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Ventricular reconditioning and pump explantation in patients supported by continuous-flow left ventricular assist devices

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Abstract

BACKGROUND—The potential for myocardial reconditioning and device explantation after long-term continuous-flow left ventricular assist device (LVAD) support presents an opportunity to delay or avoid transplantation in select patients.

METHODS—Thirty of 657 patients with end-stage heart failure supported with continuous-flow LVADs were assessed for device explantation. Each patient underwent an individualized process of weaning focused on principles of ventricular unloading, gradual reconditioning, and transition to medical therapy.

RESULTS—After varying reconditioning periods, 27 patients (16 men, 11 women; age, 39 ± 12 years) underwent LVAD explant, and 3 patients (2 men, 1 woman; age, 22 ± 6 years) were evaluated for explantation but could not be weaned. The duration of LVAD support was 533 ± 424 days (range, 42– 1,937 days) for the explant cohort and 1,097 ± 424 days (range, 643–1,483) for the non-explant cohort. The LV end-diastolic dimension, LV ejection fraction, systolic pulmonary artery pressure, cardiac output, and cardiac index in the explant cohort were significantly improved at explantation (all, $p < 0.05$). Two late deaths occurred after LVAD explantation despite satisfactory native cardiac function, and 1 patient required resumption of LVAD support 2.7 years after device removal. The remaining explant patients remain in New York Heart Association classes I to II with medical management alone (mean survival post-explant, 1,172 ± 948 days). The 3 candidates who could not be weaned ultimately underwent transplantation.

CONCLUSIONS—The potential for recovery of native LV function after long-term continuous-flow LVAD support should encourage a more aggressive approach to ventricular reconditioning

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with the goal of device explantation and a return to medical management, particularly in young patients with dilated cardiomyopathy.

Keywords

heart failure; left ventricular assist device (LVAD); ventricular unloading; ventricular recovery; ventricular reconditioning

Technologic advancements in the field of mechanical circulatory support and the relative scarcity of donor organs have resulted in the adoption of left ventricular assist devices (LVADs)—once relegated to the periphery of medical therapy—as important tools in the treatment of end-stage heart failure. Used as a bridge to transplantation (BTT) or destination therapy (DT), these pumps have improved the quality of life and overall survival of patients when all other therapeutic options have been exhausted.[1–3] However, the risks associated with LVAD therapy are far from negligible. The use of mechanical circulatory support brings an increased risk of infection, stroke, and device malfunction, whereas cardiac transplantation requires lifelong immunosuppression and is limited by the lifespan that can be expected of the donor graft.

Studies from our institution[4–7] and others[8–11] have reported an improvement in a number of anatomic, physiologic, histologic, and sub-cellular markers of native heart function after prolonged periods of mechanical circulatory support. In light of this potential to improve native LV function,[4,6,12–14] we have sought to demonstrate the ability to bridge selected LVAD patients to a return to medical therapy. In this way, pump explantation could minimize the risk of complications associated with long-term LVAD support and delay (or avoid) transplantation, especially in younger patients who are otherwise unlikely to experience an acceptable post-operative life expectancy.[15]

Thirty patients at our institution were identified as potential candidates for ventricular reconditioning. All patients were in end-stage heart failure, were being supported by continuous-flow LVADS, and expressed a desire to be weaned from the device. Our goal in these patients was a return to medical management through a process of device weaning that allowed for pump explantation after a satisfactory improvement in ventricular function. In this report we describe a large cohort of patients undergoing continuous-flow LVAD explantation for improved ventricular function.

Methods

The Texas Heart Institute Institutional Review Board approved this study, and written informed consent was obtained from the patients or an authorized representative.

Patient selection

Between August 2006 and January 2014, 30 non-consecutive patients supported by continuous-flow LVADs at our institution were evaluated as candidates for pump explantation. All patients selected for this study were outpatients in New York Heart Association (NYHA) Functional Class I who did not require inotropic support before the device-weaning strategy was implemented. Inclusion in the study cohort was determined at

the discretion of a multidisciplinary review committee and not as part of a protocol, with a particular emphasis placed on the patient's age, echocardiographic data, and overall clinical condition. Patients had to meet the heart failure criteria necessary to be added to the waiting list for transplant, including an LV ejection fraction (LVEF) of less than 20%. Younger patients were preferentially selected, because it was felt that they faced a disproportionate level of exposure to the complications associated with long-term LVAD support and were statistically unlikely to realize a normal lifespan after transplantation. Some of the patients in our 30-case series asked to be weaned from the device rather than undergo heart transplantation. All patients were required to demonstrate an understanding of the risks and benefits of a weaning protocol and to provide explicit interest in the pursuit of an explantation strategy.

