

A case of Durata ICD lead coil externalization: Inside-out lead abrasion?



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Introduction

The St Jude Medical Durata lead was produced in response to the recalled Riata and Riata ST leads in November 2011 after concerns of lead durability and inside-out abrasion. In order to protect against this susceptibility, the Riata ST Optim and Durata leads were coated with an abrasion-resistant layer of silicone–polyurethane copolymer (Optim) tubing. We report a case of Durata lead extraction with simple traction only and no requirement for dilating or powered sheaths. The extraction procedure does not account for lead damage, since only simple traction was required. Analysis of the extracted lead suggested inside-out abrasion as the mechanism of lead failure.

Case report

A 78-year-old woman had a biventricular implantable cardioverter-defibrillator (ICD) implanted in January 2008 for nonischemic dilated cardiomyopathy with a left ventricular ejection fraction of 25%, NYHA class III symptoms, QRS 130 ms, and left bundle branch block. A St. Jude Medical 7120 Durata 65 cm right ventricular (RV) ICD lead (St. Jude Medical, Sylmar, CA) with Optim coating was implanted, along with a St. Jude Medical Quicksite 1056T left ventricular lead (St. Jude Medical, Sylmar, CA) and Guidant Flexend 2 4096 52 cm right atrial lead (Boston Scientific, USA). These were connected to a St. Jude Medical Atlas+ HF V-341 generator (St. Jude Medical, Sylmar, CA).

The patient underwent an ICD lead revision in May 2008 for a raised RV pace-sense lead threshold and lead migration confirmed on a plain film chest radiograph. Subsequent to this, the left ventricular ejection fraction improved to 40%. Phrenic nerve stimulation occurred intermittently shortly after implant owing to left ventricular lead stimulation with a programmed output of 1.7 V. Left ventricular lead output

was programmed to 1.6 V, giving a very small pacing safety window.

In September 2014 a home monitoring alert for a small sensed R wave on the ICD lead and multiple electrograms showing RV lead noise led to physical device interrogation but no change in RV lead impedance, with a stable impedance trend since implant. None of the episodes of lead noise were long enough to result in inappropriate detection or device therapy. Interrogation showed a sudden drop in the sensed R wave to 0.8 mV, having been stable at 9.8 mV in June 2014. The RV lead pacing threshold was 0.5 V and pacing impedance 646 Ω . The high-voltage lead impedance was 53 Ω and had remained stable since implant. Battery voltage remained good (approximate time to explant 8 years) with a capacitor charge time of 9.8 seconds. Atrial lead sensing had gradually deteriorated over the previous year with a P wave of 0.8 mV, having been 2.4 mV at implant in 2008. Given the issues with all 3 leads, it was decided the entire system should be extracted and a new one implanted.

Lead extraction

The procedure was performed under general anesthesia. After central venous access and invasive arterial pressure monitoring were obtained, a transesophageal echo probe was used to monitor the pericardial space during the procedure. The leads and generator were dissected using the Medtronic PEAK PlasmaBlade (Medtronic, Palo Alto, CA). The helices of the atrial and RV leads were retracted. After cutting of the distal portion of the leads and insertion of a Liberator Universal Locking Stylet (Cook Medical, Bloomington, IN), simple traction alone was sufficient to extract all 3 leads in their entirety. Dilating or powered sheaths were not required during the extraction process. A new biventricular ICD system was implanted without complication.

Figure 1 shows an intraoperative photograph of the Durata ICD lead taken immediately after extraction. There is a clear breach of the outer protective Optim coating, suggesting possible inside-out lead abrasion. Closer examination of the extracted Durata lead shows the appearance of externalization of the conductor cable 5 mm proximal to the RV shock coil (Figure 2). In this region, the silicone–polyurethane copolymer (Optim, St Jude Medical) is no

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KEY TEACHING POINTS

- Although insulation abrasions occur because of friction with the implantable cardioverter-defibrillator can or other leads, Optim-coated Durata leads may be at risk of inside-out abrasion.
- In light of the recent issues with the Riata lead, increased surveillance is required for Durata leads.
- Additional studies are required to determine the incidence of these failures and, moreover, their clinical implications.

longer intact, and the intact blue ethylene tetrafluoroethylene (ETFE) insulated conductor cable can clearly be seen. The downward arrows show a crack at the distal and proximal end of the breached Optim coating. The upward arrows indicate several areas of discoloration underneath the Optim coating where biological material has collected.

