Evolving Technology

Initial United States experience with the Paracor HeartNet* myocardial constraint device for heart failure

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W.T.A., J.P.B., W.E.P., and B.K.R. report grant support from Paracor Medical, Inc.

Read at the Eighty-sixth Annual Meeting of The American Association for Thoracic Surgery, Philadelphia, Pa, April 29–May 3, 2006.

Received for publication April 28, 2006; revisions received Aug 6, 2006; accepted for publication Aug 25, 2006.

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J Thorac Cardiovasc Surg 2007;133:204-9

0022-5223/$32.00

doi:10.1016/j.jtcvs.2006.08.070

Objective: This study was undertaken to review the initial results and surgical safety data for the US Food and Drug Administration safety and feasibility trial of the Paracor HeartNet (Paracor Medical, Inc, Sunnyvale, Calif.) myocardial constraint device.

Methods: Patients with New York Heart Association functional class II or III heart failure underwent device implantation (n = 21) through a left minithoracotomy.

Results: The average age was 53 years (31–72 years). There were 18 men and 3 women, and 17 patients had nonischemic etiology of heart failure. Mean heart failure duration was 8.3 years (1.4-18.8 years). Average ejection fraction was 22% (11%-33%), with an average left ventricular end-diastolic dimension of 74 mm (55-94 mm). Previous medical therapy included angiotensin-converting enzyme inhibitors, β-blockers, diuretics, digoxin, and aldosterone receptor blockers. At implantation, 17 patients had implantable electronic devices: 1 biventricular pacemaker, 11 biventricular pacemakers with cardioverter-defibrillators, and 5 implantable cardioverter-defibrillators. Patient comorbidities included hypertension in 10 cases, diabetes mellitus in 8, myocardial infarction in 1, and ventricular tachycardia in 8. Mean operative time was 68 minutes (42–102 minutes), and implantation time averaged 15 minutes (5–51 minutes). The average time to ambulation was 1.6 days (1–4 days). The intensive care unit stay averaged 3.3 days (1–16 days), and hospital stay averaged 6.3 days (4–16 days). Atrial fibrillation occurred in 2 patients, and there were 2 in-hospital deaths.

Conclusions: The Paracor device can be implanted in patients with heart failure and reduced left ventricular function with a high degree of success. Significant surgical complications were infrequent. The initial US experience supports the conduct of a randomized, controlled, pivotal trial.

Optimal medical heart failure therapy consisting of neurohormonal blockade with angiotensin-converting enzyme inhibitors and β-blockers for all patients, with biventricular pacing for certain patients with prolonged QRS duration, represents the current standard of care for patients with symptomatic heart failure. Despite reductions in morbidity and mortality with medical therapy, there are some patients for whom neurohormonal blockade

Abbreviations and Acronyms
NYHA = New York Heart Association

fails to halt the progressive course of this disease.[1] In the current era, patients with end-stage heart failure are considered for destination therapy with a left ventricular assist device or heart transplantation as a final option.[2] Multiple therapies have been used or are under investigation in an attempt to intervene in the progression of this disease process. These efforts have centered on surgically reshaping the ventricle or using biventricular pacing to relieve mechanical and electrical asynchrony.[3-10] Recently, other mechanical therapies have been investigated for the potential to halt the progression of the failing heart and allow reverse remodeling.[11] It has been shown that a myocardial constraint device can modify the left ventricular geometry after myocardial infarction in a sheep model.[12-14] Myocardial constraint devices have also been shown to improve cardiac function, reduce left ventricular volume, and reduce mitral regurgitation in an ovine model of tachycardia-induced progressive dilated cardiomyopathy.[15]

The Paracor HeartNet (Paracor Medical, Inc, Sunnyvale, Calif) is an elastic ventricular restraint device that has been developed for patients with heart failure who continue to have symptoms and progressive cardiac remodeling, despite treatment with standard evidence-based therapies. It is implanted around the heart to reduce the wall stress and potentially allow reverse remodeling. It was hypothesized that the HeartNet could be safely implanted through a minithoracotomy in patients with heart failure and would significantly reduce left ventricular systolic function, leading to improvement in clinical and functional status. The safety and efficacy of this device are now under clinical investigation. The initial surgical experience and 6-month data for the first 21 patients treated in the United States are reported here.

Methods

After investigational review board approval of the Food and Drug Administration-approved safety and feasibility trial and informed consent, 21 patients at five US sites with New York Heart Association (NYHA) functional class II or III heart failure who had been receiving optimal medical therapy for at least 3 months were selected to undergo implantation of the HeartNet through a minithoracotomy. Patients with NYHA functional class IV heart failure and those with previous cardiac operations were excluded. Patients were evaluated at baseline and at 6-month follow up by echocardiography, 6-minute walking test, cardiopulmonary exercise testing, NYHA functional class assessment, and the Minnesota Living With Heart Failure questionnaire.