During the same period at our institution, continuous-flow LVADs were implanted in 657 patients. However, no attempt was made to pursue a strategy of ventricular remodeling, pump weaning, or device explantation to those outside the study cohort.

Before LVAD implantation, each patient had been diagnosed with severe, chronic, end-stage heart failure (NYHA Functional Class IV), despite optimal medical therapy, and did not have clinical or histologic evidence of acute myocarditis. Twenty-eight of the enrolled patients were supported by the HeartMate II (Thoratec Corp, Pleasanton, CA), and 2 patients were supported by the HeartWare HVAD (HeartWare International, Framington, MA).

Hemodynamic and echocardiographic data

Hemodynamic and echocardiographic data were recorded before LVAD implantation, throughout the period of mechanical support and weaning, after explantation or transplantation, and at all subsequent follow-up visits. Variables documented included LV end-diastolic dimension (LVEDD), LVEF, aortic valve opening time, systolic pulmonary artery pressure (SysPAP), pulmonary capillary wedge pressure (PCWP), cardiac output (CO), cardiac index (CI), septal thickness, and posterior wall thickness.

Post-operative management

After LVAD implantation, the patients underwent standard postoperative intensive care management, including early extubation, titration of inotropic medications, individualized anti-coagulation therapy, and intensive physical therapy. All patients were treated with optimal medical therapy for heart failure (β-blockers, angiotensin-converting enzyme inhibitors, digitalis, and diuretics), which were initiated at the earliest clinically appropriate postoperative opportunity.[16] After assurance of hemodynamic stability, clearance by the physical therapy service, and comprehensive inpatient device training, patients were discharged home with close outpatient follow-up.

LVAD weaning

After an initial post-operative recovery period (typically 3–6 months), the patients were evaluated monthly as outpatients to assess suitability for the initiation of a ventricular reconditioning protocol. This assessment was facilitated by echocardiographic testing performed at regular intervals to quantitate native LV function. The initial phase of our

weaning protocol was characterized by a period of ventricular unloading. The goal of this process was to reduce the LVEDD to the upper limits of normal and to correct or minimize mitral regurgitation, a condition secondary to dilated cardiomyopathy, by increasing the rpm of the device and thereby offloading the volume retained within the LV. Initially, these conditions were met only when the aortic valve remained closed throughout the cardiac cycle, allowing the pump to operate in series with the native ventricle. To avoid a resultant excessive increase in blood pressure and, we believe, the attendant risk of hypertensive-hemorrhagic stroke, the afterload was pharmacologically reduced to maximal clinically tolerated levels, typically with peripheral Doppler pressures maintained below 100 mm Hg and ideally in the 70 to 90 mm Hg range.

When a patient was clinically stable with appropriately controlled blood pressure, the device speed was briefly reduced to 6,000 rpm, and the aortic valve opening time was measured by echocardiography. This transient reduction in pump speed did not require any change in the anti-coagulation management, and patients were returned to their outpatient maintenance speed after device interrogation.

Once the aortic valve opening time was found to exceed 10% of the cardiac cycle at 6,000 rpm, the maintenance speed was gradually decreased as long as normal LV dimensions were maintained and mitral regurgitation was controlled. This process was repeated during all outpatient visits and was individualized to each patient's native LV response.

The principal criteria for consideration of device explantation were the normalization of aortic valve opening time (approximately 33% of the cardiac cycle) at 6,000 rpm and a return of LVEDDs to less than 6 cm at maintenance pump speeds. According to the manufacturer's settings, the lowest outpatient speed permissible without alarms being triggered is 8,000 rpm, which is a major limitation to such an individualized, outpatient approach to reconditioning with the HeartMate II.

Once the cardiac cycle was normalized at minimal pump speeds, most patients underwent exercise testing (dobutamine and/ or bicycle stress or stress echocardiographic analysis) and myocardial oxygen consumption (MVO_2) measurements. Overall, the patients in the explant cohort had an average maximal VO_2 value of 21.1 ± 8.9 liters/min, which fell within the 56th percentile of predicted values (±19%). However, the results of these tests were used only to supplement the outpatient echocardiography data and further substantiate the presence of sufficient ventricular compensation to allow for device removal and were not meant as a definitive measure of suitability for explant.

