Treatment of HeartMate II Short-to-Shield Patients With an Ungrounded Cable: Indications and Long-Term Outcomes

Laura Coyle, Nicole Graney, Colleen Gallagher, Robin Paliga, Gardner Yost, Pat Pappas, Gregory Macaluso, and Antone Tatooles

Despite modifications and a procedure to externally replace the distal portion of the percutaneous lead, damage to the wiring insulation causing an electrical short to ground, referred to as a short to shield (STS), has become an important factor in the longevity of the HeartMate II left ventricular assist device (LVAD). Device exchange has been the suggested treatment option. The aim of this study was to evaluate the long-term clinical outcomes of patients with an STS supported on an ungrounded cable. A retrospective review of all patients (n = 479) implanted with a HeartMate II at our center between January 2008 and December 2017 was performed. Patients with a documented STS maintained on an ungrounded cable were examined. Patient characteristics, time from device implantation to STS, treatment strategies, and duration of support on an ungrounded cable were summarized. The association between support with an ungrounded cable and clinical outcomes was evaluated. A total of 53 (11% of 479) patients (83% males and 81% DT) with an STS were supported on an ungrounded cable for a median duration of 195 days (range 2 days to 3.3 years). Patients were more active (New York Heart Association [NYHA] $p < 0.001$, 6 minute walk test [6MWT] $p = 0.003$) and had a trend toward increased weight gain ($p = 0.055$) from time of implant to STS. Duration of support before the STS was 1.9 years (range 165 days to 8.6 years). Twenty-two patients were treated directly with an ungrounded cable and 31 patients underwent an external driveline repair and still required an ungrounded cable within 2 days (range 0 days to 1.3 years). During the study period, 38 patients were maintained on an ungrounded cable: 21 patients were ongoing for 299 days (range 114 days to 2.8 years), 11 patients transplanted after 79 days (range 7–295 days), four patients died because of comorbid conditions after 1.6 years (range 141 days to 3.2 years), one patient exchanged for thrombosis after 229 days, and one patient explanted after 279 days. The other 15 patients developed a phase-to-phase electrical short after 51 days (range 2 days to 3.3 years): 14 patients underwent a successful pump exchange and one patient transplanted within 2 days. No patients died because of support with an ungrounded cable or worsening lead damage necessitating device exchange. With extended durations of support, some patients with a HeartMate II LVAD will experience device failure in the form of an STS. Select patients with an STS can be safely supported on an ungrounded cable for several years with close monitoring. This treatment approach should be considered before a device exchange. *ASAIO Journal* XXX; XX:00–00.

Key Words: left ventricular assist device, driveline, short to shield, device failure

Background

The HeartMate II (Thoratec Corp., Pleasanton, CA) left ventricular assist device (LVAD) was designed based on the development and principles of continuous axial flow pumps to improve upon the limitations of the original HeartMate I (Thoratec Corp.). These technological advances proved the HeartMate II to be more durable and efficient than its predecessor.[1,2] Coupled with a better understanding of patient selection and enhanced clinical management, a reduction in adverse events and an improved survival[3,4] led to the implantation of more than 26,000 HeartMate II LVADs worldwide.[5] Despite recent advancements in mechanical circulatory support therapy with the U.S. Food and Drug Administration (FDA) approval of the HeartWare HVAD (HeartWare, Inc., Framingham, MA) for thoracotomy approach[6] and HeartMate III LVAD (Abbott, Abbott Park, IL) considered to be superior to the HeartMate II for the treatment of advanced heart failure,[7] more than 8,350 patients remain on support with a HeartMate II LVAD.[5]

As an increasing number of patients were implanted with the HeartMate II LVAD, damage to the percutaneous lead emerged as an issue in the long-term durability of this device. Two structural changes in the percutaneous lead design, the external strain relief at the controller end in 2007 and internally at the pump-end bend relief in 2010, reduced the incidence of external and internal lead failures.[8] In addition, a procedure to replace the distal portion of the percutaneous lead was developed to avoid device exchange in those patients with isolated external lead damage.[9] Despite these modifications, driveline failure remains a factor in the longevity of the HeartMate II LVAD.[10,11]

