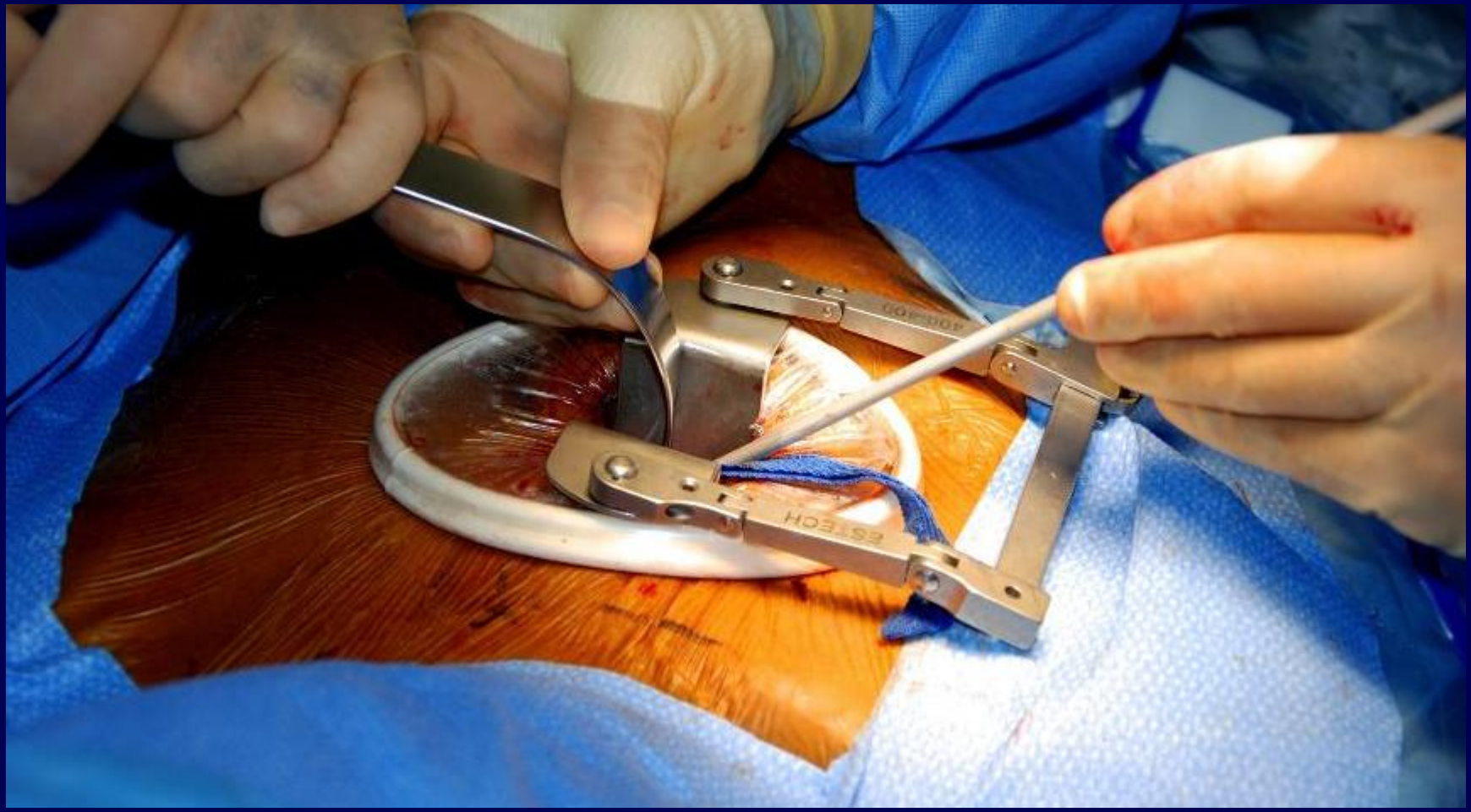
- Death
  - 0 at 30 days
  - 1 at 6 months
- Aortic Disruption
  - 1 at 137 days post implant
    - Sternal wound infection (mediastinitis) post surgery
    - CEC adjudicated as major infection, localized, procedure related
    - Infection unresolved despite repeated surgical interventions
    - Aortic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