Patients who underwent device removal were also found to have a statistically significant improvement in LVEF with minimal device support (6,000 rpm) when LVEF was compared with pre-LVAD studies. Complete “normalization” of LVEF, however, was not—and in our opinion, should not—be a prerequisite for removal of device support.

LVAD explantation

If the above criteria for ventricular reconditioning could be met and if the patients remained committed to the pursuit of device removal, the device was electively explanted. The

operative technique used for explantation has evolved over time at our institution. Initially, the pump inlet was exposed through a subcostal approach, and a felt plug was placed to occlude the cored ventriculotomy within the sewing ring after the inlet cannula was removed. The outflow graft was then oversewn, and the pump was completely removed.[17] To make explantation less invasive, we modified our technique and left the inflow cannula (coated in nonthrombogenic sintered titanium) in place by excising the inflow bend relief material and oversewing the exposed inflow graft.[18] As with the original technique, the outflow graft was oversewn, and the pump (except for the inlet) was removed.[19]

The retained graft material was well tolerated. As a result, we have now simplified the explant technique further. We use a subxiphoid approach that allows us to ligate the outflow graft (to prevent regurgitant flow) and superficially excise the driveline, leaving the inert pump in place. This technique further minimizes surgical risk. Two patients were found to have thrombosed outflow grafts during the weaning process. A simple transection of the driveline was performed in these 2 patients.

Statistical analyses

All analyses were performed with SAS 9.1 software (SAS Institute Inc, Cary, NC). Continuous variables are expressed as mean ± standard deviation (SD) or median (25th–75th percentile) and were compared by performing the Wilcoxon signed rank test. Categoric variables are described by frequency (%) and were compared by using Fisher's exact test. A p value of ≤0.05 was considered significant.

Results

Of the 30 patients studied, the etiology of cardiomyopathy was characterized as ischemic in 2 and non-ischemic in 28 (Table 1). Fifteen patients were officially listed as BTT candidates, and the rest were designated as DT because of a variety of criteria precluding transplant eligibility at the time of implant (e.g., BMI > 30 kg/m^2, pulmonary hypertension, or less than 5 years of cancer remission). Before LVAD implantation, 12 patients were supported by an intraaortic balloon pump (IABP), and 4 patients required placement of a TandemHeart percutaneous VAD (CardiacAssist Inc, Pittsburgh, PA). Five of the patients studied were originally supported by the HeartMate XVE (Thoratec Corp), and 1 had undergone HeartMate II exchange because of pump malfunction before explant. Of the 30 patients studied, 27 ultimately underwent elective LVAD explantation.

The LVADs could not be explanted from 3 patients (2 men, 1 woman) whose average age was 22 ± 6.1 years (range, 17–29 years; Table 1). These patients were supported by the HeartMate II and had been diagnosed with non-ischemic cardiomyopathy. None had significant improvement in LV function despite an aggressive weaning protocol. All 3 patients underwent successful transplantation after an average duration of continuous-flow LVAD support of 1,097 ± 424 days (range, 643–1,483 days). One patient whose LVAD was explanted required another pump implant 2.7 years after the first pump was removed because his heart failure symptoms recurred; this patient ultimately received a heart transplant after an additional 598 days of LVAD support.

The explant cohort consisted of 25 HeartMate II recipients and 2 HeartWare patients (16 males, 11 females) whose average age was 37.5 ± 12.7 years (range, 14–64 years; Table 1). The average duration of continuous-flow LVAD support before explant was 533 ± 424 days (range, 42–1,937 days). The conditions in 2 patients improved without active weaning, and their devices were removed in accordance with the above-mentioned criteria regarding normalization of the cardiac cycle. In 9 patients, the weaning process was accelerated because of device-related complications—specifically, LVAD infection in 6 and device malfunction in 3. There was no statistically significant difference in outcomes related to the surgical approach to explantation (Table 2).

Of the 27 patients whose pumps were explanted, 2 died even though they had satisfactory cardiac function. Both were outpatients at the time of their deaths. One patient died of overwhelming sepsis 341 days after device explantation due to exacerbation of a chronic pump-pocket infection. The second patient died of sudden cardiac death (presumably due to a ventricular arrhythmia) 1.5 years after the pump was explanted to allow for chemotherapy for an aggressive lymphoma. The remaining explant patients (all outpatients) have been followed up for an average of 1,172 ± 948 days (range, 106–2,856 days) and remain in NYHA Functional Class I with medical management alone (Figure 1).

