



The Paracor HeartNet™ Ventricular Elastic Support Therapy Feasibility Study: Two Year Follow Up



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Introduction: The HeartNet System (Paracor Medical, Inc, Sunnyvale CA) is a nitinol mesh device designed to improve clinical outcomes in patients with symptomatic heart failure (HF) and LV systolic dysfunction. The device is implanted via mini-thoracotomy using a custom designed delivery system and provides gentle elastic restraint throughout the cardiac cycle to reduce wall stress and to induce reverse myocardial remodeling.

Methods: Pts with EF <= 35% and Class II/III HF on conventional medical and device therapy exhibiting progression of disease were enrolled. Pts with severe MR, coronary artery bypass grafts or recent cardiac procedure or event were excluded.

Results: Successful implantation was accomplished in 51/52 patients. Two year results:

	Baseline	Change at 24 Months
Age (yrs) #	52	
Male (%) #	92	
Nonischemic (%) #	79	
Biventricular pacing (%) #	37	
EF (%) n=28	24±6.1	0.5±0.9
LVEDD (cm) n=29	7±1	-0.8±0.8*
LVEDV (cm3) n=28	333±81	-33±59***
LVESD (cm) n=29	6±1	-0.5±0.9**
LVESV (cm3) n=28	257±75	-24±64
MR n=25	1.3±0.9	-0.4±0.9****
6 Minute Walk Test (m) n=28	384±96	34±82****
MLWHF n=22	55±19	-13±18***
NYHA (I/II/III/IV) n=33	0/18/34/0	7/16/9/1*

n=52; *p<.001** p < .005; ***p<.01; **** p < .05; Of the 27 patients with follow up data for PVO2, 30% improved at least 1 ml/kg/min. There were two perioperative deaths and three deaths of non cardiac cause in long term follow up. One patient had successful emergency reoperation for an avulsed phrenic artery and four patients had either LVAD, transplant or both.

Conclusions: Implantation of the HeartNet™ bears high success rates. Early data suggest improvement in clinical parameters and significant reverse remodeling for up to 2 years post implant. PEERLESS-HF, a randomized controlled trial of the HeartNet™ in the management of HF due to LV systolic dysfunction is underway.

Participating Institutions and Enrollment

Study Site	Investigator	Number of Enrolled Patients
University of Florida, Shands	Juan Aranda, MD	10
University of Alabama, Birmingham	Barry Rayburn, MD	9
Ohio State University	William Abraham, MD	3
Penn State Milton S. Hershey Medical Center	John Boehmer, MD	4
Johns Hopkins University	John Conte, MD	1
Bryan LGH Heart Institute	Steven Krueger, MD	4
Emory University School of Medicine	Andrew Smith, MD	1
The Methodist Hospital, Houston	Guillermo Torre, MD	1
Minnesota Veterans Research Institute	Inder Anand, MD	2
University of Colorado Health Sciences Center	Brian Lowes, MD	2
Saint Luke's Hospital Mid America Heart Institute, Kansas City	Andrew Kao, MD	1
University of Maryland Medical Center	Shaun Robinson, MD	1
Bad Neudstadt/Klinikum Coburg	Prof. Dr. Johannes Brachmann	1
Medizinische Hochschule Hannover	Prof. Dr. Axel Haverich	2
University Hospital Magdeburg	Prof. Dr. Helmut Klein	10
Total		52

Disclosures

This study was sponsored by Paracor Medical, Inc, Sunnyvale, CA. Drs. Rayburn, Aranda, Anand and Abraham are consultants for Paracor Medical, Inc.

Background

Despite optimal evidence-based medical and device therapy, many heart failure patients continue to exhibit significant symptoms, progressive adverse remodeling and clinical deterioration. Thus, morbidity and mortality remain high despite "best" current therapy.

A potential option for additional therapy in such patients is elastic ventricular restraint which provides for a small inward positive force on the ventricular wall, thus altering transmural forces in a manner that favors reverse remodeling. Prior animal and clinical studies have demonstrated improvements in ventricular size and mass as well as improvement in patient symptoms. The HeartNet™ device provides such elastic restraint in a less invasive fashion than a previously reported device. The safety and feasibility of this approach was demonstrated in two multicenter, single-arm prospective trials which have been previously reported. Here we report the two year efficacy data for a subset of patients with available data from these trials.

