Surgical approach to continuous-flow left ventricular assist device explantation: A comparison of outcomes

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ABSTRACT

Objective: Ventricular reconditioning and device weaning in select patients with continuous-flow left ventricular assist devices (CF LVADs) has been shown to be feasible. However, little is known regarding the outcomes associated with different surgical methods of device removal. We examined the effect of surgical explantation approach on early and late outcomes.

Methods: We retrospectively reviewed data from all patients who underwent successful ventricular weaning and CF LVAD explantation at our center. Patients were stratified by surgical approach. Descriptive univariate statistics, multivariate regression, and survival analyses were performed. Patients were censored by transplant, device reimplantation, or end of follow-up.

Results: Twenty-seven patients were identified who underwent successful removal of a CF LVAD (25 HeartMate II, 2 HeartWare) after 532 ± 424 days of support (range, 42-1937 days). Four approaches were used that vary primarily in the degree of retained pump material: complete pump removal with plug ventriculotomy closure ($n = 13$; 48%), pump housing explant with ligation of the inflow and outflow grafts ($n = 7$; 26%), ligation of the outflow graft and driveline transection ($n = 5$; 19%), and driveline transection alone ($n = 2$; 7%). Mean overall postexplant survival was 1286 ± 947 days (range, 143-3072 days). Overall time-to-event and survival analyses showed no significant association between surgical approach and postoperative length of stay ($P = .7$), stroke ($P = .12$), reoperation ($P = .4$), or survival ($P = .12$).

Conclusions: For patients who receive device therapy, pump deactivation and removal represents a favorable outcome. All methods are feasible and produce similar early and late survival and clinical outcomes. (J Thorac Cardiovasc Surg 2016;151:192-8)

Four techniques for explanting a continuous-flow ventricular assist device.

Central Message

Continuous-flow LVADs may be deactivated and removed through a range of surgical approaches, each with similar early and late outcomes.

Perspective

A subset of patients undergoing LVAD support will be considered for pump deactivation and removal. Our approach to explantation has evolved over time in an attempt to reduce the associated risks. We describe a variety of surgical techniques for device removal with similar early and late outcomes. This report should encourage interest in both device weaning and less-invasive approaches to LVAD removal.

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The application of continuous-flow (CF) technology within the field of mechanical circulatory support has revolutionized the treatment of end-stage heart failure. However, despite the medical advantages afforded by left ventricular assist devices (LVADs), patients who require long-term LVAD support are subject to several significant device-specific risks that include infection, gastrointestinal

bleeding, device malfunction, and stroke. Thus, although device therapy can be lifesaving, the goal of device removal and a return to medical therapy should be actively pursued for this patient population.

To this end, several studies have revealed histologic and clinical evidence of myocardial rehabilitation after prolonged periods of LVAD support.¹⁻³ Efforts from our institution^{4,5} and elsewhere^{1,6-8} have sought methods and strategies for ventricular reconditioning and device weaning in select patients supported by CF LVADs. Early results have been encouraging, but the surgical options for device explantation are poorly described in the literature, and little is known regarding the clinical outcomes associated with different methods of device removal.

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Abbreviations and Acronyms

CF	= continuous flow
HM-II	= HeartMate II
HW	= HeartWare HVAD
LVAD	= left ventricular assist device
NYHA	= New York Heart Association

At the Texas Heart Institute, 27 patients completed a CF device-weaning protocol that resulted in pump deactivation and explantation. Surgical methods for device removal have evolved over time at our institution and vary primarily in the degree of retained pump material. Our goal in this retrospective review was to evaluate and compare outcomes according to the operative strategy employed for device removal.

PATIENTS AND METHODS

Patient Selection

Between August 2006 and January 2014, 657 patients were implanted with CF devices at our institution, with the majority supported by either the HeartMate II (HM-II) (Thoratec Corp, Pleasanton, Calif) ($n = 467$) or the HeartWare HVAD (HW) (HeartWare International, Framingham, Mass) ($n = 109$). Before device therapy began, each of the patients was diagnosed with severe end-stage heart failure—New York Heart Association (NYHA) functional class IV—despite receiving optimal medical therapy. By contrast, after pump implantation, the patients recovered sufficiently to be deemed eligible for explant: They were in NYHA functional class I and were being treated on an outpatient basis. The study design was approved by our center's institutional review board before initiating the project.

