SUPPLEMENTAL MATERIAL:

ICD Leads: Design, Diagnostics, and Management

Charles Swerdlow MD* and Kenneth A. Ellenbogen†, MD

* Cedars-Sinai Heart Institute and David Geffen School of Medicine at UCLA, Los Angeles, CA

† VCU School of Medicine, Richmond, VA;

Word Count (excluding title page): 1521

Corresponding author:

Charles D. Swerdlow
Cedars Sinai Heart Institute
414 N Camden Dr, Ste 1100
Beverly Hills, CA 90210

swerdlow@ucla.edu
Lead Components and Materials for the Clinician

**Conductors.** The conductor to the tip electrode usually is a helical coil that contains the stylet lumen and transfers torque when the pace-sense terminal pin is rotated to deploy the active-fixation mechanism (Figure 1D). Conductors to the ring electrode and each shock coil are cables consisting of tiny individual wire filaments (about 0.004 cm in diameter) grouped into strands that are in turn grouped to form the cable. In comparison to coils, cables have smaller diameter, lower electrical resistance, and are less prone to crush; but they are less resistant to cyclical flexion.

There are three desirable properties for conductors in ICD leads: resistance to fatigue with repetitive stress, resistance to corrosion, and low electrical resistivity. MP35N™ is the primary metal in most cables and coils, a multiphase (MP) alloy comprised of nickel, cobalt, chromium, and molybdenum. It was developed for marine applications because of its flexion and corrosion resistance, but it has relatively high electrical resistivity. To minimize energy loss in high-voltage conductors, MP35N® is filled with an efficient conductor such as silver.

**Insulation.** Insulation prevents current from escaping from the conductor into tissue. Table 1 summarizes the properties of polymer insulation materials used in defibrillation leads. Silicone elastomer comprises the bulk of all lead bodies. It is a polymer with a siloxane (silicon-oxygen, Si–O–Si) backbone and organic side chains, which is inert, biostable, biocompatible and flexible. It has a high coefficient of friction and is soft, making it prone to implant damage and cold flow (“creep”), increasing deformation under a compressive load, resulting in abrasion failure. These include both external (“outside-in”) abrasions (lead-to-lead, can-to-lead & yoke-
to-lead) from constant compressive loads or internal (“inside-out) abrasions from cyclical compression.\(^2\)

*Polyurethane refers to a class of copolymers in which nanometer-sized regions contain varying fractions of soft and hard segments. Soft segments are rubbery and deform easily; hard segments are glassy or crystalline and stabilize the structure. Polyurethanes are abrasion and impact-resistant and have a low coefficient of friction; but they are subject to oxidative degradation. Metal Ion Oxidation (MIO) is a bulk oxidative process that was first described in coaxial leads with polyurethane inner insulation that placed the polyurethane in direct contact with the conductor. For this reason, polyurethane is used exclusively as outer insulation overlying silicone. Polyurethane environmental stress cracking (ESC) is a surface oxidative process that occurs at ether linkages exposed to the body, catalyzed by peroxides released by macrophages. It begins on outer insulation and propagates inward, resulting in cracks and electrical lead failure. It can be minimized by pretreating polyurethane 55D with an inert gas, permitting its use as a tough, slippery, outside jacket.

*Optim™* (previously known as Elast-Eon™) is a silicone-polyurethane copolymer with a soft segment composed of 80% polydimethylsiloxane (silicone) used exclusively by St. Jude Medical as an outer coating (Figure 1B). It was designed for biomedical applications to have tear and abrasion resistance, lubricity, flexibility and – unlike polyurethane – resistance to oxidative degradation.\(^3\) However, it is subject to hydrolytic degradation\(^4\) and, when implanted subcutaneously, it undergoes polymer degradation and reduction in mechanical strength at a rate comparable to polyurethane.\(^3\)
Fluoropolymers polytetrafluoroethylene (PTFE) and ethylene-tetrafluoroethylene (ETFE) are highly biocompatible, have high tensile strength allowing small lead size, but are stiff, and prone to insulation micro defects. They are used as inner insulating sleeves on cable or coil conductors. Gore expanded polytetrafluoroethylene (ePTFE) has been used as a coating for ICD coils, and recent evidence suggests it reduces the risk of lead removal due to decreased tissue ingrowth.5,6