One cause of driveline failure in the HeartMate II is damage to the wiring insulation of the percutaneous lead resulting in an electrical short to ground, referred to as a short to shield (STS). The percutaneous lead has six electrical wires attached to six motor stators to power a three-phase pump. There are three stranded primary wires and three back up wires for each of the phases. An STS occurs when there is an inappropriate electrical

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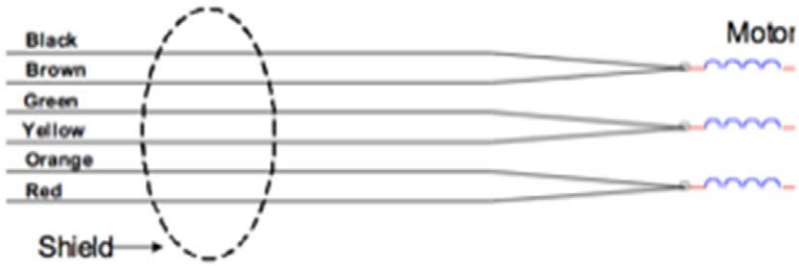

Figure 1. Illustration of internal wiring of HeartMate II percutaneous lead.

connection between one of the stranded wires and the shield, causing an disruption in the normal flow of power(**Figure 1**). The stranded wire is composed of many small wires wrapped together to form a larger conductor. These twisted conductors are surrounded by a silver-plated copper braided shield and protected by two water-resistant jackets (**Figure 2**). The shield was designed to allow for electromagnetic compatibility with other electronic devices. However, there have been no reported incidents of isolated damage to the shielding leading to electromagnetic interference.[9] With advancements in technology and no reported events, the risk of electromagnetic interference while on an ungrounded cable is considered to be very low. Physical damage to the shield, often attributed to repeated flexion or excessive twisting, can result in retraction of the shield (**Figure 3**) potentially causing wear damage to the insulation of the powered conduits. When there is a breach to the outer insulation of one of the conductors (**Figure 4**), there is the potential for unintended electrical contact between the wire strands and the metal braided shield, resulting in an STS.[9] This condition can result in speed reduction and pump stoppage when the pocket controller is connected to alternating current or a grounded power source such as the mobile power unit (MPU) and power module (PM). Placing a patient with an STS on batteries or an ungrounded cable, also referred to as a "no ground," "nongrounded," or "modified" power cable, will provide direct current and prevent the STS from occurring. If there are multiple breaches or damage to the insulation of more than one conductor, there is the potential for a phase-to-phase electrical short. This condition can cause pump stoppage if the exposed wires of the two compromised conductors make direct contact with each other or simultaneous contact with the metal braided shield regardless of power source.[9]

With a significant number of patients remaining on support with the HeartMate II LVAD for extended durations, device failure in the form of an STS will continue to become more prevalent. Recognition and treatment of an STS have not been well published, with only one case report examining this type of driveline failure.[12] We evaluated the incidence of device failure because of percutaneous lead damage and report the long-term clinical outcomes of patients with an STS treated with an ungrounded cable at our institution.

Methods

A retrospective review was conducted on 479 patients implanted with a HeartMate II LVAD between January 1, 2008, and December 31, 2017, at a single center in the United States. The incidence of device failure because of percutaneous lead damage was examined, and patients with a documented STS supported on an ungrounded cable were further reviewed. This was approved by the Advocate Christ Medical Center Institutional Review Board and allowed for at least 1 year of follow-up for all patients. Patient characteristics, time from device implantation to STS, treatment strategies, and time spent on an ungrounded cable were assessed. The association between support on an ungrounded cable and clinical outcomes was also evaluated.

