Time Course of Oversensing and Impedance Changes in Developing Implantable-Cardioverter Defibrillator Lead Fracture

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Early fracture causes oversensing before clinical impedance alert.
Time Course of Oversensing and Impedance Changes in Developing Implantable-Cardioverter Defibrillator Lead Fracture

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Abstract

**Background:** Pace-sense conductors comprise a pacing-coil to the tip-electrode and cable to the ring-electrode. Implantable-cardioverter defibrillator (ICD) lead-monitoring diagnostics include pacing-impedance (direct current resistance [DCR]) and measures of oversensing. How they change as fractures progress is unknown.

**Objectives:** Characterize the relationship between oversensing, impedance, and structural changes in ICD leads developing pace-sense conductor fractures.

**Methods:** We performed bending tests on 39 leads connected to ICD generators in an electrolyte bath with simulated electrograms. DCR was recorded every 3 min; electrograms were telemetered continuously. Twenty-two leads were tested to develop partial/complete fracture criteria confirmed by imaging, using DCR or DCR variability measured by standard deviation ($\sigma_{DCR}$). Results are reported for 17 other test leads.

**Results:** Initial oversensing occurred with partial pacing-coil fracture vs. complete ring-cable fracture and correlated with bending-induced DCR peaks. These peaks were too small to be detected by clinical impedance measurements and were characterized by small increases in $\sigma_{DCR}$ ($\geq 0.5\Omega$). Impedance-threshold alerts occurred at complete pacing-coil fracture but only later for ring-cable fractures. The oversensing alert triggered before device-detected ventricular fibrillation (VF) more frequently than impedance alerts (94% vs. 17%, P=0.00002).
Conclusions: In conductor fracture, early oversensing corresponds to partial pacing-coil fracture or complete ring-cable fracture and correlates with transient bending-induced impedance increases, which are detected by impedance variability but too small to trigger clinical impedance alerts. This explains why clinical oversensing alerts provide more warning for device-detected VF than impedance alerts and suggests how to improve impedance diagnostics based on short-term variability.

Keywords: implantable cardioverter defibrillator lead, conductor fracture, defibrillation lead fracture, oversensing, impedance
Introduction

Most failures of transvenous right-ventricular (RV) defibrillation leads involve pace-sense components, placing patients at risk for inappropriate shocks. Implantable-cardioverter defibrillators (ICDs) monitor for conductor fracture using pacing impedance\(^1,2\) and measures of oversensed non-physiologic signals.\(^3-6\)

These diagnostics may present interpretative difficulties.\(^7\) Optimal interpretation and development of improved diagnostics may be informed by knowledge of how these diagnostics change as fractures progress. However, the relationship between oversensing and pacing-impedance changes is unknown in leads with evolving conductor fracture. This study used a novel experimental design to correlate these changes with each other and with structural damage to the fractured conductor.

Methods

We performed accelerated, cyclic-bending tests of defibrillation leads placed in a saline bath and connected to an ICD generator. See Supplemental Methods, Supplemental Video and Supplemental Figures 1-4 for additional details.

ICD System

The ICD system comprised a Medtronic Cobalt\(^\text{TM}\) generator attached to Medtronic Sprint Quattro\(^\text{TM}\) RV leads. The multi-lumen leads have a helical conductor-coil to the distal (tip) pace-sense electrode (pacing-coil) and a conductor-cable to the ring
sensing electrode (ring-cable), in addition to a RV defibrillation coil (Figure 1). The pacing-coil comprises 4 filars. The cables comprise 49 filars surrounded by ethylene tetrafluoroethylene (ETFE) insulation. The number of intervals to detect ventricular fibrillation (VF) was programmed to 30/40 with a VF detection interval of 320ms.