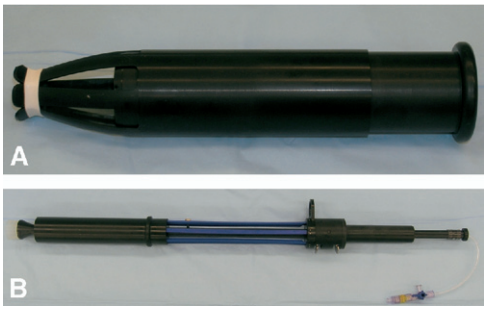

Figure 1. A, Introducer sheath used to maintain stable access to pericardial space. B, HeartNet (Paracor Medical, Inc, Sunnyvale, Calif) delivery system.

Operative Technique

All procedures were performed through a left anterior minithoracotomy with general anesthesia. Patients were positioned supine, and fluoroscopy was used to locate the cardiac apex. Minithoracotomy incision was performed slightly lower than the apex to allow the correct trajectory for the delivery system. Rib spreading was performed only to the extent necessary to accommodate the introducer sheath. The pericardium overlying the cardiac apex was opened and suspended with stay sutures. The introducer was inserted into the pericardium and expanded (Figure 1, *A*). An unobstructed path to the cardiac apex was ensured either by direct visualization or by passing a 10-mm thoracoscope through the introducer. After confirmation of the introducer positioning, the delivery system (Figure 1, *B*) was advanced through the introducer under fluoroscopic guidance. The apex was grasped with the suction cup while the device was inserted and deployed. Once the delivery system was removed, either direct visualization or the thoracoscope was used synergistically with fluoroscopy to ensure appropriate device deployment and location (Figure 2). The pericardium was loosely approximated, and a chest drain was left in place. Thoracotomy closure was accomplished in standard fashion.

Results

The HeartNet was successfully implanted in 95% of the patients enrolled (n = 20/21). The baseline demographic

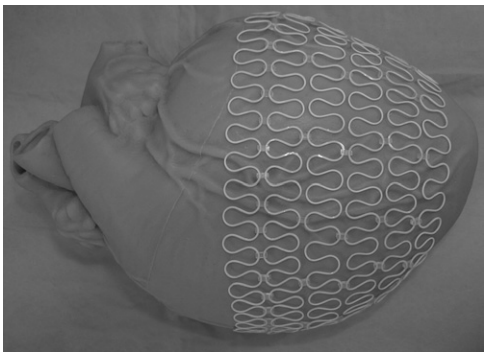

Figure 2. Paracor HeartNet device (Paracor Medical, Inc, Sunnyvale, Calif) implanted on a heart model.

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TABLE 1. Baseline demographic data (n = 21)

Age (y)	
Mean ± SD	52.8 ± 12.4
Range	31.4-72.4
Male (No.)	18 (86%)
White (No.)	19 (90%)
Etiology (No.)	
Nonischemic	17 (81%)
Ischemic	4 (19%)
Duration of heart failure (y)	
Mean ± SD	8.3 ± 6.0
Range	1.4-18.8
Cardiac medications (No.)	
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	21* (100%)
β-Blockers	20 (95%)
Diuretics	17 (81%)
Aldosterone receptor blockers	9 (43%)
Digoxin	16 (76%)
Medical history and comorbidities (No.)	
Hypertension	10 (48%)
Diabetes mellitus	8 (38%)
Myocardial infarction	1 (5%)
Ventricular tachycardia	8 (38%)
Biventricular pacemaker	1 (5%)
Biventricular pacemaker with cardioverter-defibrillator	11 (52%)
Standard implantable cardioverter-defibrillator	5 (24%)

*One patient was receiving both angiotensin-converting enzyme inhibitor and angiotensin receptor blocker.

characteristics of the patients are listed in Table 1. There was a preponderance of male patients and those with a nonischemic etiology for heart failure. All patients had been receiving optimal medical therapy for a minimum of 3 months. Clinical and functional parameters (Table 2) and baseline echocardiographic data (Table 3) demonstrated a moderately ill cohort of patients in NYHA functional classes II and III. The patients in functional class II who were included (n = 7/21) had elevated Minnesota Living With Heart Failure scores and dramatically reduced 6-minute walking test and cardiopulmonary exercise testing results, similar to the patients in functional class III (Table 4). Three patients (2 nonischemic etiology, 1 ischemic etiology) demonstrated either 2+ or 3+ mitral regurgitation on preoperative transthoracic echocardiography.

