The transvenous defibrillation lead was a critical technological step that enabled widespread adoption of implantable cardioverter-defibrillator (ICD) therapy. This lead is the most vulnerable component of the ICD system. It must remain chemically inert in a hostile biological environment, withstand flexing for hundreds of millions of cardiac cycles, and retain electrical integrity during shocks that would trip a household circuit breaker. Reliability issues concerning leads have led to the rethinking of lead design, reexamination of preclinical testing, implementation of algorithms that warn of lead failure and reduce inappropriate shocks, design of leads that can be extracted more easily, and development of a totally subcutaneous ICD system. The present review summarizes clinical aspects of defibrillation leads and reviews diagnostic and therapeutic approaches to lead failure.

**Design and Failure Modes:**

**Engineering–Clinical Correlations**

Please see the online-only Data Supplement for a brief summary of the engineering of lead design.

**Structural Overview**

Right ventricular (RV) defibrillation leads comprise a distal tip electrode with a fixation mechanism that anchors the lead to the heart, proximal terminals that connect to the generator, and a lead body that connects the two (Figure 1A). The lead body consists of a flexible insulating cylinder with 3 to 6 parallel longitudinal lumens through which conductors run from the proximal terminals to small pace-sense electrodes and larger shock coil electrodes. This multilumen design (Figure 1B) permits more conductors in smaller-diameter leads than older coaxial designs.1 The subcutaneous ICD uses a parasternal electrode in which the larger shock coil is straddled by 2 small sensing electrodes (Figure 1C).

**Clinical Significance of Functional Elements in Transvenous Defibrillation Leads**

ICD leads differ in number of shock coils, number of sensing electrodes, and type of connector terminals.

**Dual-Coil Versus Single-Coil Leads**

All transvenous leads have a distal shock coil in the RV. Dual-coil leads have an additional proximal shock coil, which usually lies in the superior vena cava (Figure 1A). Dual-coil leads were required for the first transvenous ICD systems, which preceded those in which the housing (can) of the generator served as a defibrillation electrode (active can). With contemporary biphasic waveforms and active cans, differences in defibrillation efficacy between dual-coil and single-coil shock pathways are rarely clinically significant for left-pectoral implants.

The principal disadvantage of dual-coil leads is greater risk of extraction because of fibrotic tissue ingrowth into the proximal coil.2 An additional disadvantage is the possibility of a short between high-voltage elements of opposite polarity. However, dual-coil leads retain advantages, including more reliable atrial cardioversion,3 coil-coil electrograms for morphology algorithms that discriminate ventricular from supraventricular tachycardia, and proximal coil-can electrograms that display atrial signals to improve interpretation of single-chamber electrograms.

**Integrated Versus True Bipolar Sensing**

Sensing can either be true bipolar between the tip electrode and a small ring electrode or integrated bipolar between the tip electrode and RV coil (Figure 1D). Modern integrated bipolar and true bipolar leads have similar performance for sensing ventricular fibrillation (VF)4 but differ in susceptibility to oversensing.5,6 The larger integrated bipolar antenna is more susceptible to external electromagnetic interference, R-wave double counting, and diaphragmatic myopotentials. True bipolar leads are more susceptible to T-wave oversensing, probably because of greater variations in R-wave amplitude. There is no consensus regarding which is preferred.

**Connector Terminals**

Until recently, ICD lead terminals comprised an IS-1 pin for the pace-sense bipole and a DF-1 pin for each high-voltage coil (Figure 1A, upper panel). The new DF-4 design (Figure 1A, lower panel) has a single 4-pole connector that connects to a smaller header. This reduces bulk in the pocket, obviates stress at the trifurcation/bifurcation point, and prevents accidental reversal of high-voltage connections; however, it requires an adapter to add a shock coil if defibrillation is unreliable.
Preclinical Testing and Postmarket Surveillance of Defibrillation Leads

Preclinical Testing

In collaboration with manufacturers and government, the International Organization for Standardization (ISO) has established 5 standards for preclinical bench testing relating to mechanical performance, electrical performance, biostability, biocompatibility, and interchangeability (ISO 5841-3, 14708-6, 11318, and 27186). These standards are based on properties of older lead designs that have been accepted. The ISO standards are the basis of accelerated testing. Manufacturers also perform proprietary preclinical tests, informed by studies of biomechanics and the performance of predicate leads and often assisted by computer modeling. Some tests are accelerated by increasing the temperature to alter kinetics of chemical reactions or by increasing the frequency or magnitude of mechanical stresses. However, there are few validated metrics for predicting lead performance on the basis of accelerated testing.