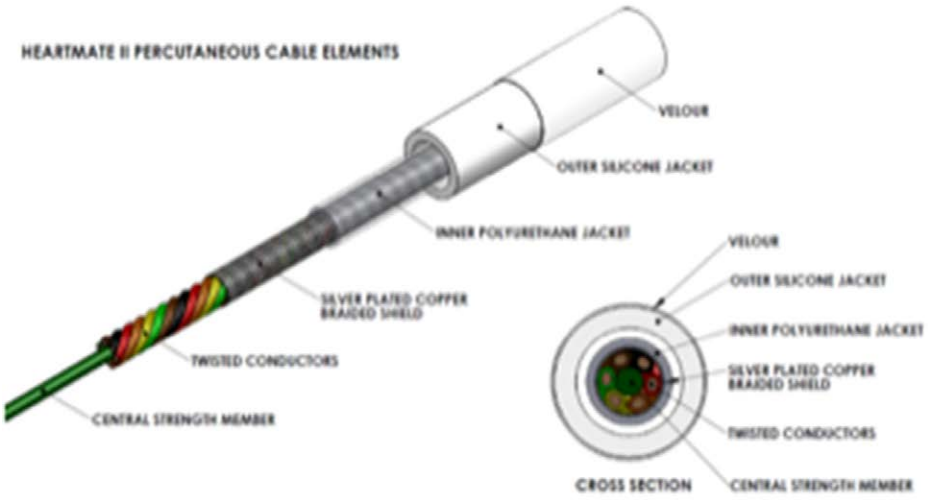

Figure 2. Schematic representation of HeartMate II percutaneous lead construction.

Figure 3. Radiograph image of breakdown of silver-plated copper braided shield.

An STS was suspected when electrical continuity testing or pocket controller diagnostics revealed that all the wires were electrically intact; however, interruption in pump function occurred when connected to a grounded power source. Clinical interrogation and review of HeartMate II log files for each patient were conducted for unusual alarms including low flow, low speed advisory, pump off, and driveline disconnected. Device failure was defined as a failure point along the percutaneous lead producing pump stoppage. An STS was confirmed with visual inspection, manual manipulation, positional changes, radio diagnostic imaging, or log file analysis validating that pump off alarms were elicited when a patient was on a grounded power source. Patients who underwent an external driveline repair and subsequently required an ungrounded cable or patients treated directly with an ungrounded cable for an STS were followed clinically to determine outcomes. A flow diagram indicating this diagnostic and treatment pathway is provided in **Figure 5**.

Paired t-tests were used to compare continuous data at the pre-LVAD and STS time points. Chi-squared analyses were used to compare categorical data. All statistical operations were computed using SPSS (IBM, Chicago, IL).

Results

Between January 1, 2008, and December 31, 2017, a total of 479 patients were implanted with a HeartMate II LVAD at our center. Seventy (14.6%) patients experienced device failure because of percutaneous lead damage. Eight (1.7%) patients immediately underwent a device exchange: five patients for confirmed damage at the pump-end bend relief and three patients for a phase-to-phase electrical short. Two (0.4%) patients underwent an external lead repair for accidentally severing the driveline. Sixty (12.5%) patients experienced device failure because of an STS. The total days on device therapy for all patients (N = 60) who experienced an STS was 3.6 years (range 1.2–9.9 years). Of these 60 patients, four patients underwent a successful external repair and remain on grounded support for a median duration of 318 days, one patient required an emergent pump exchange because of catastrophic failure during the external repair and remains on device therapy for 1.3 years, and one patient underwent a second external lead repair 284 days after the distal portion of the lead was replaced for another STS, which was unsuccessful, and subsequently underwent a device exchange resulting in a 30 day mortality. Additionally, one patient underwent an elective device exchange after 2.8 years of support because of a chronic driveline infection and died 2.9 years later because of multisystem organ failure. These seven STS patients did not receive support from an ungrounded cable and were excluded from further review.

Figure 4. Damage to the percutaneous lead with insulation abrasion exposing inner wire strands to the silver-plated copper braided shield.

Overall, 53 (11% of 479) patients were supported on an ungrounded cable for an STS. Patient demographics for this group are shown in **Table 1**. Most patients were male (83%) and implanted as destination therapy (81%). Patients were more active (NYHA class $p < 0.001$, 6MWT $p = 0.003$) and had a trend toward increased weight gain ($p = 0.055$) between the time of implant and the index STS event. There was no significant relationship between the development of a device-related infection and surgical technique in those patients who had STS (59.3% *vs.* 40.7%, $p = 0.491$). There was an increasing event rate for STS per year between the beginning of the study in 2008 and 2013 (**Table 2**). The median duration of mechanical support before the STS was 1.9 years (range 165 days to 8.6 years). Of the 53 patients, 22 (42% of 53) patients were treated directly with an ungrounded cable and 31 (58% of 53) patients underwent an external driveline repair after a median of 4 days (range 1–118 days) from their initial STS and were placed on an ungrounded cable within 2 days (range 0 days to 1.3 years) for a recurrent STS. Overall, the median duration of mechanical support on an ungrounded cable was 195 days (range 2 days to 3.3 years), with six patients greater than 1 year, five patients greater than 2 years, and one patient more than 3 years of support on an ungrounded cable.