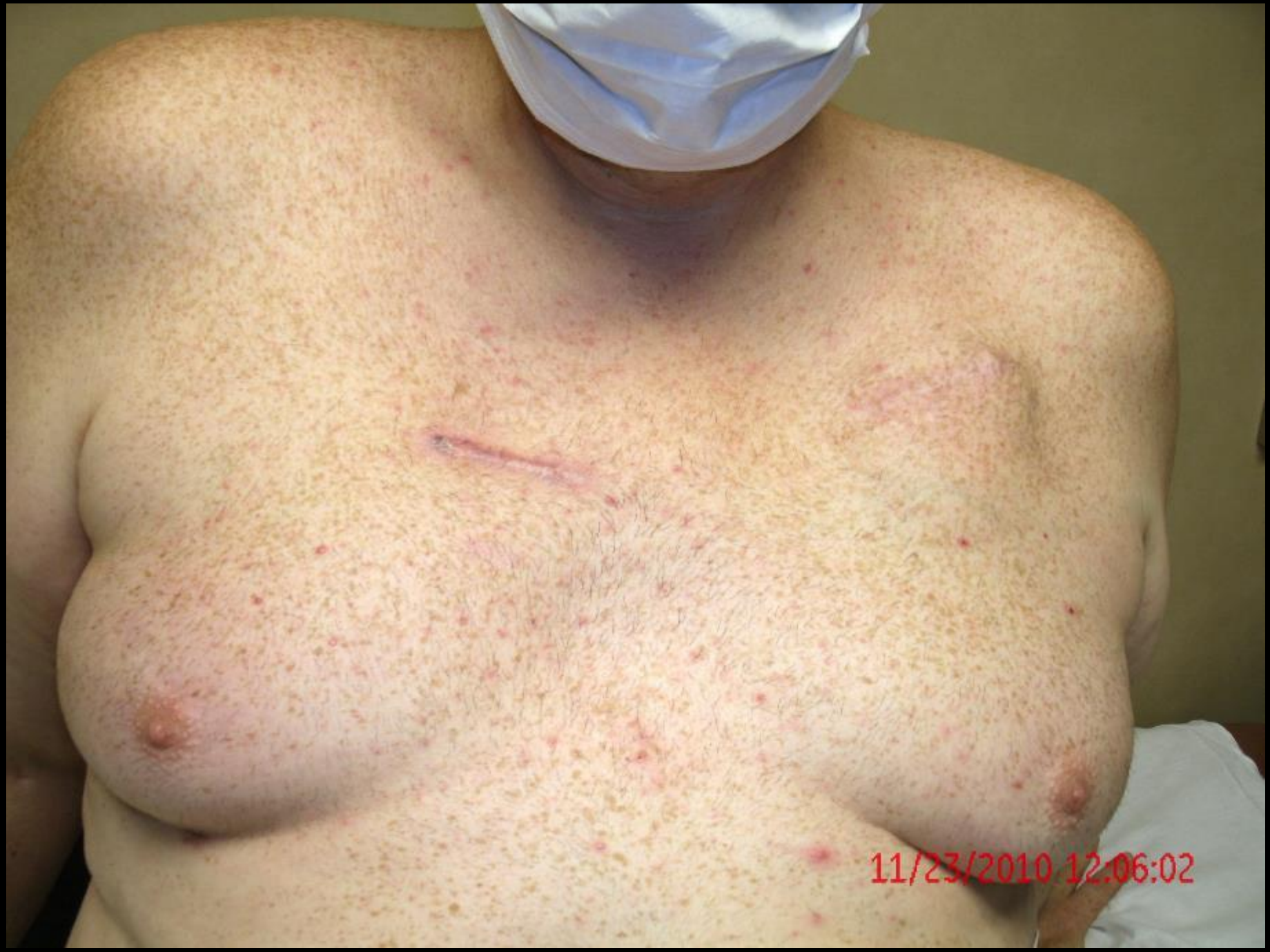
Worsening HF Hospitalizations

- 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