TABLE 2. Baseline exercise and quality of life parameters (n = 21)

Parameter	
New York Heart Association functional class (No.)	
II	7/21 (33%)
III	14/21 (66%)
Peak ventilation (mL/[kg · min], n = 20)	
Mean ± SD	16.5 ± 3.7
Range	10.8-24
Six-minute walking test (m)	
Mean ± SD	322 ± 94
Range	168-494
β-Natriuretic peptide (pg/mL)	
Mean ± SD	728 ± 261
Range	23-7575
Minnesota Living With Heart Failure questionnaire score	60

TABLE 3. Baseline echocardiographic parameters (n = 21)

Parameter	
LV ejection fraction (%)	
Mean ± SD	22% ± 6%
Range	11%-33%
LV end-diastolic dimension (mm)	
Mean ± SD	74 ± 10
Range	55-94
LV end-systolic dimension (mm)	
Mean ± SD	63 ± 11
Range	42-87
Diastolic LV volume (cm^3)	
Mean ± SD	370 ± 10
Range	193-619
Systolic LV volume (cm^3)	
Mean ± SD	294 ± 98
Range	141-548
Mitral regurgitation >2+ (No.)	3
Diastolic sphericity index*	
Mean ± SD	0.64 ± 0.12
Range	0.32-0.84)

LV, Left ventricular. *>Diastolic sphericity index is derived as EDV/π · (EDL)3/6, where *EDV* is end-diastolic volume and *EDL* is end-diastolic length.

Procedural Data

Successful implantation was accomplished through a left anterior minithoracotomy in 20 patients. In 1 patient, the

TABLE 4. Comparison of patients in New York Heart Association functional classes II and III

Parameter	Class II (n = 7)	Class III (n = 14)	Combined (n = 21)
Minnesota Living With Heart Failure questionnaire score	54	64	60
Six-minute walking test (m)	387	290	322
Peak ventilation (mL/[kg · min])	18.5	15.4	16.5
LV ejection fraction (%)	19.5%	22.6%	21.6%
LV end-systolic volume (mL)	315	283	294
LV end-diastolic volume (mL)	392	360	370
LV mass (g, calculated)	337	331	333

All values are mean. *LV,* Left ventricular.

TABLE 5. Index procedural information for 21 patients (range)

	Mean	Range
Anesthesia time (min)*	177	95-402
Skin incision to skin closure (min)	68	42-102
Incision length (cm)	9.75	5.5-15
Fluoroscopy time (min)	6	2-17
Implantation time (min)	15	5-51
Time to ambulation (d)	1.6†	1-4
Intensive care unit stay (d)	3.3†	1-16
Hospital stay (d)	6.3†	4-16

*Anesthesia time is defined as time from induction of anesthesia to patient consciousness. †>Median data 1 day, 1.5 days, and 5.5 days, respectively.

TABLE 6. Adverse events

	No. of events	No. of patients
Pulmonary complication	2*	1†
Anemia	1	1†
Obtundation	1	1†
Heart failure with hospitalization	2	2‡
Atrial fibrillation	2	2‡
Procedure-related death	2	2
Epicardial laceration	1	1

*Effusion and diaphragmatic paresis. †>Same patient. ‡>Same patients.

tissues of the pericardium and epicardium were determined to be extremely friable. After an epicardial laceration necessitated suture control, the procedure was aborted. Among the 20 patients with successful implantation, the average total anesthesia time was 177 minutes (95-402 minutes), although the time from skin incision to skin closure averaged 68 minutes (42–102 minutes; Table 5). The actual time to deploy the device and the fluoroscopy time constituted only a small part of the procedure duration.

Postoperative Course and Adverse Events

The average time to ambulation was 1.6 days (range 1–4 days, median 1 day). The average intensive care unit stay was 3.3 days (range 1–16 days, median 1.5 days). Duration of patient hospitalization averaged 6.3 days (range 4-16 days, median 5.5 days; Table 5). Perioperative pain management strategy was selected according to individual surgeon preference. Strategies included the use of epidural catheters, intercostal nerve blocks, local anesthetic infusion pumps placed into the wound, and selected use of ketorolac.

Serious adverse events (Table 6) included 1 case of unilateral diaphragmatic paresis and pleural effusion, which resolved completely. The same patient was seen with anemia 1 month after implantation and was found to have colonic polyps. This same patient returned a third time 3 months after implantation with a period of obtundation related to overmedication with narcotics. Two patients had atrial fibrillation after discharge, which necessitated an admission in each case for heart failure management and arrhythmia treatment.