Methods

Device Characteristics

- Highly elastic, compliant nitinol mesh
- Defibrillation and pacing compatible
- Delivery via minithoracotomy (Figure 1)
- Self anchoring, self tensioning
- Pre sized based on echo measurements

Efficacy End Points

- 6 minute walk test
- MLWHF Score (US only)
- Oxygen consumption*
- NYHA Class
- Echo parameters of remodeling*

* Core laboratories

Patient Inclusion

- LVEF < 35%
- Persistent NYHA Class II/III symptoms despite optimal medical / device therapy for > 3 months
- Excluded if LVEDD > 85 mm, history of prior CV surgery or anticipated need for surgery

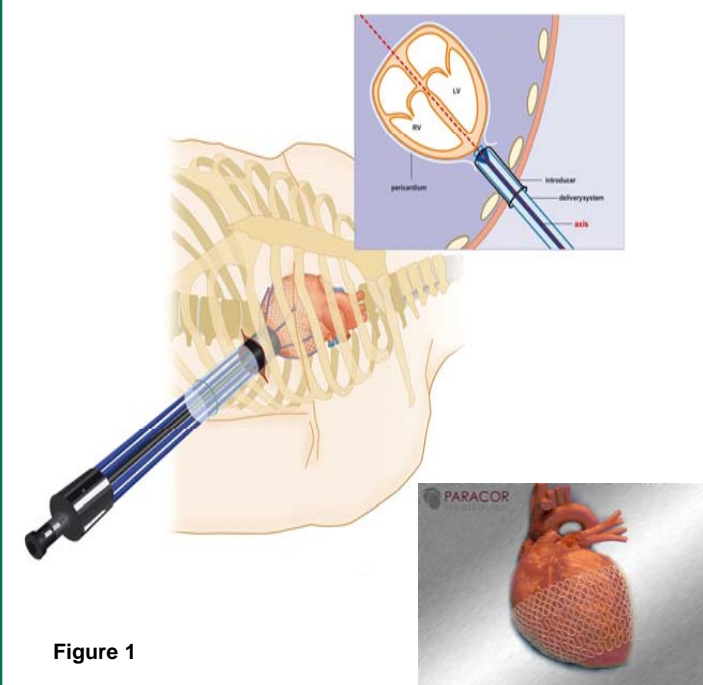


Figure 1

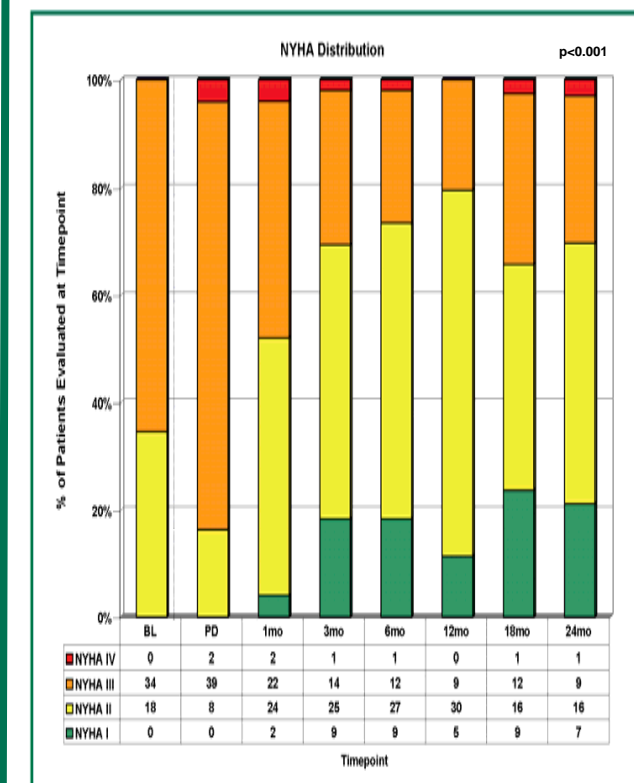
Results

Baseline Demographics (n=52)

Age	52.2 (30.4 – 72.6)
Sex (% Male)	94%
Race (% Caucasian)	92%
Etiology of HF (% Non-ischemic)	79%
Duration of HF (yrs)	6.2 (0.3 – 18.8)
ACE-I/ARB (%)	98%
Beta Blocker (%)	96%
CRT Therapy (%)	37%