Test Apparatus and Procedure

Leads were subjected to continuous, cyclic bending in a fatigue tester (Bose Model 3230, Eden Prairie, MN) at 1.3 Hz (Figure 1). The lead and generator were placed in a saline bath. Leads were oriented with the conductor under study on the inner radius to place the greatest stress on that conductor, increasing the likelihood it would fracture first. A 1-Hz simulated electrogram (EGM) signal was applied to the bath using patch electrodes. To record ICD EGMs continuously, the receiving-coil of a telemetry Holter monitor was positioned near the ICD, outside the saline bath. To measure impedance as direct current resistance (DCR), we made electrical connections to the conductors both proximal and distal to the bending site. We measured DCR every 3 min using a digital multimeter (Agilent model 3458A, Santa Rosa, CA, range $10^{-5} – 10^{38} \Omega$). We used custom LabVIEW® software to pause or end testing based on DCR or its standard deviation ($\sigma_{DCR}$) which were determined in near real time.

Each lead was imaged at the completion of testing. High-resolution radiographs (Northstar M50, Rogers, MN) were performed of all leads at minimum and
maximum bending radii. Leads oriented to stress the ring-cable were also imaged using optical microscopy because radiography did not identify all early-stage partial fractures. Representative leads were imaged using scanning-electron microscopy for the purpose of illustration.

Development and Test Lead Sets

First we tested a set of “development” leads to identify criteria for partial and complete fracture based on DCR or \( \sigma_{\text{DCR}} \). Then we applied these criteria in a set of “test” leads to determine EGM characteristics that correlate with partial and complete fracture.

The goal of development experiments was to identify the earliest, reliable DCR/\( \sigma_{\text{DCR}} \) criteria for partial and complete fracture of each conductor. To select and validate these criteria, leads were removed from the test apparatus when candidate criteria were met and imaged as described above. See Supplemental Material for details. Partial fracture was defined as discontinuity of at least 1 filar by radiograph or light microscopy; complete fracture was defined as discontinuity of all filars. Table 1A shows the partial/complete fracture criteria determined in development experiments.

All test leads were cycled to DCR\( \geq 3000 \Omega \) (open circuit) for the conductor under study. This permitted correlation of EGM characteristics with impedance (DCR/\( \sigma_{\text{DCR}} \)) changes over the entire course of developing fracture. We paid special
attention to EGM characteristics at the earliest DCR/σ_{DCR} indication of partial or complete fracture. The minimum bending radius was chosen to produce fracture of the conductor under study within 24 hours, based on development-set testing (2 mm for leads oriented to stress the pacing-coil fracture, 1 mm for leads oriented to stress the ring-cable).

Analysis of EGMs, DCR, and Lead-Monitoring Diagnostics

We analyzed both EGMs stored in the ICD and the 2 EGM channels telemetered continuously. The ICD’s Lead Integrity Alert™ (LIA), includes both oversensing and relative-impedance components. The two oversensing components are a count of ≥30 non-physiologic short ventricular intervals ≤130ms within 3 days and occurrence of ≥2 rapid non-sustained tachycardia (NST) episodes (<220ms) in 60 days. The relative-impedance component requires an abrupt change relative to a 13-day baseline (75% increase or 50% decrease). LIA is triggered when threshold criteria are satisfied for any two components.

First oversensing was defined as the first V-V interval <1000ms on the Holter marker channel. Events defined by EGMs included first oversensing, LIA triggered by both oversensing criteria, and first inappropriate detection of VF.

The ICD’s pacing-impedance diagnostic nominally alerts for impedance ≥2000Ω.

Events defined by DCR or σ_{DCR} comprised partial fracture, complete fracture, LIA relative-impedance criterion, nominal pacing-impedance alert, and DCR≥3000Ω.
Since DCR was recorded every 3 min, we correlated EGMs with the DCR recorded in closest temporal proximity. To facilitate correlation of EGM and DCR events, we normalized event times as multiples of time to partial fracture ($T_{PF}$) or time to complete fracture ($T_{CF}$).