Specific Considerations for Fidelis™ and Riata™ Leads

Routine interrogations should be inspected for alerts, stored EGMs from nonsustained episodes with nonphysiological signals, and deviations from expected pacing and high-voltage impedance trends. Duration for detection of VF should be prolonged from nominal values. Remote monitoring should be used whenever feasible. Lead alerts should be programmed ON. For Fidelis™ leads, LIA’s value depends on timely response by both patient and physician: only 27% of shocked patients have ≥ 3 days of warning.7 Once a patient presents with an alert, detection of VF should be disabled to prevent inappropriate shocks while evaluating the cause of the alert.8

For Riata™ leads, one monitoring channel should be programmed to record the EGM between RV shock coil and SVC coil. The SVC coil should be programmed OFF to prevent a short circuit if the cable to the RV shock coil abrades against the SVC coil. The manufacturer has made specific programming recommendations.9 Presently, the manufacturer and FDA provide inconsistent recommendations about whether or not to perform radiographic imaging for exteriorized cables.9,10 At generator change, testing for high-voltage short circuits should be
performed by delivering maximum output shocks through the old generator with the SVC oil programmed ON.
References


Figure Legends

Figure 1. Stored and real time EGMs and impedance trend show atypical finding of early conductor fracture. A. and B. Differential recordings isolate cyclical, nonphysiological, presystolic signals to ring-electrode cable. C. Despite no spontaneous evidence of typical lead noise on stored EGMs or in the baseline state, ventricular pacing initiates typical nonphysiological signals. D. Shortly after, impedance trend begins to show abrupt and erratic increases. This case provides a common example in which oversensing precedes impedance rise.

Figure 2. Lead Integrity Alert™ (LIA, Medtronic Inc.). The relative impedance criterion is met if any measured impedance is ≥ 75% or < 50% of an updated baseline value. The two oversensing criteria include the Sensing Integrity Count and transient, rapid ventricular intervals stored as “nonsustained tachycardias.” See text for details. NID = number of intervals to detect VF; SIC = Sensing Integrity Count; NST = nonsustained tachycardia defined as duration ≥ 5 intervals and < programmed NID.

Figure 3. Shock withholding algorithm. Continuous recording shows nonphysiological, rapid signals in VF zone (denoted by asterisks) on sensing channel (RV_{Tip-Ring}) but not shock channel (Discriminator, RV_{Coil-Can}). When the VF counter reaches the number of intervals for detection at lower left, capacitor charging is withheld and a “RV Lead Noise” episode is declared by the SecureSense™ algorithm (St. Jude Medical). The algorithm also provides a vibratory alert every 10 hours and a remote-monitoring alert.

Figure 4. Intraoperative fluoroscopic images of cardiac resynchronization ICD show incomplete insertion of right-ventricular, pace-sense lead pin into header. The ICD has been removed from
the pocket to enhance image quality. Before revision, the lead connector pin was not advanced completely into the header (arrow). The proximal connection between the ring electrode and the header was intermittent, resulting in high impedance and oversensing that caused pauses in paced rhythm. After revision, the right ventricular electrode is advanced completely into the header.

**Figure 5.** EGMs recorded from leads extracted with clinical diagnosis of lead failure. A. EGMs show myopotentials. Left panel shows myopotentials reproduced with pocket manipulation caused by in-pocket breach of insulation on conductor to ring electrode. Right panel shows diaphragmatic myopotentials reproduced by deep breathing in structurally-normal lead. B. EGMs show nonphysiological “noise.” Left panel: conductor fracture. Right panel: header-connector problem due to incomplete insertion of pace-sense terminal pin of IS-1 connector into header. Reproduced with permission.¹²
Figure 2

Triggers: 2 of 3

- Abrupt ↑ Impedance
- SIC ≤ 130 ms > 30 in 3 days
- 2 NST < 220 ms in 60 days

Specific
Sensitive
Moderately Specific

Automatic Δ VF Detection

Δ NID to 30/40

Response

Patients

Clinicians
Figure 3
Figure 5

A

RV_{Tip-Ring}

Marker

Insulation Breach

Diaphragmatic Myopotentials

B

RV_{Tip-Ring}

RV_{Coil-Can}

Marker

Conductor Fracture

Incomplete Pin Insertion