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Outcomes of external repair of HeartMate II™ LVAD percutaneous leads

Jay D. Pal^{1*}, Claudius Mahr¹, Jason W. Smith¹, Todd F. Dardas¹, Jay Pinette², David J. Farrar², and Nahush A. Mokadam¹

¹ University of Washington, Seattle, WA

² St. Jude Medical, Saint Paul, MN

* Corresponding author: jaydpal@uw.edu

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Abstract

Background

The HeartMate II Left Ventricular Assist Device (LVAD) receives power via a percutaneous lead connected to an external controller and batteries. At times, this lead can be damaged during normal wear, as well as by traumatic fracture, which may jeopardize the functionality of the LVAD. If there is significant internal damage, surgical replacement of the LVAD is required. However it is possible to repair externally damaged leads by replacing the distal portion of the lead to avoid pump replacement. We report the overall experience and outcomes in patients with external lead repairs.

Methods

A procedure for full external lead replacement has been developed and is approved for implementation by the FDA. Pre-procedural steps include examination of high resolution x-rays of the driveline and analysis of pump log files. Efficacy and outcomes of all attempted external lead repairs were evaluated between initiation of repairs in 2008 through 2014.

Results

A total of 321 repairs were attempted in 297 patients with suspected isolated external lead damage after a median of 2.0 yr [range: 7d to 8.7 yr] of support. Of 297 patients, 37 (12.5%) had attempts at external repair that were unsuccessful



due to concomitant internal lead damage. 31 patients (10.4%) had additional serious malfunctions after lead repair resulting in 17 with repeat repairs and 14 who continued on ungrounded cables, and ultimately 14 of these 31 patients required pump exchanges. 27 of the 297 patients (9.1%) with lead repairs had only minor additional problems, including cuts or abrasion in the insulation which was fixed with tape or external reinforcement. There was one catastrophic failure during attempted lead repair requiring emergent pump exchange, and there were three deaths within 14 days of attempted repair related to continued percutaneous lead damage. One of these patients refused pump exchange, and two were not candidates for other clinical reasons. 202 of the 297 patients (68%) have had no recurrence of lead problems after a median follow-up of 189 days [n=11 over 2 years, longest 5.8 yr].

Conclusions

HeartMate II dysfunction due to percutaneous lead damage is uncommon but is of serious concern due to potential abrupt pump stoppage. Lead repair by replacement of the external distal percutaneous lead can be performed by trained personnel in a standardized fashion and may provide a durable solution in select patients with isolated external lead damage, thus avoiding the need for surgical pump exchange. We provide an algorithm for evaluating potential lead damage.

Keywords: LVAD, percutaneous lead, repair, ventricular assist device

Background

The HeartMate II (St Jude Medical, Pleasanton, CA, previously Thoratec Corporation) is currently the only left ventricular assist device approved by the FDA for both bridge to heart transplantation and destination therapy. The pivotal trials for bridge to transplantation and destination therapy demonstrated significantly improved reliability compared to earlier pulsatile volume displacement devices and minimal bearing wear in explanted pumps¹⁻³. To date, over 20,000 implants have been performed worldwide, and nearly 8,000 patients remain on support. With an increasing proportion of patients being implanted as destination therapy with longer durations of support, physical wear on the external components are emerging as a factor in long-term durability. The HeartMate II LVAD, like other LVADs, is dependent on the externalized lead for electrical power and control of pump settings. The percutaneous lead is susceptible to physical damage, which may manifest as pump speed or power fluctuations, alarms, device malfunction, or at worst, potentially catastrophic abrupt pump stoppage. Due to these limitations, a new pump design of the HeartMate 3 has incorporated modularity in the external lead to mitigate this possibility⁴.

The HeartMate II percutaneous lead consists of three pairs of redundant wires that are electrically shielded and protected by two water-resistant jackets (Figure 1). The internal wiring schematic is shown in Figure 2. Damage to the external lead by repeated flexion can be manifested by retraction of the silver-coated copper



braided shield and fracture of an individual wire (Figure 3). Damage to the braided shield without internal wire fracture, can lead to a phenomenon known as short-to-shield, which can result in pump dysfunction when connected to a grounded power source⁵. There is also the possibility of a short between two different motor leads by the shield wires which cause pump stoppage even if a non-grounded shield cable is used.