Major adverse events (Table 6) included 2 deaths during the initial hospitalization and within 30 days of procedure (overall in-hospital and 30-day mortality 10%, n = 2/21). One patient had significant pulmonary dysfunction and methicillin-resistant *Staphylococcus aureus* pneumonia necessitating reintubation. The patient had progression to multisystem organ failure and died on postoperative day 16. Post mortem examination confirmed severe bilateral necrotizing pneumonia with evidence of necrotizing pancreatitis. There was no evidence of device malfunction, nor was the device implicated as the cause of death. The pericardial adhesions to the device were noted to be mild. A second patient also had pneumonia necessitating reintubation and a period of hemodynamic instability necessitating vasopressors. This progressed to multisystem organ failure, and the patient died on postoperative day 14. Autopsy showed evidence of gastrointestinal hemorrhage and bilateral lower lobe consolidation of the lungs. The autopsy report did not comment on density of intrapericardial adhesions to the device. These 2 patients had the largest left ventricular end-diastolic dimensions in this series, at 90 and 94 mm, respectively. There were no additional major adverse events in the 6-month follow up. Overall in-hospital and 30-day mortality was 10% (n = 2/21).

Six-month data available (n = 10) showed improvement in multiple clinical and functional parameters (Table 7). Although the small number of patients in this sample precludes reliable statistical analysis, favorable trends were noted in almost all parameters. The Minnesota Living With Heart Failure scores showed the most dramatic reduction after device implantation. Although these data are encouraging, they must be interpreted cautiously as uncontrolled and unblinded.

Discussion

This is the first report on the US experience with the Paracor HeartNet during the safety and feasibility trial of this myocardial constraint device. Previous reports have detailed the archetypal myocardial constraint device, the Acorn CorCap (Acorn Cardiovascular, Inc, St Paul, Minn).[11,16] The Paracor HeartNet differs from the CorCap in several important ways. The HeartNet is delivered through a minimal access left thoracotomy inside the pericardium with the aid of an introducer and delivery system and adheres the heart because of small textured areas on the epicardial side of the device. The HeartNet currently has 12 sizes available and is sized by echocardiographic parameters, in theory making the fit consistent across a large size range. It is also constructed of a nitinol mesh that is both compliant and elastic.

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TABLE 7. Change from baseline to 6-month paired data (n = 10)

Parameter (n = 10 paired)	Baseline		Change at 6 mo		*P* value
	Median	Mean	Median	Mean	
Six-minute walking test (m, n = 10)	352.0	353.0	+137.9	+151.0	.01
Minnesota Living With Heart Failure questionnaire score (n = 8)	48.5	53.5	−23.0	−27.3	.01*
Peak ventilation (mL/[kg · min], n = 9)	17.4	16.1	+1.6	+1.0	.43
LV ejection fraction (%, n = 10)	24.4	23.0	−0.6	+1.0	.67
LV end-systolic volume (mL, n = 10)	269.0	282.0	4.6	−17.9	.33
LV end-diastolic volume (mL, n = 10)	346.4	365.4	−12.0	−19.9	.27
LV mass (g, calculated; n = 8)	296.0	298.9	−20.5	−32.0	.06

LV, Left ventricular. *Calculated for Minnesota Living With Heart Failure questionnaire score with Wilcoxon signed rank test; *t* test was used for all other parameters.

The relatively large compliance range reduces the likelihood of development of a constrictive type physiology, whereas the elasticity may provide some positive epicardial pressure that may be beneficial relative to the inelastic construction of the CorCap device. The nitinol mesh may have an additional benefit of reduced adhesion formation relative to other materials, although further study is required.

Class IV heart failure and adhesions from previous cardiac operations were considered to be exclusion criteria for the initial safety and feasibility trial of the Paracor device. This may have led to a selection bias of a greater number of patients with nonischemic heart failure. It is unclear at this time what the impact of these exclusions would be on the eventual clinical adaptation of this device. Additionally, longer follow-up is required to determine the effect of device implantation on patients with mitral regurgitation (n = 3).

This report demonstrates that the HeartNet can be implanted with a high degree of surgical success (95%) in patients with heart failure and reduction of left ventricular function. The surgical implantation procedure was relatively straightforward, with only a single intraoperative complication. Major adverse events occurred in the 2 patients with the largest hearts, as measured by end-diastolic dimension. This early experience may indicate that, similar to the CorCap, the patients with the largest end-diastolic dimensions may not be optimal candidates for this therapy. In the remaining cases the postoperative course parallels what might be expected after any thoracotomy in this moderately to severely ill patient cohort. Also similar to general postthoracotomy care, adequate preoperative pulmonary evaluation and excellent postoperative pain control appear to be paramount to success. The 6-month paired data suggest a functional and clinical benefit, with a trend toward reverse remodeling, and support the conduct of a randomized, controlled, pivotal trial.