Thirty patients were evaluated as candidates for pump explantation through a selection process that has been comprehensively described elsewhere.⁹ Inclusion in the device-weaning protocol was determined on an individual basis by an institutional multidisciplinary review committee; the chief considerations were patient age, echocardiographic parameters, and overall clinical condition. Patients were required to express explicit interest in pursuing an explantation strategy and to demonstrate an understanding of the potential risks and benefits of device removal.

Device Weaning

Our institutional protocol for device weaning has been previously published in detail and consists of a stepwise progression of principles designed to optimize the environment for ventricular reconditioning.⁹ After an initial 3- to 6-month period of physical recovery from the index operation, patients are evaluated weekly on an outpatient basis to determine their suitability for the device-weaning protocol. Initially, this process involves a period of ventricular unloading at elevated pump speeds in an effort to reduce left ventricular end-diastolic dimension and mitral regurgitation. Serial echocardiography is then used to assess native heart function by briefly recording aortic valve opening times at minimal pump speeds, and by gradually reducing outpatient maintenance speeds as the measured ratio of aortic valve opening time increases within the cardiac cycle. Once the observed cardiac cycle is normalized at minimal baseline pump speeds, elective deactivation and removal of the device may be considered.

Operative Techniques for Explantation

The surgical approach to device explantation has evolved over time at our institution, resulting in 4 distinct methods, distinguished largely by

the degree of retained foreign material. Because of structural differences in pump design and changes in device availability over time, most of the explanted devices were HM-IIs. One explantation method (requiring the presence of an inflow graft) could not be adapted for use with the HW.

In the first technique, the pump body is approached through a generous left subcostal incision. After the diaphragmatic surface of the heart is exposed, the inlet cannula is withdrawn in its entirety from the left ventricle, and a polytetrafluoroethylene felt plug is quickly placed within the retained sewing ring to seal the cored ventriculotomy.¹⁰ The outflow graft is then cut and oversewn, and the pump is removed in its entirety (Figure 1, A). Because of the risk of arterial gas embolism and bleeding, this technique is performed under brief cardiopulmonary bypass via femoral cannulation. Deairing is accomplished by performing Valsalva maneuvers with a large-bore needle inserted directly through the occlusive polytetrafluoroethylene plug.

In an effort to make the explant process less complex, a modification of this technique was developed to reduce the risks associated with recovering the pump inlet. As with the original method, the pump is exposed through a left subcostal incision, and adhesiolysis is performed to reveal the pump housing, inflow, and outflow conduits. However, rather than remove the inlet cannula from the ventricle, the inflow bend reinforcement material is excised to reveal the enclosed inflow graft, which is then cut and oversewn (Figure 1, B). The HM-II inlet cannula (coated in nonthrombogenic sintered titanium) is thus retained within the left ventricle, obviating the need for cardiopulmonary bypass, ventriculotomy repair, or deairing. The outflow graft is similarly cut and oversewn, and the pump (sans inlet) is removed.

In light of the apparent tolerance of retained device material, a third approach was developed to further simplify the procedure and limit surgical risks. In this method, a limited subxiphoid incision is performed to expose the course of the outflow graft as it leaves the pump (Figure 1, C). After the outer bend-relief material is retracted, the outflow graft is encircled and ligated with heavy silk ties and a large hemostatic clip to prevent backflow through the device after deactivation. A second incision is then made along the driveline exit site, and the driveline is exposed and transected deep to the skin to prevent bacterial migration toward the retained pump.

A final variation was performed in 2 patients whose pumps thrombosed while operating at low maintenance speeds during the weaning process. Rather than surgically access the thrombosed pump, we performed a simple transection of the driveline at the bedside, leaving behind the entirety of the intracorporeal portion of the pump (Figure 1, D). This approach was implemented only in the absence of a confirmed driveline infection.

Statistical Analyses

Statistical data analysis was performed with Statistical Analysis Software version 9.1 (SAS Institute Inc, Cary, NC) on a Macintosh (Apple Corp, Cupertino, Calif) platform. Descriptive univariate analysis was performed, stratifying patients by surgical approach to device explantation. For the purpose of survival analysis, patients were censored by transplant, device reimplantation, or end of follow-up. Continuous variables were expressed as mean $\pm$ standard deviation and compared by using the Wilcoxon signed rank test. Categorical variables were described by frequency (%) and compared by using the Fisher exact test.