During the study period, 38 (72% of 53) patients did not develop worsening lead damage producing pump off alarms while treated with an ungrounded cable for an STS. Of these 38 patients, 21 patients remain ongoing with support from an ungrounded cable with a median duration of 299 days (range 114 days to 2.8 years), 11 patients were transplanted after 79 days (range 7–295 days), four patients died because of comorbid conditions after 1.6 years (range 141 days to 3.2 years), one patient was exchanged for pump thrombosis after 229 days, and one patient was explanted after 279 days of support with an ungrounded cable. No patients with an STS died because of nongrounded support on batteries or an ungrounded cable. The total days on device therapy for these patients is shown in **Table 3**.

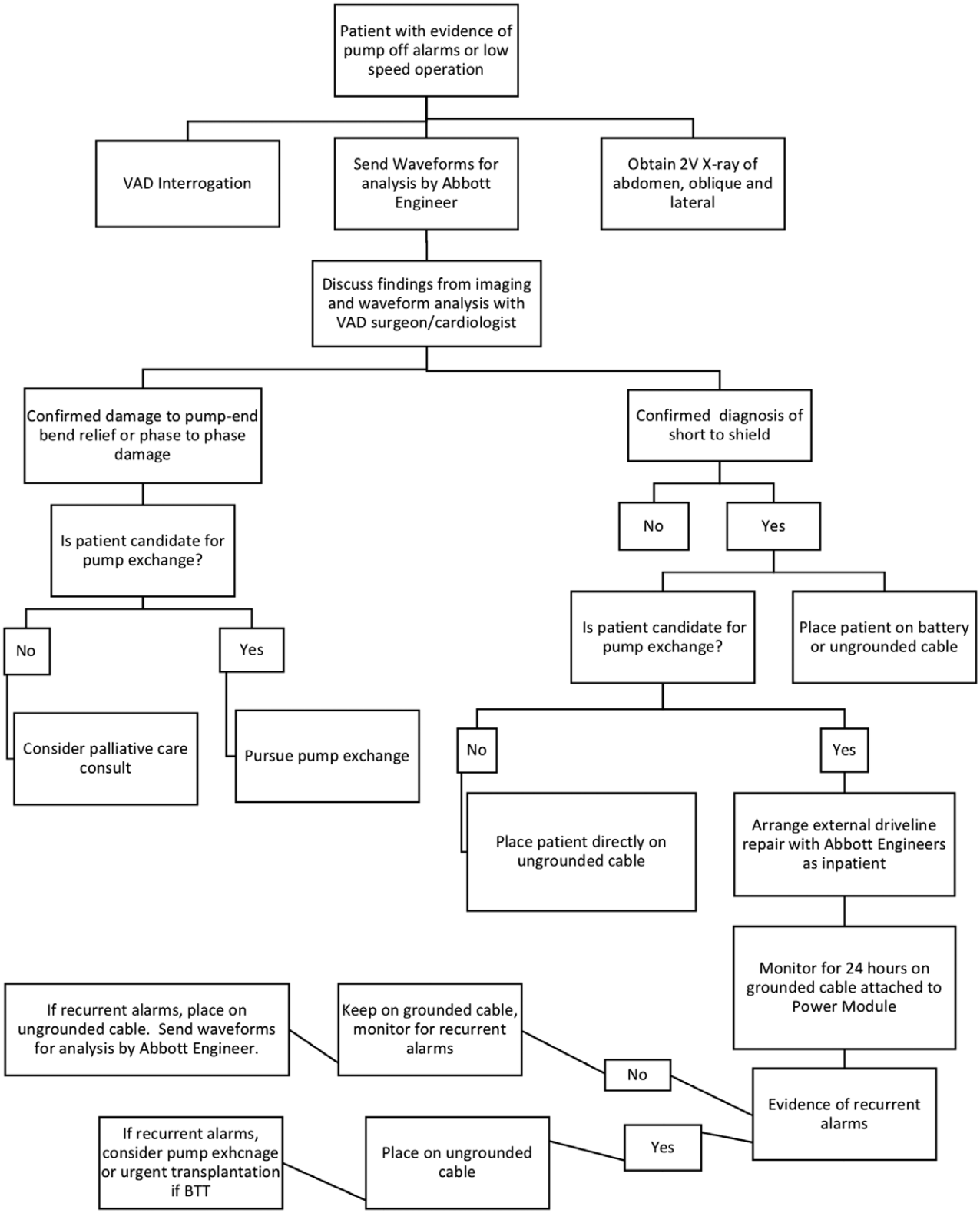

Figure 5. Flow chart indicating the diagnostic and treatment pathways for a patient with suspected short to shield. BTT, bridge to transplantation; 2V, two view; VAD, ventricular assist device.

The remaining 15 (28% of 53) patients supported on an ungrounded cable eventually developed a phase-to-phase electrical short with intermittent pump stoppage after a median duration of 51 days (range 2 days to 3.3 years). One patient remained in the hospital on an ungrounded cable and was transplanted within 2 days, and the other 14 patients

Table 1. Baseline Characteristics of Short-to-Shield Patients on an Ungrounded Cable

Variable	Pre-Implantation (n = 53)	Time of Event (n = 53)	*p*
Age (years) (median, range)	62 (25–74)	–	
Male	83%	–	
Destination therapy	81%	–	
Dilated cardiomyopathy	62%	–	
NYHA	4	2	< 0.001
6MWT	602.65 ± 423.74	1107 ± 399.30	0.003
BMI (kg/m^2) (median, range)	*27 (18–50)*	29 (18–53)	0.055
Driveline/pocket infection	–	26 (49%)	
No driveline/pocket infection	–	27 (51%)	
Implanting surgeon 1		29 (55%)	0.491
Implanting surgeon 2		24 (45%)	0.491

BMI, body mass index; 6MWT, 6 minute walk test; NYHA, New York Heart Association.

underwent a pump exchange. The outcome of these patients is shown in **Table 4**. Most patients remain ongoing with continued device support for nearly 3 years after pump exchange with a total median duration of mechanical support of 4.8 years (range 1.8–8.7 years). No patients expired because of a phase-to-phase electrical short necessitating a pump exchange while on an ungrounded cable.