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Discussion

Dr J. Chachques *(Paris, France).* Number one, I want to ask you if you evaluated the right ventricular volume dimensions and function, because I think you can make more compression in the right side than in the left. Number two, what is the evaluation of the apex in these patients? Do you have some degree of dilatation? And finally, do you have some degree of fibrosis in the clinical experimental studies which is the ration and material that has made this device.

Dr. Klodell. Thank you for those questions. Concerning the right heart function, we didn't present that data. The right heart function is evaluated by echo. There has not been any significant change in right heart function. The right heart pressures were also monitored perioperatively in the bulk of the patients and implantation of the device did not have any deleterious effects.

As far as the shape of the apex, to which you alluded, many of these patients have quite spherical hearts with elevated sphericity indices. One of the tricks of deployment is a little bit of apical traction with that suction cup to try and elongate the apex. thereby making the device deploy a little easier.

As to your third question, as far as fibrosis is concerned, we don't have any information regarding humans yet, but in the animal model at least, the degree of reaction and fibrosis to the nitinol based device has been much less than the other support device, and it is hoped that that will translate into humans as well.

Dr S. Gideon *(Beer Sheba, Israel).* Did you have any bleeding complications due to erosion of epicardial blood vessels?

Dr Klodell. No, sir, to date there have been no bleeding complications, with the exception of the epicardial laceration from the introducer that I mentioned. None of the treated patients who have had a successful implant have subsequently had any bleeding complications.

Dr P. Kurlansky *(Miami, Fla).* I was wondering if you could help us to understand the device a little better. From the graph that you showed us, this is an extremely compliant material; therefore, it doesn't seem as though there is passive restraint. It would seem that in fact this would have a lot of give to it, but it would also be, as it were, ″hugging″ the heart. If you can kind of explain to us a little better the physiology of what is going on or perhaps even the mechanics of what is going on with the device, because it doesn't seem to be the same as the other sort of passive restraint device that is attempting to be on the market. Thank you.

Dr Klodell. I think that is a great question: Basically, what are the differences between this device and the CorCap device? First of all, this device is implanted completely differently. This is a minimal access, a 9- to 10-cm thoracotomy incision, and the pericardium is left intact. This is in contrast to how the other the device is implanted via sternotomy. And the sizing of this device, to which you alluded, is a little different. This device is sized based on MRI and echo data preoperatively. Currently, there are 12 sizes, so the device is selected based on the size of the heart you are going to put it on. Because nitinol has elasticity that when exposed to body temperature tends to constrict a little bit, it conforms very nicely to the heart. As opposed to the other device, which is a passive device that only prevents dilation, this actually has some elasticity to it; although it is very compliant, it also has elasticity to it. So there is a constant pressure on the ventricle that is probably along the order of 4 mm or so of magnitude, and what that is going to do long term is unclear at this time. I will share with you that the Magdeberg Germany group has submitted an abstract to the Heart Failure Society in which, hopefully, we will be hearing then that the elasticity feature may contribute to cardiac resynchronization.

Dr J. Puskas *(Atlanta, Ga).* Dr. Klodell, you had 2 out of 10 in this original series die of device related deaths and 1 of 10 aborted due to epicardial tear. Tell us about evaluation preoperatively for epicardial and pericardial adhesions. How can we avoid the difficulties inserting these?

Dr Klodell. Very good question. Thank you. Just to be clear, it was 1 epicardial laceration out of 21 patients and 2 patients out of the 21 that we presented today.

The preoperative evaluation, the things that we have learned from the U.S. patients so far is that patients who have an ischemic etiology frequently will have some pericardial adhesions. That can be problematic, certainly. Any patients who have epicardial LV leads and things like that should be excluded. We didn't have time to cover in too much detail the operative approach, but one thing that has been very useful is when the introducer is inserted into the pericardial space to use a thoracoscope through the introducer to look at the heart and to try and make sure there are not adhesions there. When there are adhesions, at least in the European experience and in our experience in a couple of patients, those adhesions can be taken down under direct vision using the thoracoscope. But I do think that as far as the one patient that was aborted is concerned, preoperative nutrition status and overall qualitative assessment of the patient probably would have deterred that implant, and that is something to learn for the future: these need to be the same kind of relatively healthy patients who you would feel comfortable putting on bypass for a cardiac operation.