The extracted Durata ICD lead was sent to St Jude Medical for detailed examination, and visual inspection, as reported by St Jude Medical, revealed “an external insulation abrasion due to friction to another device and/or feature of the heart breaching the ring electrode cable lumen. The ETFE cable coating was intact in this region. X-ray examination found no anomalies. Electrical measurements found normal coils continuities. No short circuits were found on any conduction paths.”

In contrast to this opinion, examination of the chest x-ray image prior to extraction (Figure 3) shows that the section of lead with the insulation breach was within the right ventricle and not in contact with another mobile structure or near the generator. The section of the lead with the abrasion is straight and not angulated. Furthermore, no independent movement of the leads relative to one another is seen on the fluoroscopic images, making external abrasion, in our opinion, impossible.

Discussion

St Jude Medical Riata and Riata ST leads were recalled in November 2011 because of susceptibility of the ETFE-coated

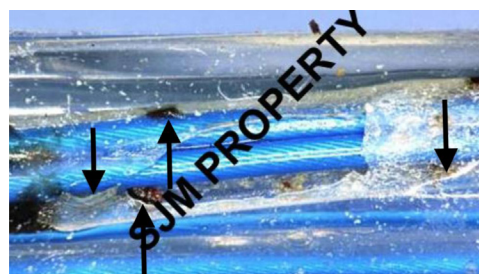


Figure 2 Appearance of externalization of the conductor cable 5 mm proximal right ventricular shock coil. The downward arrows show a crack at the distal and proximal end of the breached Optim coating. The upward arrows indicate several areas of discoloration underneath the Optim coating where biological material has collected.

conductor cables abrading through the silicone insulation owing to inside-out erosion, as a result of internal motion.¹ To protect against this susceptibility the Riata ST Optim and Durata leads were coated with an abrasion-resistant layer of silicone-polyurethane copolymer (Optim) tubing.

According to St Jude Medical, Optim is 50 times more abrasion resistant than silicone.² Despite this improved lead durability, Hauser et al³ searched the US Food and Drug Administration’s Manufacturers and User Device Experience database in 2012 to discover 15 reports for Riata ST Optim and 37 reports for Durata leads, which had failed owing to abrasions. They concluded that Optim did not prevent these abrasions, which developed ≤ 4 years after implant. Furthermore, they found that while the majority of the abrasions were the result of friction with the pulse generator can and with another device, 1 Riata ST Optim lead failure and 3 Durata lead failures were internal abrasions. These appeared to be similar to the inside-out abrasions reported in Riata and Riata ST leads.

The characteristics and frequency with which lead insulation fails vary. As such, the challenge for manufacturers has been to identify materials that are durable, flexible, and biologically stable. Optim by AorTech International PLC (AorTech, Weybridge, Surrey, UK), generated great interest. Simmons et al⁴ undertook an in vivo study of Optim and polyurethanes and found that the molecular weights decreased comparably, suggesting similar degradation properties. One year after subcutaneous

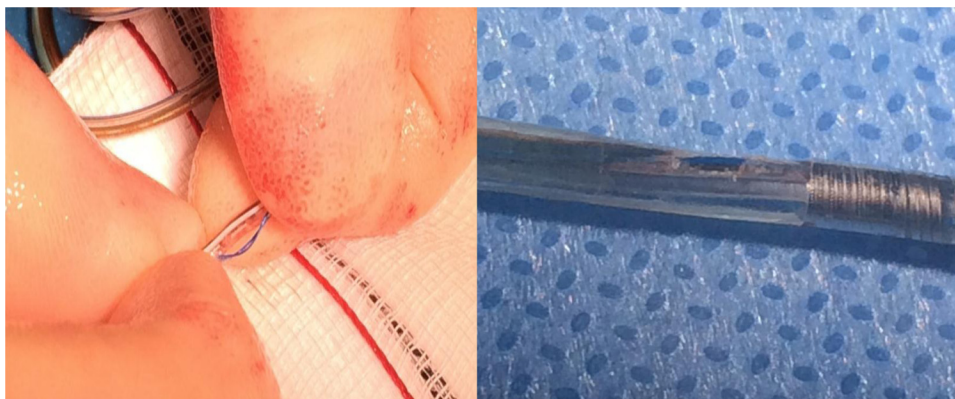


Figure 1 Images show a clear breach of the outer protective Optim coating, where the blue ethylene tetrafluoroethylene-coated conductor cables can be seen.