Figure 1: Schematic of HeartMate II percutaneous lead

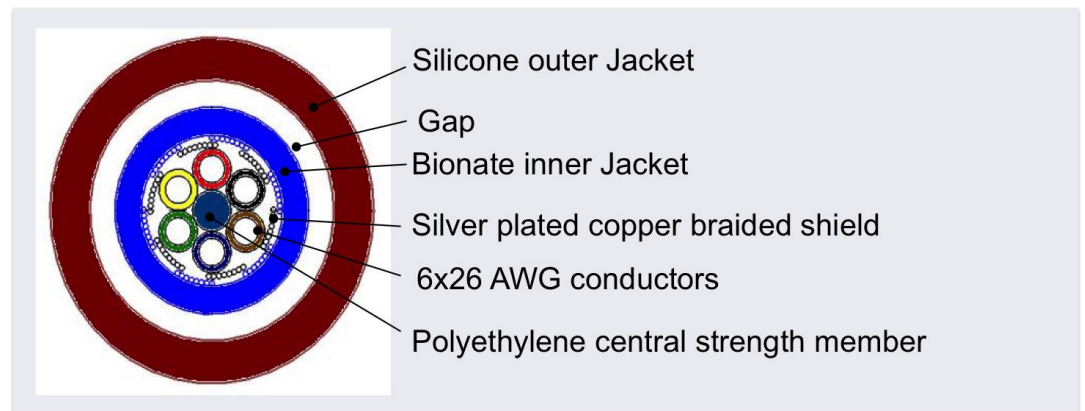
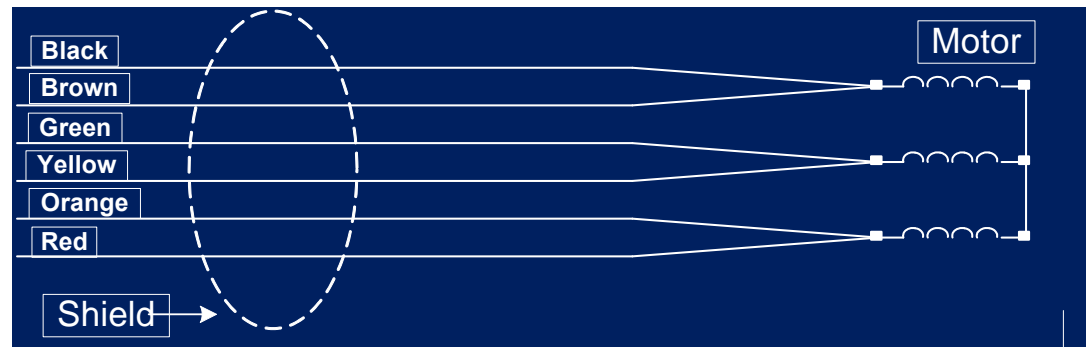


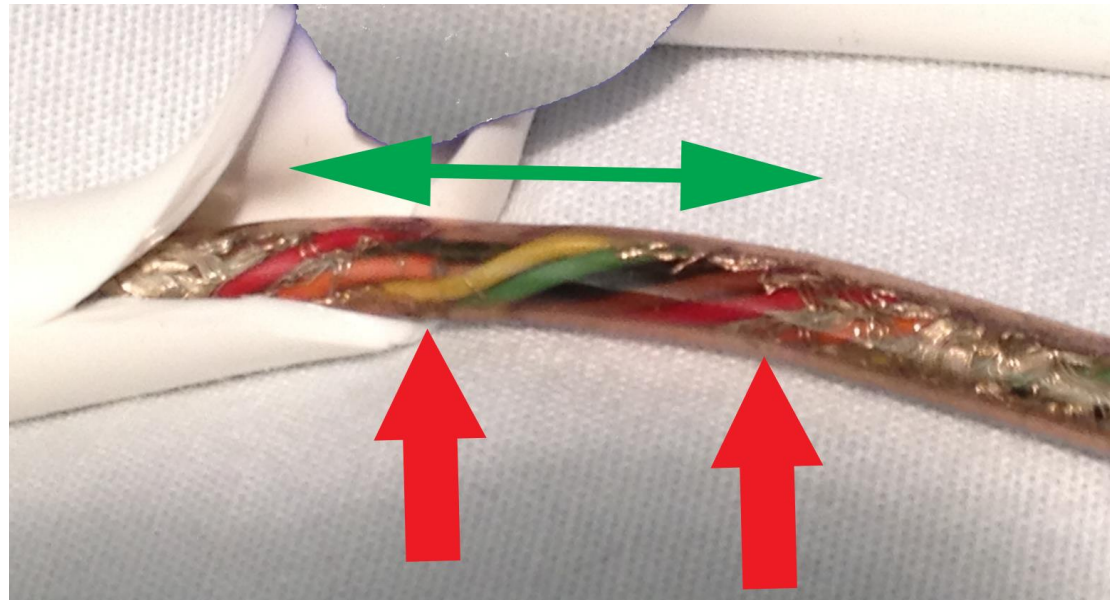
Figure 2: Internal wiring diagram of HeartMate II percutaneous lead