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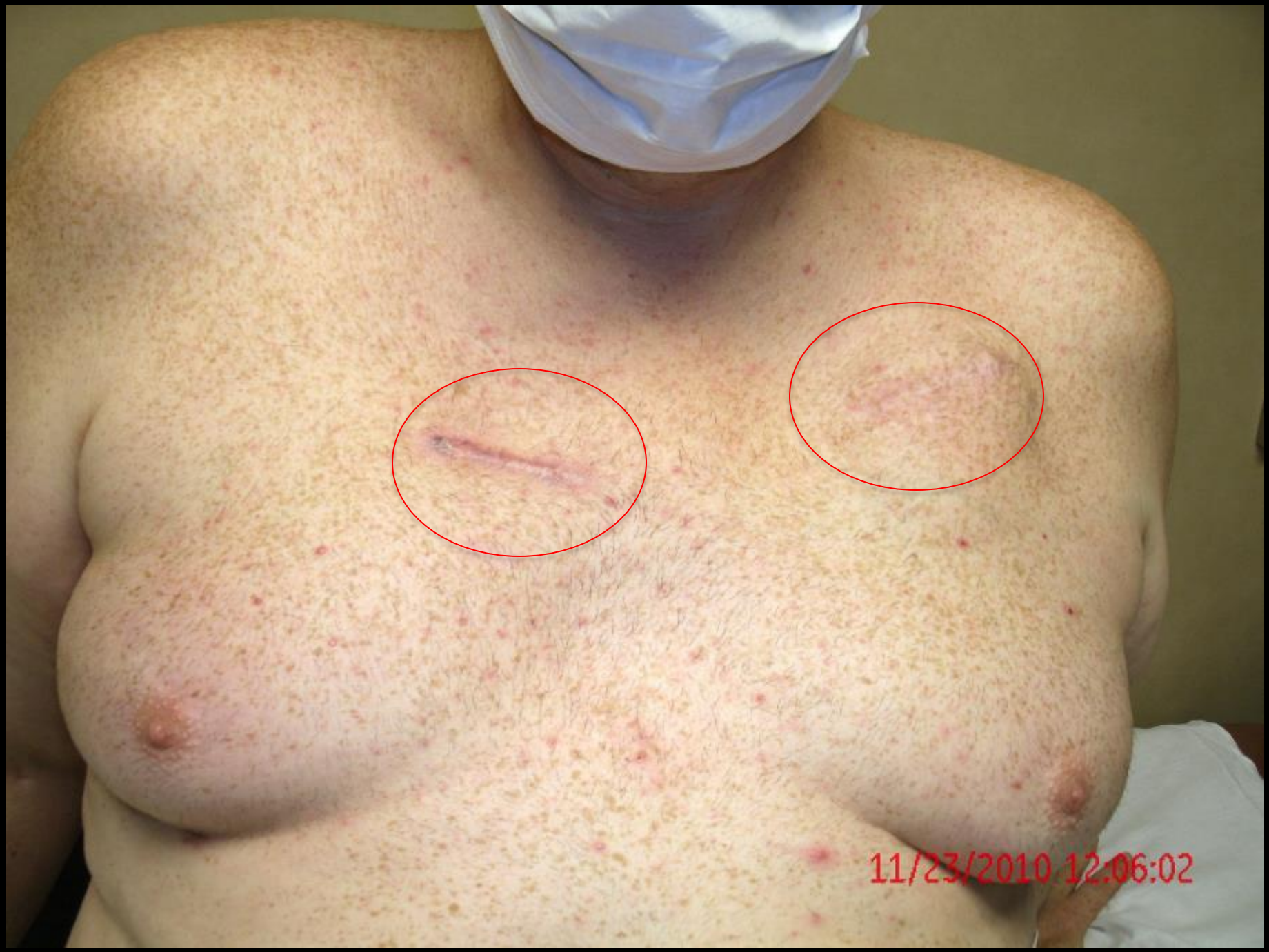
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Additional Observations