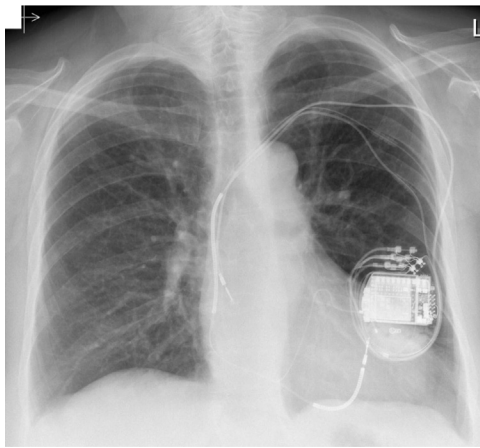


Figure 3 Plane film chest radiograph prior to the extraction procedure. The section of lead with the insulation breach was within the right ventricle and not within contact of another mobile structure or near the generator.

implant, both types of material had lost mechanical strength. Optim retained more mechanical strength than poly(ether)urethane 55D, but was weaker than Bionate 55D, a poly(carbonate) urethane. In a custom bench test, Optim had an abrasion resistance $>2,500,000$ cycles to failure compared with $>125,000$ cycles to failure for high-performance silicone.² The extracted lead in this case had been implanted more than 6 years, in comparison to the 1 year of material analysis conducted by Simmons et al. It is therefore possible that it had been exposed to more extensive degradation.

Mechanisms of ICD lead failure are varied and commonly include outside-in abrasion as a result of lead–can or lead–lead abrasion. Silicone leads without a protective coating are at highest risk. The Riata ST Optim and Durata leads have a protective coating of Optim, which is aimed at improving lead durability.^{5,6}

These leads have large-diameter lumens, which enables the ETFE-coated internal conductor cables to move freely within their lumens. This sawing motion results in abrasion and subsequent externalization from the inside out. Approximately 80% of these breaches occur between, and 10% under, the shock coils.¹ In our case, the breach occurred 5 mm proximal to the RV coil. This may be explained by the reciprocal compression-bending model by Lau.⁷ Extension of the proximal lead body owing to pectoral or cardiac motion results in reciprocal compressive bending of a more distal lead segment. This is mediated by inextensible conductor cables, which run down the lead body fixed at various points by fibrous adhesions. Commonly, the coil is an area of intense fibrous adhesion, and the sawing action of these cables under tension causes inside-out abrasion.⁸ Furthermore, compressive bending causes ovalization of the circular cross-section followed by axial buckling. Stress-induced cracks may appear, resulting in breach of the protective coating.^{8,9}

The leads in this case were explanted without laser or powered sheaths, requiring only simple traction after severing the distal portions of the leads and insertion of a locking stylet, meaning the presence of lead damage cannot be the result of the extraction process. The appearance of biological material that had collected under the breached outer Optim coating is indicative of a pre-existing insulation breach and supported by a previous study from Swedlow et al,¹⁰ who concluded that a longer duration of breach increases the likelihood of biological material collecting. They also found that in comparison with the postulated inside-out lead insulation failure of the copolymer coating, the unequivocal explant-related damage was at a different location on the lead, with a distinctive appearance (including linear tears and melting).¹⁰ In the present case, there is cracking of the proximal and distal ends of the breached Optim coating in the longitudinal plane of the lead with the appearance of the outer borders of the abrasion overlying the inner borders of the abrasion. This also supports an inside-out abrasion rather than outside-in, as well as reciprocal compressive bending. We believe the findings in this case point to inside-out lead abrasion of the Optim coating, causing ICD lead noise and sensing failure necessitating extraction.

To the best of our knowledge, we report the first case of a St Jude Medical Durata ICD lead extracted with simple traction only, with evidence suggesting inside-out abrasion of the Optim coating. Previously reported extracted Durata leads have required either laser or cutting sheaths. Given the well-reported issues and global recall of the St Jude Medical Riata ICD lead and the sharing of a similar lead design with Durata (except for the lead coating), continued surveillance of the durability of the Durata ICD lead is advisable.

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