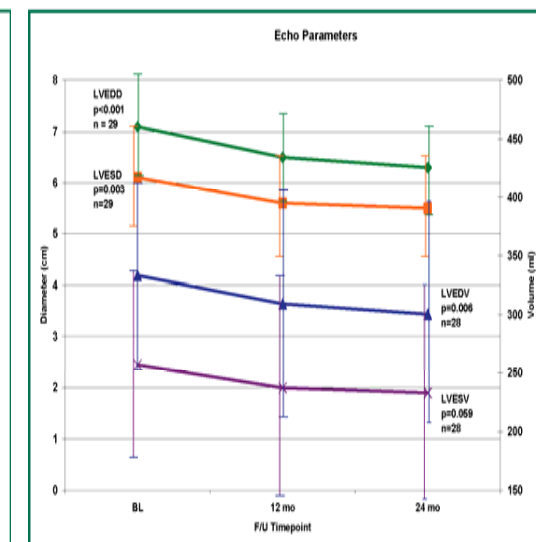
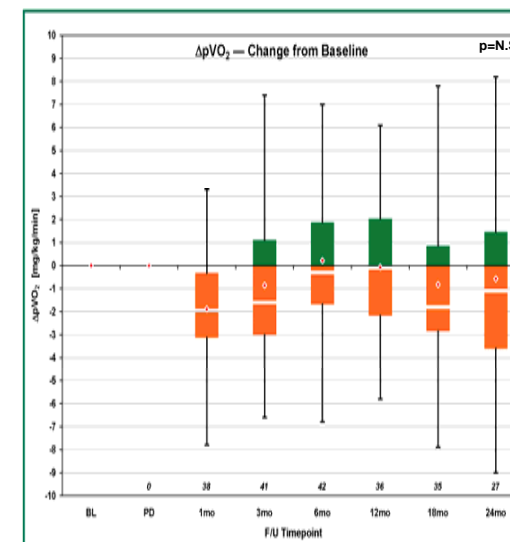
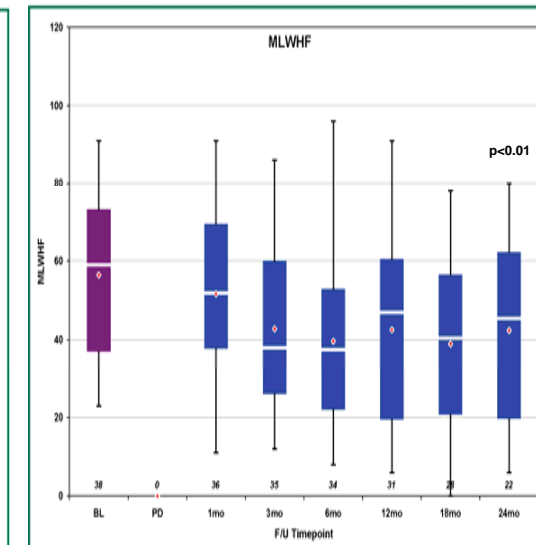
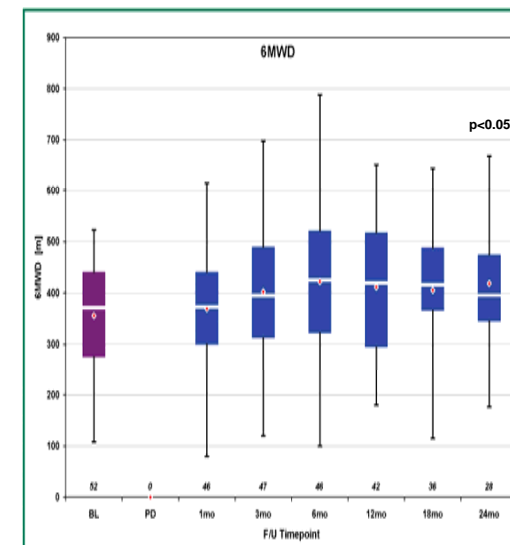
Feasibility

- 51 / 52 successful implants
- 2 perioperative deaths
- 1 reoperation for repair of avulsed phrenic artery
- 3 noncardiac deaths in late follow up
- 4 patients received VAD or transplant during long term follow up



Conclusion

This report provides two year follow up data for the Paracor HeartNet™ Ventricular Elastic Support Device. These data suggest an ongoing benefit in patient symptoms, ventricular remodeling and quality of life two years after implantation. The non-randomized nature of this safety and feasibility trial limits broad applicability. Further evaluation of this therapeutic device is warranted, and such evaluation is underway in the PEERLESS-HF trial.



A responder analysis was prepared for interpretation of pVO2, 6 minute walk test and Minnesota Living with Heart Failure score. The "responder" threshold for each parameter, and the percentage of patients exceeding that value is shown below.

Peak VO2 (1 ml/kg/min): 30%
6 Minute Walk Test (45 m): 46%

MLWHF (7 points): 68%

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

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Effective Date: 04/07/09