Various hemodynamic measurements showed that LVAD support substantially improved the explant patients' cardiovascular function (Table 3). Compared with preimplantation values, the patients' mean CO, CI, PCWP, SysPAP, LVEF, and LVEDD were significantly improved at the time of LVAD explantation ($p < 0.05$). Compared with pre-implant echocardiographic studies, the presence and severity of mitral regurgitation were also significantly reduced before device removal (Figure 2).

Discussion

The results of this descriptive, non-randomized study indicate that continuous-flow LVADs can be successfully removed and that cardiac function can be sustained for more than 7 years after device explantation. As patients have become more sophisticated regarding treatment options for heart failure, some have asked about the possibility of LVAD removal, with the hope of avoiding or delaying transplantation. In the explant cohort in this study, 33% of patients were aged younger than 30 years at the time of their implant. Our younger patients, in particular, realize that they are statistically unlikely to have a normal lifespan after cardiac transplantation. In the senior author's (O.H.F.) experience, 130 of 487 patients (27%) who received heart transplants between 1982 and 1992 were aged younger than 40 years (average age, 25). Only 32 of these patients are still alive, 9 of whom required a retransplant (adjusted median survival, 11.8 years).

The potential for improved cardiac function after LVAD support has been previously documented. In 1992[20] and again in the mid-1990s,[4,6] we reported improved ventricular function with chronic LV unloading in BTT patients who were supported by LVADs for extended periods. In our 1994 series, 18 patients with implanted pulsatile LVADs showed normalization of left-sided cardiac anatomy, physiology, histology, and subcellular calcium metabolism. In 1994, Loebe et al[21] successfully removed an LVAD from a chronically

supported patient whose heart function had improved. Birks et al[22] reported the use of clenbuterol, a β_2 receptor agonist, as adjuvant therapy to assist with successfully weaning patients from pulsatile LVADs. Several more recent prospective studies have reported successful, although limited, device explantation after improvement in ventricular function.[23]

With the widespread use of continuous-flow blood pump technology, patients with advanced, decompensated heart failure can now benefit from prolonged, efficacious LVAD support. All of the patients in the study cohort remained in NYHA Functional Class I while they were LVAD dependent. With effective LVAD support, the decompensated heart has the potential to be reconditioned, allowing for the possibility of LVAD removal and a patient's return to medical management. This possibility was realized in 27 of our 30 study patients. We could not safely unload the ventricle in the remaining 3 patients enough to allow the diseased myocardium to be reconditioned. In these patients, the high pump speeds needed to normalize ventricular dimensions caused excessively elevated blood pressure, which was the principal limitation to weaning. We were unwilling to accept the known increased risk of hemorrhagic stroke associated with elevated nonpulsatile blood pressure, particularly in these young patients.

Although the HeartMate II is a significant advance in LVAD technology, it was not designed to allow for effortless ventricular reconditioning. In fact, with continuous-flow devices placed outside the ventricle, the inlet cannula acts as a restrictor to inflow, which helps ensure the presence of an adequate ventricular reservoir, thus optimizing device flow. This also protects against septal shift, which helps to preserve adequate right ventricular function. However, the restriction of flow by the extracardiac positioning of the pump (and the resulting inflow restriction) limits LV unloading, an important prerequisite for ventricular reconditioning.[24] Once aortic valve opening is achieved, the pump changes from operating in series to operating in parallel with the heart. Only with parallel flow between the LV and the pump can ventricular reconditioning occur. Once parallel flow is successfully achieved, our approach is to increase the workload of the native ventricle gradually by decreasing the rpm and by using the aortic valve opening time (at 6,000 rpm) as a surrogate for assessing improvement in native ventricular function. We have found that such active intervention (i.e., unloading and gradually reloading the failed ventricle) may facilitate ventricular reconditioning and allow successful device removal.

Frequent echocardiographic evaluation is needed to assess ventricular function. We have an ultrasound station in our outpatient clinic, which allows evaluation of patients' functional cardiac dynamics in real time by clinicians actively involved in their care, thus minimizing cost and improving the efficiency of reconditioning efforts.

Once the cardiac cycle normalized and overall patient reconditioning occurred (as shown by outpatient functional status or satisfactory exercise test results), we considered withdrawing device support. Although this approach to reconditioning has been successful, it can be painstakingly slow and took longer than 5 years for 1 patient, 3 years for 2 patients, and 2 years for 4 patients. Because of the controller limitations, patients had to return to the clinic frequently for us to actively assess native heart function at variable speeds to maximize

ventricular reconditioning. At 8,000 rpm (the lowest outpatient setting), the device may still unload the ventricle, making it difficult to optimally recondition the heart.