Postmarket Surveillance

Preclinical testing and short-term clinical trials in small populations cannot identify all failure modes during the service life of ICD leads. Three methods of postmarket surveillance are used to protect patients from failure modes that occur only during long-term implantations. The first is analysis of returned products and complaints. This method is critical to determine the root cause of failures and facilitate improved lead designs; however, passive surveillance that depends on physician reporting cannot determine the status of leads that have not been reported to the manufacturer. Estimation of lead survival based on passive methods requires assumptions about the status of unreported leads and thus introduces potential errors. The second method comprises long-term prospective audits that actively monitor the status of each lead in research studies or registries. Such active methods permit better estimates of lead performance if investigators collect and report data meticulously; however, even active methods may not identify important lead failures that result in patient death. Furthermore, because cost limits the sample size of active methods, they may not estimate the rate of rare failure modes accurately. These methods are supplemented by a third, analyses of Internet-based remote-monitoring networks. This enables surveillance of large populations of leads and usually permits determination that a lead has been replaced but is less accurate than active methods and provides less detail. Because the method of data collection influences reported performance, lead performance should not be compared between studies that use different methods.

Incidence and Mechanisms of Lead Failure

The incidence of defibrillation lead failure has been studied in large single-center and multicenter registries. In one study, the overall incidence of clinical lead failure was 1.3 per 100 lead-years, excluding leads with known high failure rates. There are 2 primary structural mechanisms of lead failure: Conductor fracture, best studied in recalled Sprint Fidelis (Fidelis) leads from Medtronic (Minneapolis, MN), and insulation breach, best studied in the recalled Riata family of leads from St. Jude Medical (St Paul, MN).

Fidelis Conductor Fractures

Fidelis is a highly flexible lead that permits bending with a short radius, which increases the force applied to the coil and cable. Analysis of malfunctioning Fidelis leads found that pace-sense conductors failed in 94%. Of these, 43% involved the central helical coil to the tip electrode and 57%...
involved the cable to the ring electrode. All coil fractures occurred at the anchor sleeve (Figure 2A), a region of low-cycle, high stress associated with shoulder motion. Sharp angulation at axillary vein insertion sites may increase the risk of failure. In contrast, most cable fractures occurred proximal to the ring electrode, where the lead undergoes high-cycle, weak stress with each cardiac cycle. To make the distal lead less flexible, silicone backfill was injected into the cable lumen at this location. Fractures occur at this transition from the more flexible lead body to the less flexible distal segment. The root cause is restricted motion of the cable in its narrow lumen, which prevents it from sliding with each cardiac cycle so that this transition serves as a hinge point for the cable.

High-voltage fractures occur in 14% of failed Fidelis leads, 6% in isolation and 8% with pace-sense fractures. In 25 leads, 56% of high-voltage fractures occurred in the cable to the distal coil, 36% in the cable to the proximal coil, and 8% in both.6

**Figure 2. A.** Conductor fracture at tie-down sleeve (Medtronic Sprint Fidelis). Upper left, Radiograph shows sharp angulation (arrow) of lead at axillary vein insertion site, often associated with fracture of pace-sense coil to helix. Upper right, Photograph during bench testing reproduces fracture (arrow) with sharp angulation just distal to sleeve (S). Lower left, Industrial-quality radiograph shows fracture. Lower right, Scanning electron micrograph shows fractured helix coil in radiograph to right.

