Inside-out insulation failure of a defibrillator lead with abrasion-resistant coating

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Clinical report

A 78-year-old woman had a cardiac resynchronization implantable cardioverter-defibrillator implanted in January 2008 for nonischemic cardiomyopathy with New York Heart Association class III heart failure, left ventricular ejection fraction 22%, and left bundle branch block. A St Jude Medical Model 7121 Durata right ventricular lead (St Jude Medical, St Paul, MN) and a Medtronic Model D224TRK Consulta generator (Medtronic, Minneapolis, MN) were implanted. Three months later, ejection fraction improved to 47% and heart failure improved to class I.

In July 2010, a combination of recent short intervals ≤140 ms and rapid, repetitive oversensing triggered the Lead Integrity Alert.1 Interrogation showed an inappropriate detection of ventricular tachycardia treated with antitachycardia pacing. Stored electrograms showed nonphysiological signals, some of which occurred synchronously with the cardiac cycle, timing with the T wave. Pacing threshold was 1.0 V, the R wave was stable at 10 mV, and both pacing and high-voltage impedances were within nominal ranges. However, the weekly minimum pacing impedance decreased by approximately 150 Ω (from 470 to 320 Ω) in February 2010. Differential real-time and telemetry Holter recordings isolated the nonphysiological signals to the cable to the ring electrode rather than the helix to the tip electrode (Figure 1A). Corresponding recordings from shock channels determined that simultaneous nonphysiological signals were present on the distal coil, but not the proximal coil. Additional diagnostic steps excluded other causes of oversensing.

Initially, the patient declined lead replacement. But when frequent oversensing caused the percentage of biventricular pacing to decrease below 90% in late 2012, lead replacement was recommended to preserve resynchronization. Cinefluoroscopy (Figure 1B) showed no exteriorized cables or mechanical lead-lead interaction.

Explanted lead

In January 2013, the lead was extracted by using a 14-F laser sheath without an outer sheath. After obtaining separate vascular access, lasing was performed at binding sites in the innominate vein and at the proximal coil. Then the lead tip came free with gentle traction/countertraction, and the lead was withdrawn smoothly into the laser sheath, without resistance; the sheath and the lead were removed together.

Four locations on the lead showed visible damage. We arbitrarily labeled them zones 1–4 from distal to proximal. Figure 2A shows the distal 3 zones. Figures 2B–2D show progressively magnified views of the lead near the proximal end of the distal coil (zone 1). Figure 2B shows that the distal end of the outer tubing, composed of a silicone-polyurethane copolymer (Optim™, St. Jude Medical), does not extend to the coil. Instead, the tubing and the coil are separated with silicone backfill. At the coil’s proximal margin, the ring-electrode cable has abraded inside-out through the silicone wall of its surrounding lumen. The upward arrow shows the cable’s intact blue ethylene tetrafluoroethylene (ETFE) insulation. The downward arrow indicates where the cable has abraded through the ETFE, revealing the underlying conductor, which contacts the distal coil. In Figure 2C, the arrow indicates where the cable to the distal coil also abraded through the wall of its lumen, with the ETFE tubing intact. Figure 2D shows that the exposed cable filars are flat, rather than round, as a result of abrasion against the coil.

Figure 3A is an intraoperative photograph taken immediately after explant. The inside-out abrasion extends proximally from zone 1 to zone 2 (7.6–8.5 cm from the tip). Between them, ETFE insulation is visible immediately beneath the Optim tubing on cables to both the ring electrode and the distal coil. The ring electrode cable is also visible in an oval-shaped defect in the tubing (1.5 × 3 mm). There is a crack in the trough between the defect and the ridge immediately distal to it. The tubing adjacent to the defect is discolored by underlying deposits of the biological material. Figure 3B shows zone 2 after the removal of the tubing. The ring electrode cable exits its silicone lumen near the proximal end of the removed tubing, defining the proximal boundary of the abrasion (downward arrow). The upward arrow indicates biological deposits that were under the tubing until it was removed.