To be more effective in reconditioning the failed ventricle, continuous-flow pumps should ideally have a setting that allows intermittent phasing of pump flow. For a set number of seconds every minute, a lower rpm setting would decrease the pump flow to allow the aortic valve to open and the pump and ventricle to operate in parallel.[25] This operational mode is currently available only for the Jarvik 2000 (Jarvik Heart, Inc. New York, NY) pump. By incrementally increasing the time during which the pump rpm is decreased and the pump operates in parallel with the heart, ventricular reconditioning with the goal of device removal would be facilitated.

Two patients died after their pumps were explanted. In the first patient, the device was removed because the pump was infected, and heart function seemed acceptable for device removal. However, at explantation, the infection was found to extend to the actual implant site on the myocardium. Despite stable ventricular function, this patient died of sepsis more than 1 year after the explant. The other post-explant death occurred suddenly in an outpatient who was clinically stable despite undergoing active treatment for lymphoma. This death was presumably due to an arrhythmia and has caused us to carefully assess patients for possible implantation of an automatic internal cardioverterdefibrillator.

This study is limited by its size and by the overall observational, descriptive design, which involved a 30-case patient series. The study was not protocol driven, and some of the patients asked to be weaned from the device rather than undergo heart transplantation. A strength of this single-center experience is that it had a large cohort of patients with continuous-flow LVADs who underwent ventricular reconditioning with a long follow-up.

Finally, it is important to remember that a major barrier to heart failure remission and device removal is the failure to actively pursue a reconditioning strategy. Cardiac function, as a rule, did not completely return to normal in our explant patients. However, the patients were found to have progressed to a state of compensated heart failure, which safely allowed device removal. For example, 1 post-explant patient has consistently had an ejection fraction of 30% to 40% and continues to be maintained on conventional medical therapy. Six years after device removal, she is very active, teaching school and caring for her family. The patient who developed a recurrence of heart failure symptoms nearly 3 years after explant initially received his pump at the age of 17 (i.e., as an immature adolescent). By the time he received his heart transplant, he was nearly 6 years older and had become a compliant and responsible young adult with a job and a family and, thus, also a better transplant candidate.

In summary, continuous-flow LVADs have given physicians options for long-term, reliable circulatory support. We believe that device removal, if feasible, remains the best outcome of device implantation, particularly for young heart failure patients, who are unlikely to live a normal lifespan even after a successful heart transplant. Late complications occur despite the relative safety and long-term durability of continuous-flow pumps. The risks of prolonged mechanical circulatory support, coupled with the ease of successful explantation of these devices, should encourage an aggressive approach to cardiac reconditioning with the

ultimate goal of device explantation and returning the patient to routine medical management. However, until LVAD centers are actively pursuing this approach, the true incidence of sufficient ventricular recovery to allow LVAD explantation will not be known.

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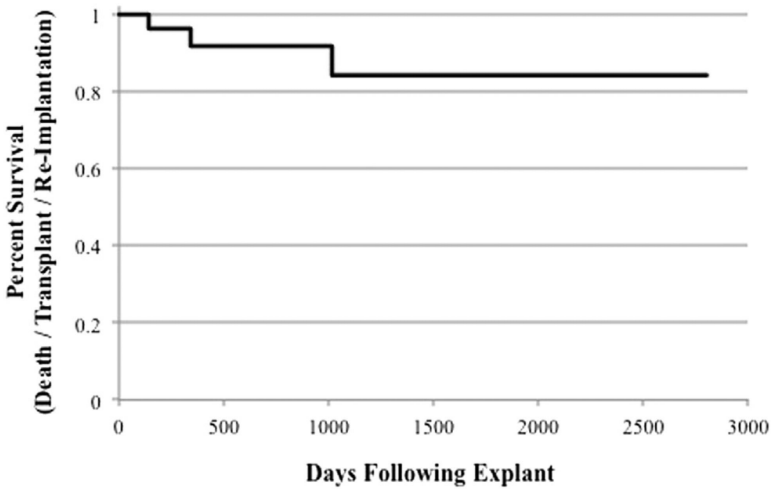

Figure 1.

Kaplan-Meier survival curve for the explant cohort. Overall survival was defined as days free from death, transplant, or device reimplantation.