Traditionally, damage to the external lead not resulting in pump dysfunction was treated by external reinforcement of the driveline. Damage of the driveline causing abnormal LVAD function typically required LVAD exchange, usually through a repeat sternotomy, but more recently via a subcostal approach⁶⁻¹⁴. In 2009, Thoratec (St. Jude) developed a procedure for external driveline repair to reduce the need for pump exchange procedures. We reviewed the aggregate clinical experience to date of external driveline repairs of HeartMate II LVADs.



Figure 3: Damage to the external lead by repeated flexion can be manifested by retraction of the silver-coated copper braided shield and fracture of an individual wire (orange).



Methods

A retrospective review was undertaken of all percutaneous lead repairs performed by the St Jude Medical Technical Services Team. The HeartMate II log file for each patient was reviewed for alarms, unexplained pump stoppages, pump speed and/or power fluctuations. Each patient initially underwent a controller exchange and close examination of visible connectors to ensure adequate contact. A radiograph of the externalized portion of the percutaneous lead was obtained, and examined for evidence of broken wires or abnormal shielding. If external damage was identified (Figure 4), preparation for repair by St. Jude Medical personnel was undertaken.

A procedure for external percutaneous lead replacement was developed and approved for implementation by the U.S. Food and Drug Administration. The repair technique involves removing the silastic covering from the driveline, separating each pair of wires, and splicing a new lead to the damaged set of wires (Figure 5). The pump continues to function on the intact wires of the original lead. The new lead is then tested, and control transferred to the new controller. The second set of wires is then transferred to the new lead, and the repaired section is re-insulated and encapsulated in a water-resistant enclosure (Figure 6). Of note, the external percutaneous lead repair requires approximately 15cm from the skin exit site, and must not include any velour-covered areas.



Patients who underwent external driveline replacement were then followed clinically to determine success of repair, durability, and potential need for further intervention on the percutaneous lead or pump exchange.