Discussion

In this population of patients supported with the HeartMate II LVAD, the overall incidence of device failure because of percutaneous lead damage was 14.6%; this is higher than previous reports ranging between 6.0% and 9.2%.[8,10] The difference is likely because of a considerably longer duration of LVAD support of 3.6 years (range 1.2–9.9 years) in our study, during which there was a greater period for the percutaneous lead to be exposed to physical damage. Despite two revisions in the lead design,[8,9] damage to the internal wiring insulation of the percutaneous lead accounted for the majority (63 of 479 patients, 13.2%) of driveline failures in our patients. Although most of these failures (12.5%) initially presented as an STS, this type of wire damage attributed to fatigue from repetitive movement of the driveline in a specific area is likely to progress. This was demonstrated in our study after 15 of our STS patients supported on an ungrounded cable developed more extensive lead damage resulting in a phase-to-phase electrical short.

In cases where the percutaneous lead damage is in the external component of the driveline with no evidence of internal lead fracture or additional causes of electrical failure, an external percutaneous lead repair has been shown to be safe[9] and was considered a viable treatment option for our patients with an STS. A successful repair will replace the distal portion of the lead, allowing the patient to return to grounded power and fundamentally protecting them from electromagnetic interference. This also confirms clinical suspicion that the damage causing the STS was in the external portion of the driveline. Although uncommon, abrupt pump stoppage during the external repair can occur if there is concomitant intracorporeal lead fracture or additional damage to the internal wires, which was not previously recognized.[9] This was the case in one of our patients with an STS who underwent this procedure and experienced complete pump failure prompting an emergent device exchange. For that reason, the candidacy of a patient for pump exchange must be taken into consideration when planning an external lead repair.