**B.** Inside-out silicone insulation breach (St. Jude Medical leads). Top, Riata lead with exteriorized cables; cinefluoroscopy frame (left; white arrows denote exteriorized cables) and corresponding photograph (right) of explanted lead. Bottom, Durata lead with outer copolymer tubing removed in central section. Blue ethylene-tetrafluoroethylene insulation is visible on cable to ring electrode, which has abraded inside-out through the lumen of its tubing. Additional cables at top and bottom remain within their lumens.

**Riata-Family Insulation Breaches**

Outside-in in-pocket, lead-can, or lead-lead abrasions may occur with any lead, but silicone leads without an outer protective coating are at highest risk. Abrasion of pace-sense components against the can results in oversensing of pectoral myopotentials, whereas abrasion of the cable to the distal coil shorts the high-voltage output, which prevents shocks from reaching the heart. Despite protection circuitry that aborts shocks into shorted outputs, excessive current in the output circuits may cause catastrophic generator failure.12,13

St. Jude multilumen silicone-body leads include the 8F Riata and downsized 7F Riata ST, which lack an outer protective coating. The 7F Riata ST Optim and Durata models have an outer copolymer coating to prevent coil-can abrasions. (See Appendix in the online-only Data Supplement; Durata also has a redesigned tip to minimize risk of cardiac perforation at implantation.) All of these leads have large-diameter lumens that permit the cables to move more freely than narrower lumens. Internal motion of cables is the root cause of a unique failure mode in which the cables abrade against and through the silicone elastomer insulation that constitutes the walls of their lumens,12,15 which results in inside-out insulation breaches (Figure 2B).14 Approximately 80% of these breaches occur between the shock coils, and 10% occur under the coils.14

In leads without external copolymer tubing, abrasions between the coils present most commonly as exteriorized cables14 that are identified radiographically. At diagnosis, routine follow-up identifies >70% of leads as having normal electrical function6 because of the biocompatibility and high dielectric strength of intact ethylene-tetrafluoroethylene (ETFE) insulation (Figure 1; Appendix in the online-only Data Supplement). Some engineering considerations predict that inside-out abrasions should occur less frequently in 7F leads than 8F leads because the conductor lumens are narrower and closer to the central axis.17 This is supported by a prospective study in which exteriorized cables were more common in 8F leads than 7F leads (17.9% versus 9.4% for leads implanted <6 years). However, variation in reported rates may be caused by lack of standardized imaging and uniform definitions. External copolymer tubing prevents cable exteriorization but not the root cause, inside-out abrasions.

Inside-out abrasions that do not cause exteriorized cables are significant clinically when they cause interactions between conductors. Of these, the most important occur under the shock coils and are not identified radiographically. Contact between the proximal coil and cable to the distal coil shorts the high-voltage conductors, which prevents successful defibrillation.18–20 Contact of the ring electrode cable with either shock coil results in sensing abnormalities.20,21

**Lead Failure: Clinical Presentation and Diagnostic Tools**

**Clinical Presentations**

Pace-sense malfunctions account for the majority of clinically diagnosed lead failures.9 The most common presentation of either conductor fracture or insulation breach is oversensing of rapid nonphysiological signals.11,22 Before diagnostic tools that incorporated oversensing, pace-sense fractures presented most
commonly as inappropriate shocks, despite daily automated measurements of pacing impedance. Oversensing also results in inhibition of pacing. Pace-sense malfunctions may also present with loss of capture. Functional pace-sense failure at the electrode-myocardial interface may result in undersensing of low-amplitude electrograms or elevated pacing threshold.

Because there are fewer diagnostic tools for shock components than pace-sense components, the true incidence of shock-component failures may be higher than identified. Clinically, patients may present with failed defibrillation. Insulation breaches that short high-voltage outputs may cause catastrophic failure of the pulse generator. Presently, however, lead failure is often detected before clinical consequences occur because of diagnostic tools that include electrograms, impedance measurements, and lead-failure algorithms.