Figure 4: Radiographs of lead damage

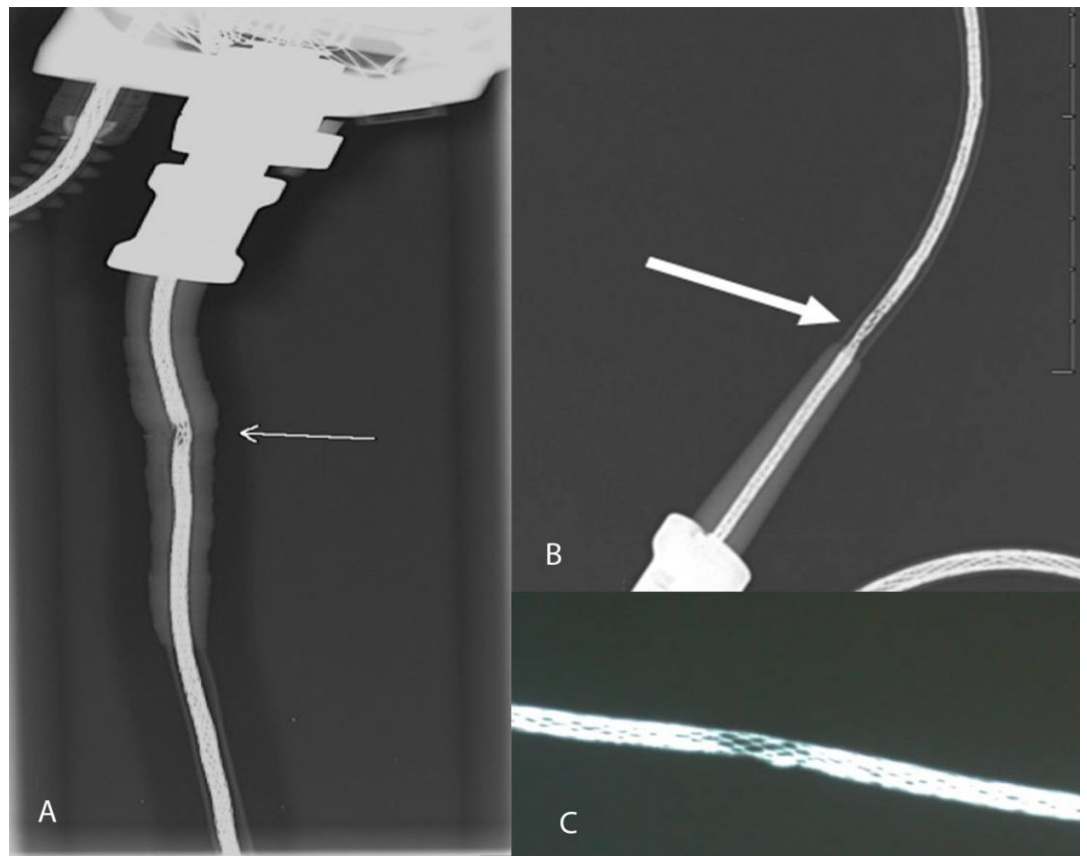


Figure 5: Repair of external percutaneous lead





Figure 6: Completed percutaneous lead repair



Results

Between January 1, 2008, when the external percutaneous lead repair procedure was initiated, until December 31, 2014, a total of 321 repairs were undertaken in 297 patients. The median duration of mechanical support prior to the repair procedure was 2.0 years (range 7days -8.7 years). 202 of the 297 (68%) patients had resolution of pump dysfunction with no recurrence of lead problems. The median duration of support after lead replacement was 189 days, with 11 patients greater than two years. Twenty-seven of 297 (9.2%) of patients had minor additional problems such as abrasions of the insulation without electrical damage that were repaired with tape and external reinforcement.

Thirty-seven (12.5%) patients had unsuccessful external replacement of the percutaneous lead due to concomitant intracorporeal lead damage. Thirty-one (10.4%) patients continued with serious malfunctions after lead replacement. Of these, 17 patients underwent repeat repair, and 14 continued on ungrounded cables. Fourteen of these 31 patients ultimately underwent pump exchange (Table 1).

One patient required emergent pump exchange due to catastrophic failure during the external lead replacement procedure. In this specific instance, there was a concomitant internal driveline fracture that had not been detected prior to external repair. There were three deaths within 14 days of attempted lead repair due to ongoing lead damage and electrical malfunction of the LVAD. One patient refused pump exchange, and the other two were deemed not candidates for repair due to clinical reasons.



Table 1:

Repair Outcome	Number (%)
Successful without additional intervention	202 (68)
Successful with minor additional repair	27 (9.1)
Additional serious malfunctions	31 (10.4)
Repeat Repair	17
Continue support on ungrounded cable	14
Unsuccessful	37 (12.5)

Discussion

Since approval of the HeartMate II LVAD in 2008, more than 20,000 implants have been performed. During this period, an increasing number of patients are implanted as Destination Therapy, and extended durations of support are becoming the norm. This has led to longer time periods during which the external percutaneous lead is exposed to physical damage.

Early experience with external percutaneous lead failures were exclusively treated with urgent pump exchange procedures¹⁵. While exchange procedures can typically be performed safely, there remains additional risk from the repeat surgical procedure, as well as the financial impact of that care episode. Stulak and colleagues reported on a series of LVAD exchanges and found that while the operative mortality was encouragingly low (3.5%), patients were at risk for late mortality, increased morbidity and frequently repeated device exchange¹⁶. In addition, Moazami *et al* reported on a series of LVAD exchanges, and found that 30% of patients ultimately died within one year of pump exchange¹⁷. Despite this, Anand *et al* found that pump exchange prolonged support time in a manner similar to the original implant¹⁸. Kalavrouziotis and colleagues recently reported on the incidence of percutaneous lead failures among patients supported with HeartMate II LVADs and found that 9.2% of implanted pumps developed lead damage¹⁹. They concluded that lead failures played a significant role in the long-term durability of left ventricular assist devices. Two significant revisions in the percutaneous lead design, in 2007 and 2012, have reduced the incidence of lead failure.

We report on the external percutaneous lead repair technique and associated long-term outcomes of patients supported on repaired leads. Isolated external lead damage can be successfully repaired in a significant number of patients, thereby avoiding the morbidity and mortality risk of a pump-exchange procedure. In some



patients, additional minor repairs (such as external reinforcement) are necessary, while others may require more extensive additional repair. In rare occasions, a patient is maintained on an ungrounded cable to prevent short-to-shield phenomena. The incidence of abrupt pump stoppage during the repair procedure is exceedingly rare.

A cohort of patients experienced ongoing pump dysfunction after lead repair, necessitating LVAD exchange. This could be due to concomitant intracorporeal lead fracture, or other electrical damage not grossly visible on examination of the driveline. Therefore, we recommend comprehensive and careful radiographic evaluation to ensure that the intracorporeal portion of the percutaneous lead is intact, and that areas not easily visible on radiographs are directly examined prior to proceeding with external percutaneous lead repair.

