

Improvement in Mechanical Dyssynchrony in Patients with Dilated Cardiomyopathy:

Impact of LV Mesh

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Introduction

Previously, we demonstrated in an ovine model of surgically invoked ischemic heart disease that a Nitinol wrap placed around the heart could prevent LV remodeling. We extend the study to patients presenting with signs and symptoms of dilated cardiomyopathy (CMX) to study regression addressing whether a device surgically placed around the heart could thwart LV remodeling over time as compared to those without the LV wrap.

Hypothesis

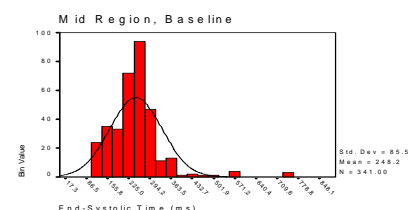
We hypothesize that the HeartNet™ (Paracor Medical Inc, Sunnyvale, CA) surgically placed in patients with severe dilated CMX improves dyssynchrony.

Goals

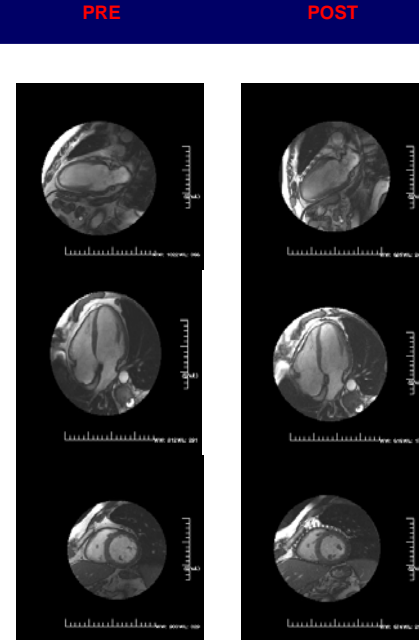
To demonstrate that, by cardiac MRI, in contradistinction to the ACORN Trial, that the novel concept of buttressing LV dilation with an externally placed device has solid clinical utility warranting continued investigation

Methods

Eight male pts (47±9 yrs) with mean Eight male pts (47±9 yrs) with NYHA Class 2.3±0.5 on optimal medical therapy (maintained throughout the study) underwent preoperative 3D cardiovascular MRI to assess LV function. Using Medis Mass software (Leiden, The Netherlands), endocardial and epicardial boundaries were outlined in contiguous short-axis slices. Circumferentially, the myocardium was divided into 16 equally spaced segments and end-systolic (ES) time was automatically identified as time of maximal wall thickening. End-systolic times were analyzed to assess dyssynchrony: dispersion of data indicating severity and progression of mean ES time from base to apex assessed by ANOVA. All pts underwent minimally invasive left thoracotomy with deployment of the HeartNet™, designed to conform to the epicardium. Follow-up MRI was performed at 6 mo.



Results in a 64 YO WM

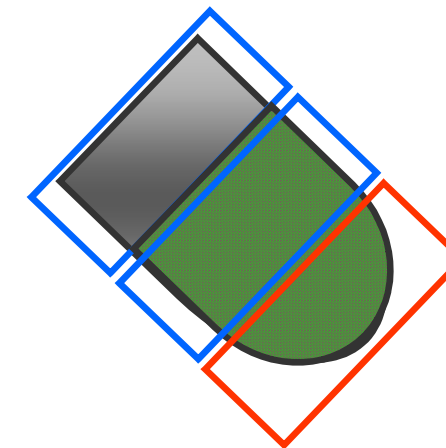


Results in a 64 YO WM

	PRE	POST
LVEDV	402	401
LVESV	337	265
LVSV	65	135
EF(%)	16	33
LVmass(g)	227	215
PER(ml/s)	535	1215
PFR(ml/s)	425	766

Technique

- Only basal and mid regions were analyzed
 - Basal region was unconstrained by the mesh
 - Mid region was constrained by the mesh
 - Apical regions were excluded to avoid partial volume effects



Results

- All pts survived HeartNet™ placement and were available for 6 mo follow-up. NYHA class decreased to 1.9±0.6 (p<0.04). One pt was admitted for CHF in the first month.

Summary

- Global LV wall thickening improved (129±29% vs. 136±35%, p<0.001) and ES wall thickness increased (10.2±2.7 vs. 10.8±3.0mm, p<0.001).
- The LV dyssynchrony index was reduced in the basal region (254 vs. 220, p<0.05, f= 12.8).
- Temporospacial analysis of the progression of ES time from base to apex demonstrated lack of an appropriate gradient at baseline (p=0.3), but at 6 mo the normal progression of ES time was restored, being earliest at the base (330±220ms), progressing to the mid region (346±224ms) and arriving lastly at the apex (372±219ms), p<0.05.

Conclusions

- Against a background of a general paucity of novel therapies for the treatment of dilated CMX, the minimally invasive HeartNet™ LV wrap demonstrated that at the myocardial level a clear improvement in function was produced with restoration of a more appropriate electromechanical contraction pattern and decreased LV dyssynchrony.
- The singular advantage of this approach is that the ease of conversion to a minimally invasive placement approach is possible.
- A registered clinical trial in USA and Europe is currently underway.