**Electrograms in Lead Failure**

Because oversensing is the primary presentation of pace-sense lead failure, electrograms and their annotated event markers (commonly referred to by the trademarked term Marker Channel [Medtronic]) play a central diagnostic role. Events that occur on the sensing channel but not the shock channel indicate oversensing. Stored electrograms are the primary source data for oversensing that results in inappropriate detection of nonsustained or sustained VF. Real-time electrograms are useful in troubleshooting by demonstrating reproducible oversensing. These include lead or connector problems in the pocket that may be identified by pocket manipulation or arm exercise and pectoral or diaphragmatic myopotentials, which do not necessarily indicate lead failure and can be provoked by pectoral muscle exercise and straining, respectively.

**Pace-Sense Conductor Fracture**

Typical nonphysiological fracture electrograms validated by analysis of explanted leads have 5 subjective characteristics (Figure 3)\(^2\). They always have (1) high frequency and (2) occur intermittently. In true bipolar leads, (3) they are not recorded on the shock channel. Typically, (4) they are highly variable in amplitude and frequency (noisy) and usually have a component that is unrelated to the cardiac cycle. Often, (5) they saturate the sensing amplifier. In our experience, the simultaneous occurrence of the first 4 characteristics is specific for lead-system issues (fracture or connector problem), and the combination of all 5 is diagnostic. We refer to the first 4 findings with or without saturation as lead-system noise; however, lead-system noise is only moderately sensitive. In one study, 28% of fractures presented with no or only minor oversensing. Nonphysiological signals are often atypical, including only low-amplitude signals and signals that vary with the cardiac cycle, which indicates an intracardiac source (Figure I in the online-only Data Supplement). Fracture-related signals may be precipitated by pacing, especially high-output pacing (Figure I in the online-only Data Supplement).\(^2\)

The mechanism of fracture-related signals is not established. They are often referred to as make-break potentials because such signals can be generated by connecting and disconnecting cables from the sensing circuit\(^2\) and because it is surmised that a similar process generates signals during intermittent contact between fractured sections of the helix or broken filaments of a cable (Figure 2A). However, make-break potentials do not explain how pacing can induce fracture-related signals.

**Insulation Breach**

Data are limited regarding characteristics of pace-sense electrograms in leads with insulation breaches. Unlike conductor fractures, insulation breaches themselves do not generate abnormal signals. Instead, they result from secondary effects on conductors. These include physiological signals conducted through the insulation breach and nonphysiological signals that arise from interactions of different conductors within the lead body. Intermittent high-amplitude pectoral myopotentials on the sensing channel suggest in-pocket, outside-in abrasion (Figure 4A)\(^2\); however, continuous pectoral myopotentials may be recorded on shock electrograms and do not indicate lead failure. Electrograms associated with clinically diagnosed failures of Riata leads often showed characteristic spikes on both sensing and shock channels that may represent interactions between conductors in the lead (Figure 4B). Simultaneous nonphysiological signals on the shock and sensing electrograms have been reported in inside-out abrasion of the ring electrode cable against the RV shock coil (Figure 4C). When cyclical, they may be confused with physiological T waves.\(^2\)

**Impedance and Impedance Trends**

**Pace-Sense Circuits**

Electrical integrity is evaluated by periodic measurement of the entire circuit’s direct-current electrical resistance (R), commonly referred to as impedance monitoring, by measuring voltage (V) and current (I) and applying Ohm’s law (R=V/I). The circuit comprises the connection between the generator’s header and the lead, the conductors to the tip and ring electrodes, and the electrode-myocardial interface. The pace-sense conductors and electrodes account for only 30 to 50 Ω of the typical circuit’s 300- to 1000-Ω impedance. Because most of the resistance is at the interface between tissue and the tip electrode, impedance is insensitive. A few fractured cable filaments may generate nonphysiological signals without measurable...
alteration in circuit impedance. Out-of-range values occurred before oversensing in only 28% of confirmed Fidelis fractures and 15% of clinically diagnosed Riata failures.

Abrupt relative changes in impedance are more specific than absolute measurements, which record out-of-range values for gradual changes at the electrode-myocardial interface, but a single abrupt change can be spurious. Pacing impedance <200 Ω is thought to indicate an insulation breach, but evidence is limited (Figure 5).