RESULTS

After 533 ± 424 days of CF LVAD support, 27 patients (16 men; mean age, 39 ± 12 years) completed a ventricular reconditioning protocol at our institution to allow deactivation of their HM-II ($n = 25$) or HW ($n = 2$) device. All but 2 patients were diagnosed with nonischemic cardiomyopathy. Measured left ventricle end-diastolic dimension, cardiac

FIGURE 1. Pump explantation procedures. A, Complete pump explant. After removal of the pump housing (including the inlet cannula), the outflow graft is ligated, and the ventricular sewing ring is occluded with a polytetrafluoroethylene plug. B, Inflow and outflow ligation. The inflow bend relief material is excised to allow ligation of the inner graft and retention of the inlet cannula. The pump housing is removed after similar ligation of the outflow graft. C, Outflow graft ligation. The outflow graft is exposed and ligated through a subxiphoid incision. The driveline is then transected at the level of the skin. D, Driveline transection. The pump is left in place, and the percutaneous driveline is cut at the exit site.

index, and pulmonary artery pressures were significantly improved at the time of explantation when compared with values recorded before device therapy began ($P < .05$) (Table 1).

Overall postexplant survival (defined as time preceding transplant, device reimplantation, or end of follow-up) was 1286 ± 947 days. Despite the improvement in native cardiac function, 3 patients died: 2 of sepsis (on postoperative days 341 and 513) resulting from chronic pump-pocket infections, and 1 of a sudden ventricular arrhythmia 1.5 years after explant. Another patient's heart failure symptoms recurred nearly 3 years later; this patient underwent device reimplantation 1015 days after explantation. He ultimately received a heart transplant after an additional 598 days of CF LVAD support. The surviving patients have been followed-up in the outpatient setting for an average of 1422 ± 954 days, and they remain in NYHA functional class I with medical management alone.

Four surgical approaches were used: complete pump explant with plug ventriculotomy closure ($n = 13$ complete

removal; 48%), pump explant and ligation of the inflow and outflow grafts ($n = 7$ inlet retention; 26%), subxiphoid ligation of the outflow graft and driveline transection ($n = 5$ subxiphoid ligation; 19%), and driveline transection alone ($n = 2$ driveline transection; 7%). Primary incisions were subcostal ($n = 19$; 70%) or subxiphoid ($n = 5$; 19%), with 1 (7%) conversion to redo sternotomy. The patients exposed to the various surgical techniques were not significantly different in age, gender, or duration of CF support (Table 2).

The choice of surgical approach was primarily determined by chronology, because the technique for device removal evolved with our growing institutional experience. This imbalance in timing is reflected in the average postoperative survival associated with each successive method. However, Kaplan-Meier survival analysis stratified by surgical approach revealed no statistically significant differences in postoperative survival among the 4 groups (Figure 2). Although postoperative length of stay was equivalent, postoperative intensive care unit stays became

TABLE 1. Overall explant cohort characteristics

Characteristic	Result
Age at explant (y)	39.1 ± 12.4
Gender	
Male	16
Female	11
Cause of heart failure	
Nonischemic	25
Ischemic	2
Left ventricle end-diastolic dimension (cm)	
Before CF LVAD implantation	6.49 ± 0.9
Before explantation	4.94 ± 0.9
Cardiac index (L/min/m ²)	
Before CF LVAD implantation	1.8 ± 0.5
Before explantation	3.34 ± 0.9
Systolic PAP (mm Hg)	
Before CF LVAD implantation	34.4 ± 12.3
Before explantation	21.4 ± 9.2
Duration of CF LVAD support (d)	532.5 ± 423.6
Postexplant length of stay (d)	16.9 ± 11.7
Postexplant survival (d)	1286 ± 947

Values are presented as mean ± standard deviation or n. CF LVAD, Continuous flow left ventricular assist device; PAP, pulmonary artery pressure.

shorter over time, because each approach was less invasive than its predecessor.