To approximate clinical warning times corresponding to lead-monitoring diagnostic alerts in this study, we set the median time from test onset to LIA-oversensing alert to 5 years (60 mo) of clinical service. This is conservative based on clinical median time from implant to LIA-oversensing alerts for conductor fracture of 118 mo.\textsuperscript{10}

**Statistical Analysis**

Median times to analyzed events were compared using the Wilcoxon signed rank test. The Bonferroni method was used to adjust p-values to correct for multiple comparisons. A p-value <0.05 was considered significant.

**Results**

We studied 22 development leads to determine partial/complete fracture criteria and 17 test leads to correlate EGM characteristics with impedance ($\frac{\sigma_{DCR}}{DCR}$) changes (total 39 leads). The conductor under study was the pacing-coil in 8 test leads and the ring-cable in 9 test leads. Additional details are in Supplemental Results, Supplemental Tables, and Supplemental Figures 5-11.
Imaging Findings

Figure 2 shows examples of partial and complete ring-cable and pacing-coil fractures. At complete ring-cable fracture, ETFE inner insulation constrained fracture faces in apposition, so complete discontinuity could be verified only by removing the inner insulation.

Electrogram and DCR Changes

Progressive Changes

Figures 3 shows the progression of DCR and EGM changes in a representative pacing-coil fracture. Figures 4 show the corresponding progression in a representative ring-cable fracture. Legends for each figure correlate DCR and EGM changes. For both conductors, the earliest sign of fracture is a low-amplitude, transient DCR peak, synchronous with the bending cycle. As fractures progress, the amplitude of bending-induced peaks increase but the baseline between peaks increases only minimally.

For pacing-coil fracture, earliest oversensing correlates with the first DCR evidence of partial fracture (Figures 3B-3C), but neither the relative nor fixed impedance-threshold is reached until complete fracture (Figure 3G). In contrast, for ring-cable fracture oversensing does not begin until complete fracture; and impedance thresholds are not reached until even later (Figure 4G) when macroscopic conductor separation occurs at the fracture site. So for both
conductors, bending-induced $\sigma_{\text{DCR}}$ increased abruptly near the onset of oversensing (pacing-coil partial fracture and ring-cable complete fracture).

In Figures 3-4, the LIA oversensing alert triggers before inappropriate VF detection, but impedance alerts do not trigger until after inappropriate VF detection.

When the pacing-coil was stressed, complete pacing-coil fracture always occurred before partial ring-cable fracture. However, when the ring-cable was stressed, partial pacing-coil fracture developed before complete ring-cable fracture in 4 of 9 test leads. Thus, in the test dataset, oversensing was attributed to pacing-coil fracture in 12 leads and ring-cable fracture in 5 leads.

Table 1B shows the values of mean $\text{DCR}/\sigma_{\text{DCR}}$ for the 17 test leads, stratified by the conductor that caused oversensing. At either partial fracture or LIA oversensing alert, the increase in mean DCR from test onset is too small to be detected by clinical impedance for either conductor. For the ring-cable, this is also true at complete fracture. Additionally, even the DCR peak increases at the onset of oversensing were too small to be detected by clinical impedance (pacing-coil peak at partial fracture 3.6±2.5Ω, ring-cable peak at complete fracture 8.9±9.4Ω).

At test end, transient DCR peaks remain synchronized to the bending cycle for fractures of both conductors, independent of DCR peak amplitude (Figure 5).

Oversensing stops and EGMs normalize when bending stops (Figure 5).

Radiographs in Figure 5 show overlapping filar ends at the minimum bending
radius, explaining how electrical continuity is preserved despite complete fracture.

DCR retained an isoelectric baseline 16 of 17 test leads (94%). Central Figure 6 summarizes the relationship between structural changes, oversensing, and DCR/impedance increases as fractures progress.