Shock Circuits
The circuit comprises the connection between header and lead, high-voltage conductor cables, shock electrodes, blood in the right atrium and RV, and (provided that the can is included) heart, lung, and chest wall. High-voltage cables and shock electrodes have low impedance (1–2 Ω). The overall circuit typically has resistance in the range of 30 to 50 Ω for single-coil leads and 50 to 80 Ω for dual-coil leads. Two factors complicate low-voltage, painless impedance measurement. First, because tissue resistance is inversely related to voltage, painless measurements must be corrected to approximate high-voltage measurements. Second, respiratory variation is greater at low voltages.

Shock Impedance in Failures of High-Voltage Lead Components
Impedance measurements remain the primary diagnostic tool for high-voltage conductors.

High-Voltage Conductor Fractures
High-voltage conductor fractures present either as asymptomatic abrupt increases in impedance or as unsuccessful shocks. Limited data indicate that an impedance threshold >100 Ω or an abrupt 75% increase in chronic impedance identifies Fidelis fractures. Abnormally high shock impedance may also be caused by high-voltage connection issues or improper calibration of low-voltage measurements.

High-Voltage Insulation Breaches
Low impedance has been reported, but thresholds have not been validated. Furthermore, diagnosis of partial insulation...
breaches remains a critical challenge: Low-voltage test pulses below the dielectric-breakdown voltage encounter intact insulation, but high-voltage shocks above that voltage may cause catastrophic short circuits in either outside-in in-pocket coil abrasions or inside-out abrasions of the cable to the distal coil under the proximal coil. Abnormally low impedance may also be caused by reversed connection of proximal and distal shock coils to the header on IS-1 leads.

**Diagnostics for Pace-Sense Lead Integrity**

Monitoring of both rapid oversensing and impedance improves early detection of lead failure compared with monitoring of impedance alone.

**Sensing Integrity Count**

Extremely short R-R intervals near the ventricular blanking period do not represent successive cardiac depolarizations except occasionally during VF. Medtronic ICDs count sensed ventricular intervals ≤130 ms as a measure of nonphysiological oversensing and store it as the sensing integrity count. A rapidly increasing sensing integrity count (>10 per day for 3 consecutive days) is a sensitive indicator of pace-sense lead fracture, but in isolation it has low specificity (≈20%). The most common causes of isolated extremely short intervals are nonphysiological combinations of physiological signals (eg, T-wave oversensing followed by a premature ventricular beat).

**Lead Integrity Alert**

The lead integrity alert algorithm includes 1 criterion related to abnormal pace-sense impedance and 2 related to transient rapid oversensing (Figure II in the online-only Data Supplement). If any 2 criteria are fulfilled, it immediately triggers an audible alert tone, which repeats every 4 hours. If enabled, it triggers an Internet-based alert. The false-positive rate is low, and lower for true bipolar than for integrated bipolar leads because...
of triggering by electromagnetic interference in integrated bipolar leads (<1/400 versus 1/80 patient-years).11,26,32 Once an alert is triggered, the lead integrity alert sounds an audible tone, initiates an immediate remote-monitoring notification in ICDs with wireless telemetry, and reprograms the number of intervals to detect VF to 30/40, which reduces inappropriate shocks caused by transient, fracture-induced oversensing.11 In a prospective study, the lead integrity alert reduced inappropriate shocks compared with conventional impedance monitoring (lead integrity alert 38% versus control 70%, P < 0.001).

**Algorithms That Compare Sensing and Shock Electrograms**

Two algorithms (Medtronic lead noise algorithm and St. Jude SecureSense) identify oversensed, nonphysiological pace-sense signals as those that do not correlate temporally with electrograms on the shock channel. Both withhold shocks if sufficient oversensing occurs (Figure III in the online-only Data Supplement). In preclinical testing, the lead noise algorithm did not prevent or delay therapy for true VF.28 Clinical performance has not been published for either algorithm; however, both may be triggered by oversensing unrelated to lead failure. A limitation of these algorithms is that they do not identify nonphysiological signals that occur simultaneously on sensing and shock channels, such as those caused by cable-coil abrasions31 (Figure 4C).