KEYWORDS Lead failure; Implantable cardioverter-defibrillator

ABBREVIATIONS ETFE = ethylene tetrafluoroethylene (Heart Rhythm 2013;10:1063–1066)

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Zones 2 and 3 (9.3–11.0 cm from the tip) flexed with each cardiac contraction, and zone 3 corresponds to the shortest radius of curvature, resulting in the greatest mechanical stress (Figure 1B). Figures 3C and 3D show that the tubing in zone 3 displays a pattern of wrinkled axial ridges on the inner curvature, with multiple parallel cracks of varying length and width. In contrast, Figure 3E shows damage in zone 4 (proximal to the proximal coil in the innominate vein) caused by lasing and mechanical sheath manipulation. The defect has soft rolling edges with material flow marks consistent with melting. There is a linear tear from a mechanical cut at lower right. The tubing on either side of the defect is clear, indicating the absence of underlying deposits.

Figures 4A–4C show photomicrographs of tubing removed from zone 2 to zone 4. In zone 4 (Figure 4C), it is easy to see how the smooth melted edges of the defect fit together. In contrast, the edges of the defects in zones 2 and 3 (Figures 4A and 4B) have multiple fine protrusions and do not fit together. Each defect has a delicate strand of tubing in the middle (arrows), an L-shaped peninsula in zone 2, and a bridging filament in zone 3. In Figure 4B, the tubing at the left edge of the defect is wrinkled and set. The image at the right of Figure 4B shows a cross section approximately at the dotted line. The tubing is smooth with uniform thickness on the side opposite to the defect (outer curvature in Figure 1B). There were no indentations of the inner surface, suggesting deformation by cables.

Discussion
St Jude Medical recalled Riata and Riata ST leads are susceptible to abrasion because of the internal motion of the ETFE-coated cables against and through the silicone elastomer insulation that comprises the walls of their lumens. These “inside-out” insulation failures often present as exteriorized cables. Riata ST Optim and similar Durata leads have an additional abrasion-resistant coating of the silicone-polyurethane copolymer (Optim) tubing. Durata has performed well over 3 years. However, external abrasion has been reported; and a search of the Food and Drug Administration’s Manufacturers and User Device
Experience database identified both external abrasions and 4 failures consistent with inside-out abrasions.3

An intact external Optim tubing prevents cables that have abraded through their lumens from exteriorizing, but it does not alter the fundamental process of inside-out abrasion. Our lead’s inside-out abrasion occurred between the 2 shock coils, the most common location for Riata inside-out abrasions2; and analysis of our explanted lead confirmed the same root cause.

On the lead’s exterior surface, Optim tubing is separated from the shock coils with silicone backfill (Figure 2B). Thus, under the shock coils, Optim-coated leads are identical to similarly designed leads without Optim tubing and they provide no additional protection against inside-out cable-coil abrasion. St Jude Medical’s product performance report lists 4 under-the-shock coil shorts of Durata leads.6 Abrasion under the proximal shock coil could short the distal coil’s conductor to the proximal coil, preventing successful defibrillation.3 In our case, the ring-electrode cable abraded against the distal coil, penetrating the ETFE and shorting to the coil, lowering pacing impedance, and generating nonphysiological signals that resulted in oversensing and inappropriate therapy. The Lead Integrity Alert triggered an alarm, possibly preventing inappropriate shocks. Nonphysiological signals did not occur on the conductor to the tip electrode, which occupies the central lumen. Some nonphysiological signals were synchronous with the T wave, suggesting that cyclical cardiac motion contributed to their genesis. We propose that the pattern of cyclical, nonphysiological signals recorded simultaneously on both the shock and sensing channels is a signature of shorting between the ring cable and the distal coil.

