

## Background

Heart Failure represents a continuum beginning with risk factors and culminating in end stage or refractory disease. There are known risk factors and structural prerequisites leading to the development of Left Ventricular systolic dysfunction and the clinical syndrome of heart failure. It is now widely accepted that the natural history of heart failure is inextricably linked to the progression of such structural abnormalities (i.e. pathological remodeling) including increase in left ventricular dimensions and volumes, reduction in left ventricular ejection fraction and increase in mitral and tricuspid regurgitation.

Likewise multiple randomized clinical trials have shown a survival benefit when the therapy under study attenuates or reverses the pathological remodeling process. This has been seen with ACE inhibitors, beta blockers and more recently CRT. Not surprisingly all of these therapies are incorporated into the HF guidelines.

We tested the hypothesis that the HeartNet™ (HN, Paracor Medical, Inc. Sunnyvale CA) Ventricular Elastic Support Therapy (VEST) a nitinol based elastic ventricular support device that is delivered through a minithoracotomy used in addition to standard HF therapy produces incremental benefits on remodeling.

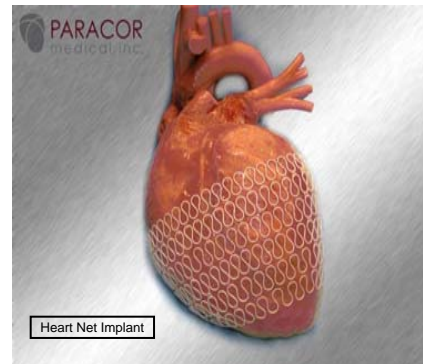
## Methods

51 patients (age=52, 94% males, 80% nonischemic, NYHA II/III 35%/65%, 98% ACEI/ARB, 96% BB) were implanted with HN and underwent serial echo analysis by a central core lab. All patients who were available for 3, 6 and 12 month follow up were analyzed for LV and RV dimensions, volumes, ejection fraction, mass, mitral regurgitation and E/E'. The degree of MR was assigned a value in 0.5 unit increments by the echo core lab. E/E' was determined in standard fashion.

## Methods

A total of 49 subjects had at least some collected echo data at each of the visits at baseline, 3, 6 or 12 months. For 36 subjects the last follow-up visit was at 12 months, and for 11 subjects the last follow-up visit was at 6 months. Patients with paired data were analyzed for 6 and 12 month response to therapy by student t-test.

We performed linear regression of the parameter value vs. time for all echo measurements. Small numbers of values for parameters were missing for subjects at some visits, but these are not thought to appreciably affect the general trends.



## Results

VEST significantly reduced LV diastolic dimension at 6 and twelve months, compared to baseline. This reduction in LVEDD was progressive from baseline to 12 months as shown by the linear trend analysis including values at baseline, 3, 6 and 12 months.

## Results

VEST had a similar effect on LV systolic dimension. In addition to the finding that the paired data at 12 months was significantly reduced, there was a progressive reduction in LVESD determined by linear trend analysis including values at BL, 3, 6 and 12 months.

Left Ventricular volume and mass show significant improvement at six months further supporting the positive impact of VEST on ventricular remodeling. There was also significant reduction in mitral regurgitation and improved diastolic function as determined by a significant reduction in E/E' at twelve months.

### Baseline Echo Data

	n	
LVEDD (cm)	46	7.3 (5.4 - 9.8)
LVESD (cm)	46	6.3 (4.2 - 8.8)
LVEDV (ml)	49	353 (193 - 652)
LVESV (ml)	49	278 (134 - 559)
LV EF (%)	49	22 (11 - 34)
LV Mass (gm)	45	326 (187 - 535)

### Six Month Follow-up

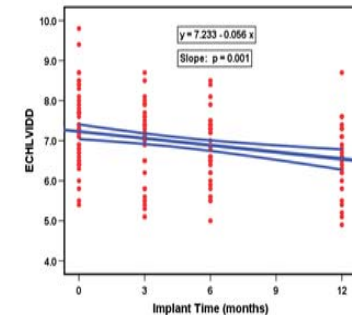
	n	Δ	p
LVEDD (cm)	39	-0.4	0.007
LVESD (cm)	39	-0.2	0.1
LVEDV (ml)	43	-35	0.004
LVESV (ml)	43	-32	0.006
LV EF (%)	43	1.7	0.1
LV Mass (gm)	36	-21	0.05

### Twelve Month Follow-up

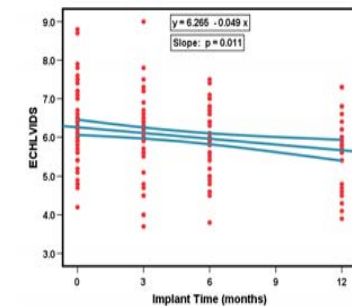
	n	Δ	p
LVEDD (cm)	28	-0.4	0.002
LVESD (cm)	28	-0.3	0.05
MR (units)	34	-0.3	0.02
E/E' (units)	13	-2.7	0.0055

## Results

### LV Diastolic Dimension (cm)



### LV Systolic Dimension (cm)



## Summary

The addition of VEST to standard HF therapy appears to result in further improvements in cardiac structure and systolic function, and a suggestion of improvement in diastolic function at 12 months on top of standard drug and device therapies for HF. This notion is being tested in a prospective randomized controlled trial, PEERLESS-HF.