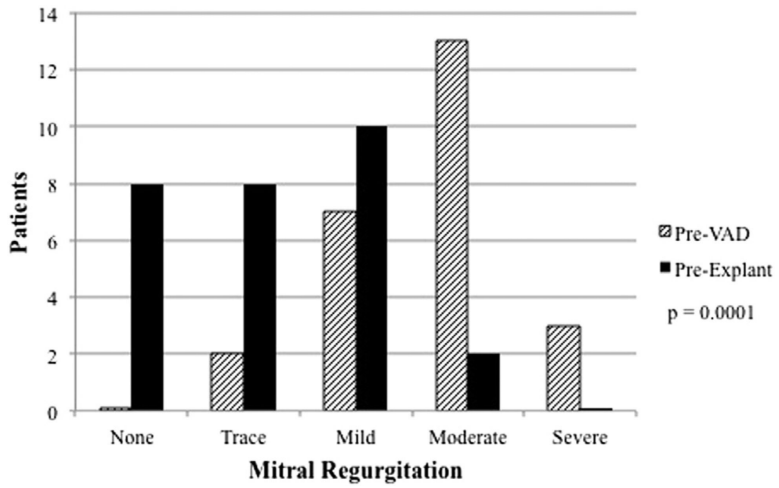

Figure 2.

Presence of mitral regurgitation before left ventricular assist device (VAD) implant and explant ($p = 0.0001$).

Table 1

Demographic and Preimplantation Characteristics of the Study Patients

Characteristics[a]	Explant (*n* = 27)	Non-explant (*n* = 3)
Age at implant, years	37.5 ± 12.7	22 ± 6.1
Body surface area, m^2	2 ± 0.29	1.74 ± 0.18
Sex		
Male	16	2
Female	11	1
Cause of cardiomyopathy		
Ischemic	2	0
Non-ischemic	25	3
Device implanted		
HeartMate II[b]	25	3
HeartWare[c]	2	0
LVAD designation		
Bridge to transplant	12	3
Destination therapy	15	0
Support before LVAD		
Intraaortic balloon pump	11	1
TandemHeart[d]	3	1
HeartMate XVE[b]	5	0
Prior LVAD exchange, No.	6	0
CF support duration, days	532.5 ± 423.6	1,097.2 ± 424

CF, continuous flow;LVAD, left ventricular assist device.

[a] Values are shown as the mean ± standard deviation for continuous variables and as the number for categoric variables.

[b] Thoratec Corp., Pleasanton, California.

[c] HeartWare International, Framington, Massachusetts.

[d] CardiacAssist Inc, Pittsburgh, Pennsylvania.

Table 2

Support, Intervention, and Outcome Characteristics of the Explant Cohort

Variables	Mean ± SD or No.
Age at explant, years	39.1 ± 12.4
Device	
HeartMate II[a]	25
HeartWare[b]	2
Duration of CF-LVAD support, days	532.5 ± 423.6
Total duration of LVAD support, days	602.2 ± 516.1
Surgical approach	
Sub-costal/excision/plug	13
Sub-costal/excision/ligation	7
Sub-xiphoid/ligation	5
Driveline transection	2
Post-explant length of stay, days	16.9 ± 11.7
Post-operative outcomes	
Transplant	1
Device reimplantation	1
Stroke	3
Death	2
Overall survival post-explant, days[c]	1,097 ± 925.8

CF, continuous flow;LVAD, left ventricular assist device;SD, standard deviation.

[a] Thoratec Corp., Pleasanton, California.

[b] HeartWare International, Framington, Massachusetts.

[c] Overall survival defined as days free from death, transplant, or device reimplantation.

Table 3

Explant Cohort Hemodynamic and Echocardiographic Data

	Pre-LVAD	Pre-explant	
Variables	**Mean ± SD**	**Mean ± SD**	**p-value**
Fick CO, liters/min	3.73 ± 1.1	6.41 ± 1.9	<0.0001
Fick CI, liters/min/m^2	1.8 ± 0.5	3.34 ± 0.9	<0.0001
PCWP, mm Hg	25.9 ± 10.5	11.5 ± 8.4	<0.0001
Systolic PAP, mm Hg	34.4 ± 12.3	21.4 ± 9.2	0.0009
LVEF, %	20.3 ± 8	46.93 ± 7.9	< 0.0001
LVEDD, cm	6.49 ± 0.9	4.94 ± 0.9	< 0.0001

CI, cardiac index;CO, cardiac output; LVEF, left ventricular ejection fraction; LVEDD, left ventricular end diastolic dimension; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; SD, standard deviation.