- 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

*Results from single center experience-Saint Luke's Mid America Heart Institute

Myocardial Recovery

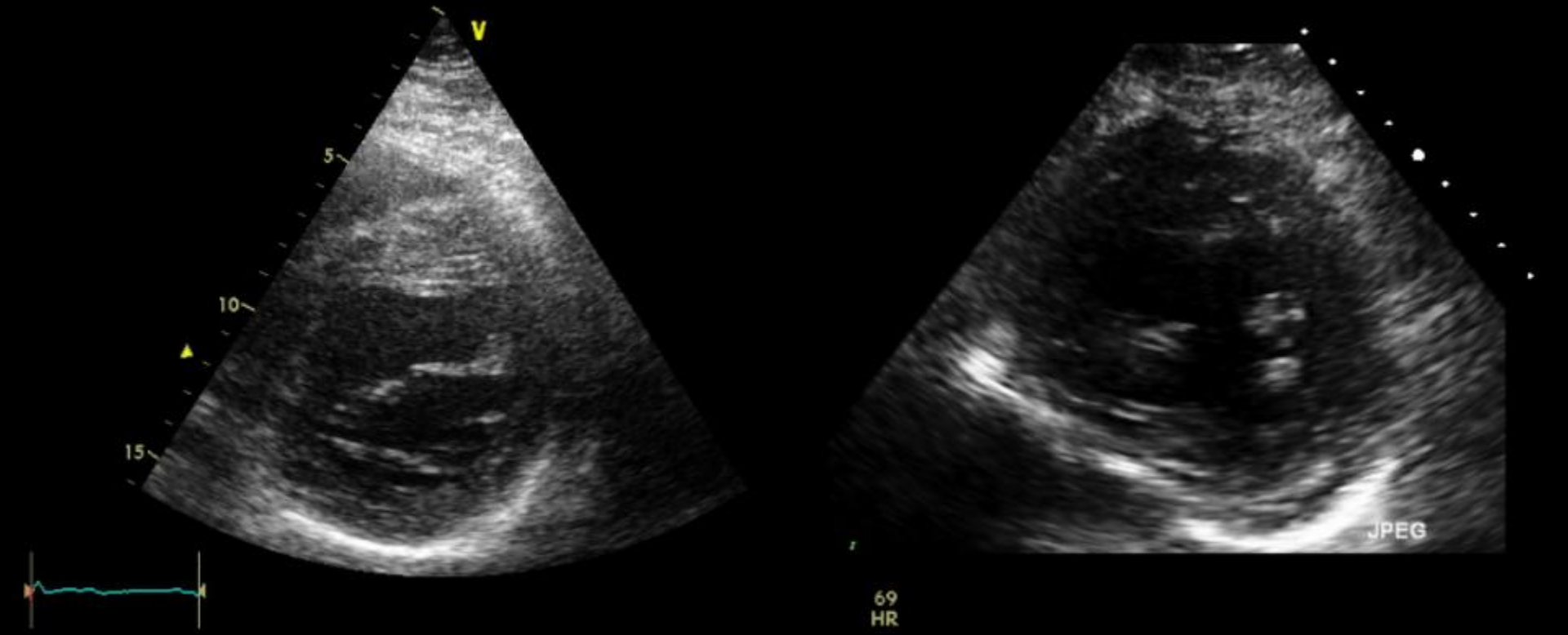
- Mean duration of support with C-Pulse was 659 days (range 534 – 793 days)
- Mean EF improved from 18.3% to 29.3% (one patient EF has improved from 21% to greater than 40%)
- Mean reduction in LVEDD of 1.1cm
- No readmissions for heart failure (follow up time range approximately 1-2.5 years)

*Results from single center experience-Saint Luke's Mid America Heart

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)

*Results from single center experience-Saint Luke's Mid America Heart


V
5
10
15
JPEG
69
HR

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

*Results from single center experience-Saint Luke's Mid America Heart

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

*Results from single center experience-Saint Luke's Mid America Heart