**Remote Monitoring**

Remote Internet-based monitoring facilitates diagnosis of lead failure. ICDs with wireless telemetry automatically transmit stored data, including lead alerts. Wireless remote monitoring shortens the time from the alert to decision making or intervention.33 The combination of wireless remote monitoring and a lead integrity alert reduces inappropriate shocks.33

**Radiography and Other Imaging**

Imaging plays a limited role in diagnosing lead failure. The chest radiograph is important primarily for the exclusion of alternative diagnoses such as dislodgement with or without perforation and incomplete insertion of connector pins into the header25 (Figure IV in the online-only Data Supplement). The latter may require spot films or intraoperative radiographs. On the radiograph, the lead should be inspected for conductor discontinuity, kinks or sharp bends (especially at lateral axillary venous insertions; Figure 2A), and evidence of twiddler’s syndrome. Riata leads should be inspected for exteriorized cables. Usually, however, the radiograph in lead failure is unrevealing.

Cinefluoroscopy is the primary method of identifying Riata exteriorized cables. These present characteristic images in which the inner cables protrude outside the outer insulation (Figure 2C). They are identified if either the separation between conductors is larger than the diameter of the shock coil or the radius of curvature of a suspected externalized conductor is significantly different from that of the rest of the lead body.17

**Differential Diagnosis of Pace-Sense Failures**

Accurate diagnosis is important because other conditions can cause both abnormal impedance and oversensing,25 and overdiagnosis results in unnecessary lead replacements. Table 1 summarizes the differential diagnosis.

**Abnormal Pacing Impedance With or Without Oversensing**

Gradual impedance rises without oversensing occur in normally functioning leads because of changes at the electrode-myocardial interface; however, high impedance combined with oversensing indicates a fracture or connection problem. Electrogram characteristics of lead-system noise do not differentiate fractures from connection problems (Figure V in the online-only Data Supplement), but impedance trends can discriminate them (Figure 5).25

Connection problems include loose setscrews, weakened ICD header bonds, adapter problems, and incomplete contact between the lead pin and header; they constitute up to 10% suspected fractures.11,25 Abrupt impedance rise within 30 days after a new lead implantation is a connection problem, provided that lead dislodgement is excluded. However, incomplete pin insertion may cause late impedance rises; 46% of cases presented >6 months after the last surgical procedure.25 A long period in which impedance returns to baseline after an abrupt rise indicates a connection problem. Radiography reliably diagnoses incomplete contact between the lead pin and header. If operative intervention is required, the ICD should be inspected for incomplete insertion of the lead pin into the header, loose setscrews, and other header problems before the lead is disconnected. Table 2 summarizes characteristics of connection problems caused by incomplete pin insertion.

Reduced pacing impedance has been reported with insulation breaches in older coaxial defibrillation leads and rarely in silicone abrasions of multilumen leads,25 but most breaches in multilumen leads present with impedance within the nominal range, although some have reduced impedance within that range. Optimal diagnostic criteria are unknown.

### Table 1. Differential Diagnosis of Pace-Sense Lead Failure

<table>
<thead>
<tr>
<th>Electrogram</th>
<th>Impedance†</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead-system noise</td>
<td>High; abrupt increase</td>
<td>Fracture or connector</td>
</tr>
<tr>
<td>Lead-system noise</td>
<td>Normal</td>
<td>Fracture, insulation breach†</td>
</tr>
<tr>
<td>Spikes, myopotentials on true bipolar electrograms</td>
<td>Normal or low</td>
<td>Insulation breach</td>
</tr>
<tr>
<td>Other rapid oversensing‡</td>
<td>Normal</td>
<td>Normal lead</td>
</tr>
<tr>
<td>Normal</td>
<td>High; abrupt increase</td>
<td>Fracture or connector</td>
</tr>
<tr>
<td>Low</td>
<td>High; gradual increase</td>
<td>Normal lead</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Insulation breach</td>
</tr>
</tbody>
</table>

*High impedance=75% > baseline. Abrupt increase indicates the maximum value for 1 week exceeds baseline of past 3 weeks by 75%. Gradual increase does not meet abrupt criterion. Impedance < 200 Ω is considered low, but data correlating insulation breach with impedance changes are limited, and most insulation failures have impedance within normal range.