Four patients (1 complete removal and 3 subxiphoid ligation) had a documented neurologic event after the pump was deactivated. All such events were ischemic in origin and occurred an average of 147 ± 194 days after the explant procedure. Two of these events were attributed to acute surgical complications outlined below. The remaining events included a transient mental status change following a hypotensive episode during percutaneous intervention 1 week postexplant, and a temporary change in mental status reported by an outpatient 415 days after the pump was explanted, believed to be the result of chronic medical comorbidities. All of the patients eventually returned to their baseline neurologic status after the event, and none had recurrent cerebrovascular episodes.

TABLE 2. Explant patient characteristics and outcomes by surgical approach

Characteristic	Explant/plug	Explant/ligation	Subxiphoid ligation	Driveline transection
Patients	13 (48)	7 (26)	5 (19)	2 (7)
Age (y)	33.9 ± 10.7	43.9 ± 8.6	44.3 ± 18.7	42.7 ± 5.5
Sex				
Male	9	4	3	0
Female	4	3	2	2
Duration of CF LVAD support (d)	571.2 ± 320	446.8 ± 393	669.6 ± 726	238.0 ± 253
Chronic infection	5	3	3	0
Postoperative ICU stay (d)	6.8 ± 2.9	5.6 ± 2.5	4.8 ± 5.3	2.5 ± 2.0
Postoperative length of stay (d)	14.5 ± 10	19.7 ± 11	16.8 ± 9	24.0 ± 33
Stroke, (days postexplant)	1 (415)	0	3 (3, 7, 163)	0
Reoperation	3	2	3	1
Death	1	1	0	0
Postexplant survival, d	1892.7 ± 999	903.4 ± 425	615.0 ± 342	357.5 ± 3.5

Values are presented as n (%) or mean ± standard deviation. CF LVAD, Continuous flow left ventricular assist device; ICU, intensive care unit.

Nine patients required reoperation after the initial procedure. One patient underwent thoracotomy for retained hemothorax 13 days later, and a second underwent conversion to inlet retention 27 days after concern for embolic phenomenon obligated reexploration and revision of her previous subxiphoid ligation procedure. The remaining 7 patients (3 complete removal, 2 inlet retention, and 2 subxiphoid ligation) required additional surgical intervention for persistent device-related infection despite efforts to remove infected tissue during the initial procedure (Figure 3). Six of these patients had a documented chronic driveline infection before the initial explant procedure. Four underwent incision and drainage only; the other 3 required further retrieval of retained infected material. Two patients ultimately died of complications from sepsis despite multiple surgical debridement procedures. There was no association between surgical approach to explant and the rate of reoperation.

DISCUSSION

Beginning in the early 1990s, a series of studies revealed the potential for histopathologic improvement in myocardial tissue samples after prolonged periods of LVAD support.^{1,4} Clinical demonstration of this concept soon followed: Improved ventricular function was seen in bridge-to-transplant patients after chronic unloading with pulsatile LVADs.^{5,7} More recently, this observation has been reported in patients supported by CF devices.^{9,11} These findings helped to establish the theory that select patients could benefit from a strategy of ventricular reconditioning and deactivation of the pump. However, in patients for whom device removal may be considered, little has been reported regarding the various operative techniques for explantation, much less the outcomes associated with these techniques.

Twenty-seven patients supported by CF LVADs completed a device-weaning protocol at our institution that allowed deactivation of the device. One patient ultimately required resumption of device therapy, and 3 patients died

FIGURE 2. Kaplan-Meier survival analysis stratified by surgical approach to explantation.

an average of 332 days after device removal. Although 2 deaths were the result of pump-related infections, none were directly attributed to the method of device explant, and the remaining patients have experienced an average of 1422 ± 954 days of postoperative survival. Of the 4 surgical methods for device explant described, no significant differences were found with regard to associated rates of reoperation, stroke, or overall survival. The less-invasive approaches were associated with shorter intensive care unit stays, but overall postoperative length of stay was

equivalent, probably because of the subsequent titration of pharmacologic heart failure therapy. Explantation of the early-generation pulsatile LVADs was associated with significant perioperative morbidity because of the need for redo sternotomy, obligatory cardiopulmonary bypass, and extensive adhesiolysis to retrieve the large pump housings. As a result of this experience, our approach to device removal has evolved over time in an effort to reduce the surgical risks associated with explantation.

FIGURE 3. Time-related depiction of reoperation for infectious causes stratified by surgical approach to explantation. Vertical markings represent reoperative events, with color changes indicating conversion to an alternative explant approach through the removal of additional device material.