Our findings also suggest that identifying the location of the STS can be difficult. Many patients who underwent an external lead repair still required support from an ungrounded cable within 2 days (range 0 days to 1.3 years), indicating that the STS may not have been in the distal portion of the driveline replaced. It is important to recognize that the action required to perform the external repair can induce or add another failure point along the driveline. This too may have contributed to some patients requiring nongrounded support so soon after the repair. Historically, the external repair was thought to be the long-lasting solution for external lead damage, including the STS.[9] However, our experience demonstrated that it was a relatively short-term solution as 89% (31/35) of patients who underwent an external lead repair to address an STS eventually required an ungrounded cable to circumvent pump stoppage because of an ongoing or recurrent STS. Therefore, we feel that optimal care requires individualization with appropriate consideration of the risks associated with this procedure.

Table 2. Number of STS Per Year

Year	STS	Number of Implants	Event Rate Per Year (%)
2008	1	17	6
2009	3	36	8
2010	3	35	8
2011	3	37	8
2012	3	41	7
2013	11	77	14
2014	10	62	16
2015	12	80	15
2016	4	54	7
2017	3	40	8

STS, short to shield.

Table 3. Total Days on Device Therapy for 72% (38/53) of STS Patients on Ungrounded Cable

Population	Median Days
Ongoing (n = 21)	3.4 years (range 1.4–9.9 years)
Transplanted (n = 11)	2.9 years (range 1.2–5 years)
Died (n = 4)	2.8 years (range 1.3–8 years)
LVAD exchange (n = 1)	2.8 years
Explant (n = 1)	3 years

LVAD, left ventricular assist device; STS, short to shield.

Table 4. Outcomes of 28% (15/53) Who Progressed to Phase-to-Phase Short Requiring Pump Exchange

	Ongoing (n = 10)	Expired (n = 3)	Explanted (n = 1)
Days of support on second device	2.8 years	1.4 years	292 days
Median, range	110 days to 7.2 years	1.1 to 3 years	–
Total days of LVAD support	4.8 years	4.3 years	–
Median, range	1.8 to 8.7 years	3.6 to 4.8 years	–

One phase-to-phase patient was transplanted while hospitalized on an ungrounded power cable.
LVAD, left ventricular assist device.

In cases where an external driveline repair is considered, a policy or procedural checklist that includes a comprehensive examination of the internal and external percutaneous lead is essential. This should include a thorough clinical examination, visual inspection and manipulation of the percutaneous lead with position changes, interrogation of the device parameters and log file analysis, analysis of radiographic imaging with device trained personnel, and ultimately detection of breakdown in the shielding or external lead damage confirming the necessity of this procedure. An external repair is not recommended when radiographic imaging indicates internal lead damage or in the presence of a driveline fault alarm and log file analysis confirming a damaged or broken wire. Additionally, having a plan of preparedness in place before performing this procedure is required if the patient experiences pump off alarms during or after the repair. This was shown in our study when a patient suffered complete pump stoppage during the repair because of thinning of the shield at the pump housing, which went undetected before the procedure, and several patients continued to experience transient pump stoppage when reconnected to a grounded power source within 24 hours, signifying an internal STS. The MPU is not compatible with an ungrounded cable; therefore, having the appropriate equipment, including a PM and ungrounded cable in addition to surgical support readily available, is necessary. To prevent interruption in pump function by connecting an STS patient to a grounded power source, a discernable controller lead is advised. Additional staff and patient education in the hospital and clinic setting, including the development and implementation of protocols regarding the appropriate use of equipment and monitoring of STS patients, is essential.

Advanced technology and device enhancements have provided many HeartMate II patients with more than 5 years of device support.[13] Moving forward, new and improved devices on the market will likely decrease the number of HeartMate II LVADs implanted. Additionally, as the field of MCS progresses, concerted effort will be made to replace the external driveline with a fully implantable device, likely powered by a form of transcutaneous energy transmission. These systems use an external coil, connected to a power source, which transmits power to an internal coil by electromagnetic induction.[14,15] As implantable battery and device controller technology improves, it is likely that these devices will become increasingly common, obviating the need for, and the complications associated with an external driveline. However, with more than 8,350 patients still supported on the HeartMate II device,[5] more patients will experience transient pump stoppage triggered by an STS with extended durations of support.