†Data supporting correlation between insulation breach and lead-system noise are limited.
Rapid Oversensing With Normal Pacing Impedance
Because connection problems always present with high impedance after the perioperative period, lead-system noise with a normal impedance strongly favors lead failure if it presents >30 days postoperatively.25 However, conditions other than ICD system issues can cause repetitive, extremely short sensed R-R intervals with normal impedance, and their electrograms must be distinguished from lead-system noise. Uniform, rapid, medium-frequency signals shortly after implantation or generator change are caused by air trapped in the header that escapes through a seal plug. Lead-lead mechanical interactions32 can be suspected on the basis of history or radiography. In extremely rapid true VF,32 the shock electrogram confirms the diagnosis. High-frequency diaphragmatic myopotentials occur most commonly with integrated bipolar leads placed at the RV apex.25 They are distinguished by uniformly low amplitude and relatively uniform morphology (Figure VA in the online-only Data Supplement).

Approach to the Patient
Suspected Pace-Sense Component Failure
Detection of VF should be disabled immediately in any patient with lead-system noise that is the cause of inappropriate shocks. Diagnosing a single out-of-range impedance measurement without other signs of lead malfunction is less urgent and may require observation. In true bipolar leads, connection problems caused by incomplete pin insertion may be corrected by programming integrated bipolar sensing (if this option is available), but long-term outcomes of this programming strategy have not been reported. Integrated bipolar sensing also resolves oversensing related to failure of the ring electrode conductor. This is not recommended as a long-term solution in Fidelis leads, because other lead elements have a higher risk of failure.10 For normally functioning leads with a gradual impedance rise to <2500 Ω, limited data support follow-up without operative intervention.31 If the impedance rise is abrupt, incomplete pin insertion should be excluded by radiography or intraoperative inspection before lead replacement. Insulation breaches typically require lead replacement.

Suspected High-Voltage Component Failure
Abnormally low-voltage measurement of shock impedance should be confirmed by a high-voltage shock to exclude erroneous measurements. There is no consensus on whether isolated fractures of the proximal coil require lead replacement or only that the proximal coil be programmed out of the shock circuit and that defibrillation be retested. Abnormally low shock impedance requires prompt lead replacement for insulation breach, provided that reversed shock coil connections are excluded. If the ICD generator is to be reused, a high-voltage shock should not be delivered because of the risk of damaging the output circuit.

Managing At-Risk Leads
At Recall
The whole story is rarely clear. Usually, understanding of failure rates and optimal management strategies is incomplete. We are quick to optimize patient-specific programming, to confirm appropriate remote monitoring, and to notify patients empathetically, but slow to replace normally functioning leads, and careful to reassess over time. Physicians must provide explanations that patients can understand,36 and physicians

Table 2. Clues to Diagnosis of Header-Connection Problems Caused by Incomplete Pin Insertion

- Electrogram lead-system noise indistinguishable from fracture
- Differential recordings* localize nonphysiological signals to proximal sensing electrode, not tip electrode
- Abrupt increase in impedance (Z); trends often distinct from fracture
  - Long periods of return to baseline impedance after impedance rise
  - First impedance rise may occur >6 months postoperatively
- Preoperative radiograph is diagnostic
- Exclude connector problems intraoperatively before disconnecting lead

*See Figure I in the online-only Data Supplement.