Experimental Measurements vs. Clinical Diagnostics

Figure 7 displays event times normalized to the DCR event that correlated with the onset of oversensing (partial fracture [$T_{PF}$] for pacing-coil, complete fracture [$T_{CF}$] for ring-cable). The LIA-oversensing alert triggered ≥1 min before inappropriate VF detection in 14 leads (82%). With a median time to oversensing alert of 401 min, 1 min in this experiment corresponds conservatively to 4.6-days of clinical warning. In 2 additional leads, LIA alerts corresponded to warnings of 5.4 hours and 2.4 days. Overall, LIA triggered before inappropriate VF detection in 16 leads (94%, $P=0.0005$). In the remaining lead, the first repetitive oversensing event progressed to inappropriate VF detection, so a second NST was not recorded. In contrast, the LIA relative-impedance criterion and impedance alert triggered before inappropriate VF detection in only 3 leads (18%, $P=0.00002$ vs. LIA oversensing alert).

Oversensing began later in the course of ring-cable fractures than pacing-coil fractures, and the LIA oversensing alert triggered correspondingly later (Table 1B).

However, once oversensing started, it progressed faster to inappropriate VF detection for ring-cables than pacing-coils ($1.08 T_{CF}$ vs. $1.27 T_{PF}$, $P=0.012$, Figure 7).
Fracture-Induced Signals

The first fracture-induced signals were always discrete and occurred once per bending cycle. Common features across leads included intermittent occurrence, non-physiologic short intervals, variability, and high-frequency components. Signal truncation caused by sensing-amplifier saturation became more likely as fractures progressed. It occurred in only 1 lead at earliest oversensing but in all leads at open circuit. Sixteen of 17 leads (94%) had near-continuous oversensing at open circuit.

Discussion

Previously, the relationship between oversensing and pacing-impedance changes was unknown in leads with developing conductor fracture. In-vitro bending tests show that small changes in pacing impedance/DCR are sensitive for conductor fracture; but clinical lead-monitoring alerts that measure oversensing are more sensitive than those that measure impedance. Usually, bending tests are performed on short conductor segments rather than complete leads, continued to complete fracture so the onset of partial fracture is not determined, and performed in air so fracture-induced signals cannot be recorded. By testing complete leads connected to an ICD generator in saline, we determined the sequences of EGM and DCR/impedance changes and correlated them, both with each other and with structural changes in developing fractures.
Study Findings

Principal Findings

(1) The onset of fracture-induced oversensing correlates with intermittent, bending-induced peaks in DCR. (2) For the pacing-coil, oversensing begins at earliest partial fracture. In contrast, for the ring-cable oversensing does not begin until complete fracture. (3) As fractures progress, DCR/impedance varies cyclically with lead bending, but mean and baseline values increase only minimally. Thus, measures of short-term DCR variability (e.g. $\sigma_{DCR}$) are more sensitive than single measurements of DCR. (4) As oversensing progresses to device-detected VF, DCR/impedance changes remain too small to be detected by clinical impedance alerts until late in the fracture process.

Mechanism of Fracture-Induced Oversensing

In this experiment, DCR varied synchronously with the bending cycle as soon as partial fracture occurred. This indicates that the fracture faces of individual filars lose contact at specific phase(s) of the bending cycle. In the remainder of the cycle, fracture faces appose, preserving electrical continuity. The earliest oversensed signals correspond precisely with bending-induced peaks in DCR, both in timing and morphology; repetitive oversensing corresponds to multiple DCR spikes per bending cycle; and EGMs normalize when bending stops, even after complete fracture. It has long been hypothesized make-break potentials,\textsuperscript{13} caused by intermittent contact between fracture faces, are responsible for
fracture-induced oversensing. This experiment provides the first direct evidence to support this hypothesis.

Characteristics of Fracture-Induced Signals and Intervals

Our late-stage, experimental fractures reproduce features of oversensing described clinically: intermittent occurrence, non-physiologic short intervals, and highly-variable “noisy” EGMs with both high-frequency components and high-amplitude components that saturate the sensing amplifier.