To date, this is the largest review examining the outcomes of patients supported on an ungrounded cable as a primary treatment strategy for an STS. In our cohort, 53 (11% of 479) patients were treated with an ungrounded cable to mitigate an STS. We demonstrated that these patients can be safely sustained for a prolonged period on an ungrounded cable. We also identified an increase in functional status and weight gain, along with extended durations of support, to be potential risk factors for developing an STS. Advanced end-stage heart failure patients who require durable LVAD therapy frequently suffer from cardiac cachexia and low nutritional status.[16] Treatment with a CF-LVAD has demonstrated significant improvement in functional class and quality of life.[17] In addition, most studies show that LVAD patients gain weight after LVAD implantation.[18] Therefore, it is reasonable to assume that patients with an improved functional status and quality of life resume normal activities of daily living (ADLs), which may lead to increased physical damage to the driveline because of repeated flexion or twisting. It is not surprising that some patients with a HM II LVAD who gain weight and return to normal ADLs will experience an STS. Additional study to gauge the role of surgical technique at the time of implant and long-term environmental factors in the development of an STS may be reasonable. Notably, preservation of pump function with an ungrounded cable allowed 12 of our bridge to transplant patients with an STS to avoid device exchange and the added risks of a reoperation before their heart transplant. Furthermore, no deaths occurred because of watchful waiting for STS patients on an ungrounded cable to experience worsening lead damage warranting a device exchange.

Limited publications exist regarding the clinical diagnosis and management of an STS,[9,12] and traditionally, a pump exchange has been the suggested treatment approach in the setting of a failed external repair.[9,10,12] Although LVAD exchange can be performed with durations of support comparable with the initial implant,[10,19,20] it is a major operation with substantial risk factors[10,19] and is not suitable for everyone. The candidacy for a patient requiring a pump exchange should be closely examined. Several of our STS patients were not ideal device exchange candidates because of listing status, severe right ventricular failure, multiple comorbid conditions, unsafe psychosocial histories, or significant noncompliance. Therefore, these patients were maintained on an ungrounded cable to provide them with continued LVAD support. None of these patients expired because of device failure. Certainly, the urgency for a pump exchange after a failed external repair for an STS should be reexamined and elective treatment with an ungrounded cable should be considered in certain circumstances.

The physical damage causing an STS will conceivably lead to a phase-to-phase electrical short causing pump stoppage on batteries or an ungrounded cable. The risks and timing associated with the development of worsening electrical lead damage

on an ungrounded cable are largely unknown. However, with conservative follow-up, all 15 of our patients who developed a phase-to-phase electrical shortage were either successfully exchanged or transplanted. With some patients not suitable for device exchange, we will be able to further examine the outcome of patients experiencing worsening electrical lead failure while on an ungrounded cable.

Limitations of this study include those of a retrospective review and single-center experience. Decisions and timing regarding performance of an external lead repair, use of an ungrounded cable, and pump exchange varied. In addition, many of the details surrounding the events and results of diagnostic evaluation performed leading up to a confirmed STS relied on the review of patient medical records and log files. We could not obtain device analysis reports on pump components, which were not explanted. This study did not have a contemporary dataset for patients without an STS to compare with our STS patients. Additional studies evaluating the risk *versus* benefit of supporting patients with an STS on an ungrounded cable as the primary treatment approach *versus* device exchange is sensible.

Conclusions

In conclusion, we have shown that with longer durations of support, some patients with a HeartMate II LVAD will experience device failure in the form of an STS. Most patients with an STS who undergo an external driveline repair will have a recurrent STS and require an ungrounded cable to prevent transient pump stoppage. Select patients with an STS can be safely supported on an ungrounded cable for several years with close monitoring. This treatment approach should be considered before a device exchange and in conjunction with listing status, compliance, and medical comorbidities.

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