Our algorithm to evaluate suspected percutaneous lead damage is to analyze the pump log files for evidence of pump speed or power fluctuations, unexplained pump stoppage, or alarms (Figure 7). If concern exists for an electrical malfunction of the left ventricular assist system, comprehensive radiographs are obtained of the external component of the driveline. Computed tomography may be required for evaluation of the internal portion of the percutaneous lead. If a lead fracture if the external part is identified, the St Jude Medical Technical Services Team is called to perform an external lead repair. Internal lead damage must be excluded prior to external repair to avoid the possibility of abrupt pump stoppage during repair or persistent pump malfunction. We perform the repair procedure in patient's room in an intermediate care telemetry unit or intensive care unit. Given the low likelihood of pump stoppage, we do not routinely take precautions, such as surgical stand-by for emergent pump exchange.

Limitations

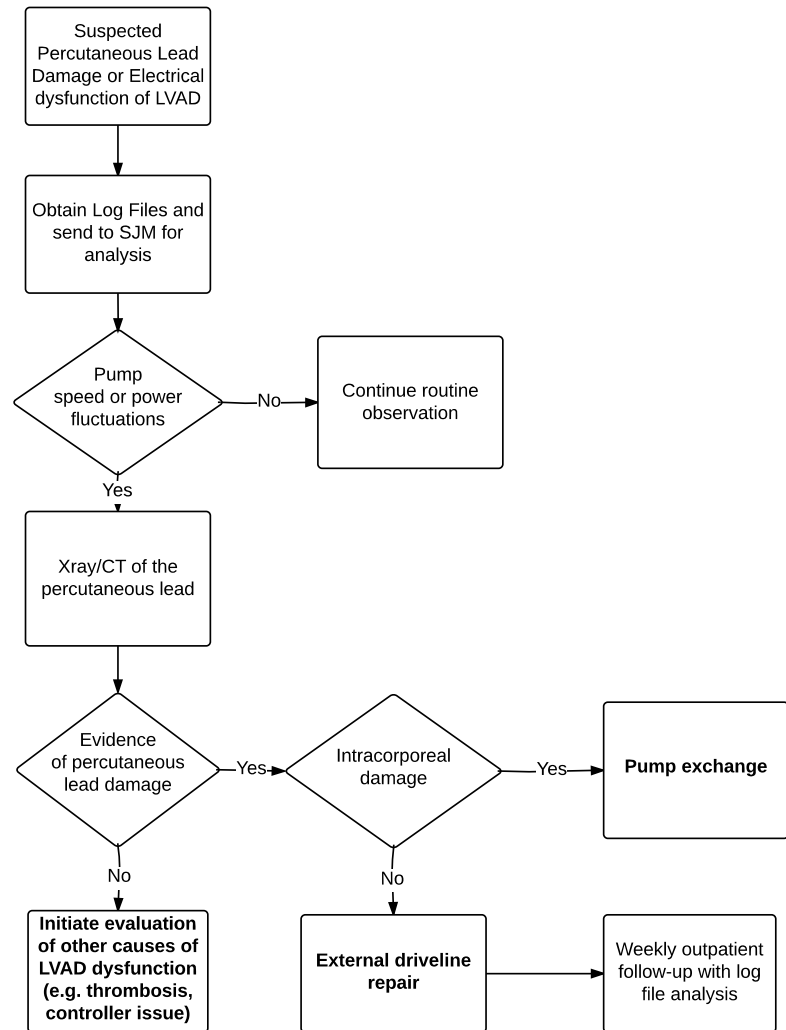
The true denominator of percutaneous lead failures may be underestimated by this methodology. Additionally, since this procedure is relatively recent in the history of the HeartMate II, there were patients who underwent pump exchange despite having repairable external leads. Further, since there are regions of the percutaneous lead that are not easily visible on radiographic examination, there may be additional patients who may have benefitted from this repair technique.

Conclusions

Replacement of the external percutaneous lead by the St Jude Medical Technical Support Team can be performed safely, and in most instances, can resolve electrical malfunction of the LVAD associated with a fracture in the external component of the lead, and in the absence of an internal lead fracture. This repair has been shown to be effective and durable. In patients with no evidence of internal lead fracture, and in whom other causes of electrical failure have been excluded, we believe that external lead repair should be attempted prior to pump exchange.



Figure 7: Algorithm





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