Table 3. Risk–Benefit Considerations for Managing Normally Functioning At-Risk Leads

<table>
<thead>
<tr>
<th>Patient related</th>
<th>Pulse-generator related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker dependence*</td>
<td>Elective replacement because of battery depletion</td>
</tr>
<tr>
<td>Primary vs secondary prevention</td>
<td>Reprogramming options to mitigate clinical risk</td>
</tr>
<tr>
<td>Identified patient subset with higher failure rate (eg, age, ventricular function)</td>
<td>Algorithms for early detection of lead abnormality</td>
</tr>
<tr>
<td>Patient prognosis, including comorbidities</td>
<td>Physician related</td>
</tr>
<tr>
<td>Risk of future ventricular tachycardia/fibrillation</td>
<td>Individual physician experience with lead extraction</td>
</tr>
<tr>
<td>Procedural risk of adding or extracting a lead</td>
<td>Center’s experience and facilities for lead extraction</td>
</tr>
<tr>
<td>Patient anxiety about lead failure after counselling</td>
<td>Malfunction mechanism known/understood</td>
</tr>
<tr>
<td>Access to remote monitoring, especially wireless remote monitoring</td>
<td>Specific adverse clinical consequences of lead failure</td>
</tr>
<tr>
<td>Prior cardiac surgery</td>
<td>Single- vs dual-coil lead</td>
</tr>
<tr>
<td>Age and severity of cardiac/noncardiac disease†</td>
<td>Duration of lead implantation</td>
</tr>
<tr>
<td>Lead burden</td>
<td>Lead related</td>
</tr>
<tr>
<td>Vein patency</td>
<td>Rate of abnormal performance (observed or projected)</td>
</tr>
<tr>
<td>Identified lead subset with higher failure rate (serial numbers, vascular access, etc)</td>
<td>Malfunction characteristics (gradual vs sudden, predictable vs unpredictable, etc)</td>
</tr>
<tr>
<td>Malfunction mechanism known/understood</td>
<td>Specific adverse clinical consequences of lead failure</td>
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must understand that risk is perceived differently when it is personal. Management requires both a patient-specific and patient-centered approach. The online-only Data Supplement Appendix provides specific considerations for Fidelis and Riata leads.

At Generator Replacement

Generator replacement provides the opportunity to replace normally functioning at-risk leads and the generator at a single procedure, potentially avoiding infection risks of a subsequent procedure to replace a failed lead. The best approach depends on accurate knowledge of procedural risk, failure rate, and consequences of lead failure. If mortality is the only consideration, generator replacement alone is usually preferred to lead replacement for Fidelis leads, except possibly in pacemaker-dependent patients. In practice, the preferred strategy depends on trade-offs among mortality, procedural complications, cost, quality of life as measured by inappropriate shocks, and patient anxiety. If lead replacement is selected, options include insertion of a new lead only or extraction and replacement. The decision depends on the risk of extraction, which in turn depends on the patient, operator/institution, and specific lead model. Table 3 summarizes factors relevant to this decision.

Future Directions and Summary

Present research includes development of antibacterial coating to reduce infections, polymer coatings to facilitate extraction, and design changes to make leads conditionally safe for magnetic resonance imaging. However, development of bio-stable and durable transvenous defibrillation leads remains both a materials science and mechanical engineering challenge. Until that challenge is overcome, clinicians must be able to recognize presentations of lead failure and understand the trade-offs among management options. Data from registries of patients are especially important, because failure rates may vary over time, and systematic failures may not be identified until years after implantation. Cooperation and open communication among physicians, industry, and the US Food and Drug Administration will facilitate rapid dissemination of evidence-based strategies to achieve the best outcomes for our patients.

Disclosures

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References


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Charles D. Swerdlow and Kenneth A. Ellenbogen

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SUPPLEMENTAL MATERIAL:

ICD Leads: Design, Diagnostics, and Management

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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.¹ 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.¹

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.

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. However, it is subject to hydrolytic degradation and, when implanted subcutaneously, it undergoes polymer degradation and reduction in mechanical strength at a rate comparable to polyurethane.
**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 1

A) January 27
Can-ring
Tip-ring

B) February 4
ECG
Tip-ring
Tip-coil

D) March 23

March 23
Can-ring
Tip-ring

Graph showing ohms from 12/01/09 to 04/27/10 with markers on March 23.
Figure 2

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

Triggers: 2 of 3

**Specific**

**Sensitive**

**Moderately Specific**

Automatic Δ VF Detection

Δ NID to 30/40
Figure 5

A

Insulation Breach

Diaphragmatic Myopotentials

B

Conductor Fracture

Incomplete Pin Insertion