One concept that has guided our approach is tolerance of the human body to retained material after a period of device support. In DeBakey's original report¹² of the first use of a device for left heart support, the inflow and outflow grafts were ligated (under local anesthesia) and left in place underneath the skin on deactivation of the pump. The approach was apparently well tolerated without subsequent complications related to the retained material. More recently, our institution similarly reported the tolerance of retained blind graft limbs after removal of a Jarvik 2000 (Jarvik Heart, New York, NY) device, even in bridge-to-transplantation patients who required immunosuppression.¹³ The retained outflow grafts were found to thrombose quickly and without extension of the thrombus into the higher-pressure system of the aorta. By dramatically reducing the extent of surgical dissection required, this concept has been instrumental in guiding our efforts to reduce the morbidity of explant procedures.

Despite previous documentation of its safety, the presence of retained material is considered by some to be a possible risk factor for cerebrovascular events after device explant. In the present study, 4 patients were diagnosed with a stroke after the pump was deactivated. All strokes were ischemic in origin, but none were found to be directly attributable to an inherent hematologic disturbance caused by the retained material. Two of the events were directly related to acute surgical complications. One patient experienced multiple strokes and splenic emboli in the initial postoperative days after subxiphoid ligation of her HW device. Surgical reexploration revealed that the hemostatic clips used to occlude the outflow graft had migrated, allowing residual flow through the graft conduit and showering of incompletely formed thrombi. The device was removed through a left thoracotomy, and the HW sewing ring was closed with a felt plug. The other patient required reoperation after 163 days for persistent infection of the pump housing after subxiphoid ligation. A stroke was then diagnosed in the immediate postoperative period and was attributed to manipulation of the thrombosed outflow graft at the level of the ascending aortic anastomosis during resection via minithoracotomy. The remaining 2 events—1 that occurred 415 days after complete removal in a patient with multiple comorbidities, and the other after instrumentation for percutaneous coronary intervention and Impella support after myocardial infarction with subsequent hypotension—are likewise believed to be unrelated to the presence of retained device material.

The presence of a chronic infection remains a significant risk factor for reoperation after device removal. Although there was no significant difference in the risk of reoperation associated with the different surgical approaches, 6 of the 10 patients with a documented preoperative superficial driveline infection required eventual debridement or further retrieval of infected material. Additionally, among the 9 patients who required reoperation, 7 of the procedures were necessitated

by an infectious process, and 2 deaths were directly related to sepsis in patients who required multiple surgical debridements. Due to the risk of infectious complications, we believe that complete excision (and thus removal of all foreign material) to represent the most appropriate approach in the presence of known infection or overt seeding of device material. However, the pursuit of complete pump excision did not significantly affect the overall risk of reoperation for infection in our patient population. The 2 patients who underwent driveline transection alone (ie, who had the most retained material) were evaluated preoperatively to ensure the absence of chronic superficial infection due to the perceived risk for bacterial seeding of the devitalized pump.

Finally, there has been considerable debate regarding whether anticoagulation should be continued in postexplant patients. With no flow through the deactivated pump or thrombosed grafts, the pump circuit is excluded from the circulation after the explant operation. Furthermore, the inlet cannula of the HM-II is coated in sintered titanium, resulting in an endothelialized (and thus nonthrombogenic) surface after prolonged contact with the bloodstream. As a result, we believe that the presence of retained device material (including the inlet) should not be considered an indication for long-term anticoagulation after device explant. Rather, the decision to prescribe anticoagulants to these patients should be based solely on standard medical indications.

Although CF LVADs represent a lifesaving option for patients with end-stage heart failure, we believe that deactivation of the pump and a return to medical therapy represents a favorable outcome for this patient population. Should explantation be considered, various surgical options exist for deactivating the pump, and the choice of approach should be made on a case-by-case basis. Our study is limited by its small size, and although no approach appears significantly more advantageous than the others, more experience and analysis is required to fully evaluate the comparative risks. Nonetheless, each method is feasible and well tolerated, providing a range of available options when device deactivation is considered. The risks associated with long-term mechanical circulatory support and the viability of these methods for explantation warrants an active and aggressive strategy of ventricular reconditioning and device weaning in all patients receiving device support.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: left ventricular assist device (LVAD), ventricular reconditioning, ventricular recovery, device explantation

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