There is great interest in whether Optim tubing will contain inside-out insulation failures and prevent the occurrence of exteriorized cables as that occurs in Riata leads.3,4,7 Simmons et al8 found that the molecular weights of subcutaneously implanted Optim and polyurethane decreased comparably, indicating comparable polymer degradation. At 1 year, both lost mechanical strength; Optim was stronger than poly(ether)urethane 55D but weaker than Bionate 55D, a poly(carbonate) urethane.8 Optim is less prone to oxidative degradation than polyurethane,8 but it undergoes hydrolytic degradation.9 The present lead was implanted longer (4 years) than leads analyzed for molecular weight or tensile strength in the study of Simmons et al (1 year). Thus, it is likely to have degraded further.

Figure 2 Distal lead. A: Photograph identifies locations of zones 1–3. B–D: Photomicrographs show a short between the ring cable and the distal coil in zone 1. B: 20x. Horizontal arrows denote the border between the distal end of the tubing and silicone backfill. C: 100x. Magnification of yellow rectangle in image B. D: 100x. Enlargement of red rectangle in image C. See text for details. Variation in color is caused by changes in lighting.

Figure 3 Zones 2–4. A: Photograph taken in the operating room before the lead had been cleaned shows zones 1 and 2. B–E: 20x photomicrographs. B: Zone 2 with Optim tubing removed. C: Zone 3 perpendicular to ridges. D: Tubing removed from zone 3. E: Zone 4 from the section of the lead in the innominate vein shows explant-related damage. See text for details.
In addition to chemical degradation, tubing in implantable cardioverter-defibrillator leads is subject to cyclical stress, which is greater in small-diameter leads than in large-diameter leads and greatest where the leads flexes most (zones 2 and 3). Compressive bending causes ovalization of the tube’s circular cross section followed by axial buckling, resulting in a pattern of ridges or wrinkles on the surface of the compressed side (eg, Bardi and Kyriakides: Figures 2 and 6; Limam et al: Figures 5, 6, 12, and 16), which is similar to that on the inner curvature in zone 3. Stress-induced cracks may form at either ridge peaks or troughs. Limam et al showed that internal pressure stabilizes thin tubes and resists buckling. In Durata, silicone provides this internal pressure to stabilize the overlying tubing. Conversely, abrasion that removes supporting silicone may facilitate buckling (eg, zone 2). The pattern of axial buckling on our lead is typical of compressive bending.

A possible explanation for the Optim breaches in zones 2 and 3 is that the buckled zones cracked in vivo after years of cyclical compressions and chemical degradation; the cracks then coalesced into larger defects. Alternatively, defects in regions that were subjected to high stress in vivo and pulled smoothly into the sheath without resistance during explant. (1) Longer duration of breach increases the likelihood that the biological material will be deposited under the tubing (zone 2). In contrast, there are no deposits under the tubing adjacent to the explant-related damage in zone 4. (2) It would be coincidental if explant-related abrasions were confined to regions that were subjected to high stress in vivo and pulled smoothly into the sheath without resistance during explant. (3) In regions of buckling, external abrasion could cause cracks at peaks but would be unlikely to cause cracks in troughs between them, as occurred in this lead. (4) The features of defects in zones 2 and 3 suggest a gradual process (such as chemical degradation and/or repetitive weak cyclical forces) rather than a single strong abrasion or tear: The edges have multiple fine protrusions; and the largest defects have overlying thin strands, including a bridging filament in zone 3. A strong abrasion or cut would likely have torn this filament. In contrast to the explant-related damage in zone 4, there are no adjacent mechanical tears. However, there are no established criteria for distinguishing clinical failure from explant-related damage. Furthermore, this lead’s electrical failure was caused solely by shorting between the cable and the coil, not by failure of the Optim tubing.

To the best of our knowledge, we present the first detailed report of an inside-out abrasion of an Optim-coated lead. It illustrates how the tubing does not protect against critical short circuits caused by under-the-shock-coil abrasions. The pattern of simultaneous, cyclical, nonphysiological signals on both the shock and sensing channels should alert clinicians to the possibility of shorting between the ring cable and the distal coil.

References