However, early-stage, experimental fracture cause signals that differ from those described clinically: they are discrete and rarely saturate the sensing amplifier.

Differences in Diagnostics Between Pacing-Coil and Ring-Cable Fractures

Structural differences explain different time courses of $\frac{\text{DCR}}{\sigma_{\text{DCR}}}$ changes and oversensing in ring-cable vs. pacing-coil fractures. The much greater number of filars in ring-cables (49) vs. pacing-coils (4) determines both why fracture of one or a few filars causes a smaller increase in $\frac{\text{DCR}}{\sigma_{\text{DCR}}}$ for the ring-cable vs. pacing-coil and why, as individual filars break, $\sigma_{\text{DCR}}$ increases gradually for the ring-cable vs. abruptly for the pacing-coil. The ETFE inner insulation that constrains the ring-cable maintains conductor electrical continuity, explaining the much smaller increase in $\frac{\text{DCR}}{\sigma_{\text{DCR}}}$ for the ring-cable vs. pacing-coil at complete fracture. The ring-cable’s combination of more filars and constraint by inner insulation may also explain why make-break potentials and oversensing do not occur until complete fracture.
Clinical Correlation

Lead Surveillance

Our findings elucidate the structural bases for the oversensing and impedance changes that trigger lead-monitoring diagnostics. Partial ring-cable fracture cannot be detected clinically. Oversensing alerts correspond to partial pacing-coil fracture vs. complete ring-cable fracture. The first discrete, variable-amplitude fracture-induced signals differ from clinically-described, high-amplitude, noisy signals, which only occur later. So, unexplained, discrete, oversensed signals should raise suspicion for conductor fracture.

For both conductors, impedance alerts always indicate complete fracture. However, even with complete fracture, lead bending is required to trigger an impedance alert until permanent conductor separation occurs. Most fractures occur in the shoulder region near the anchor sleeve or under the clavicle. If the fracture faces appose in the shoulder’s resting position, periodic impedance measurements will be normal unless recorded during shoulder motion. In contrast, oversensing is monitored continuously and will detect fracture-induced signals triggered by motion. This experiment provides the mechanistic basis that explains why clinical oversensing alerts are more sensitive than impedance alerts, impedance abnormalities in the absence of oversensing rarely indicate fracture, and out-of-range impedance is not required to diagnosis fracture.\textsuperscript{2-6, 11, 15}
Differences between ring-cable and pacing-coil fractures contribute to clinical variations in progression from initial oversensing to device-detected VF. Inter-patient differences in lead bending also contribute. Since remote-monitoring usually does not identify the fractured conductor or rate of bending, all suspicious oversensing alerts should be investigated promptly.

**Future Developments**

Future impedance diagnostics could identify an increase in the short-term variability of a series of rapid measurements rather than comparing single measurements with a threshold. Repetitive measurements could be coupled with greater precision to improve sensitivity. The minimum resolution of pacing impedance is $\geq 10\,\Omega$ for all manufacturers, even though resolution of $\leq 1\,\Omega$ is feasible and implemented for shock impedance. Until then, when oversensing patterns are not diagnostic, rapidly-repeated, manual impedance measurements during shoulder motion may detect fracture-induced abnormal variability.

**Limitations**

This study does not fully reproduce the clinical environment. Most clinical fractures are caused by intermittent and varying bending stress over years. In contrast, we applied continuous, cyclic stress at a constant amplitude and frequency to cause complete fracture in a practical, experimental time frame. The minimum radius of curvature for implanted leads is under investigation in an ongoing multicenter study, using 3-dimensional reconstruction of biplane
Based on a preliminary report, the minimum radii in the present are at the lower end of in-vivo values. Additionally, our study does not address mechanisms of conductor fracture unrelated to flexural fatigue, such as crush injury.

This study was not powered to detect significant differences in mean DCR between test onset and partial fracture or LIA trigger. Our $\sigma_{\text{DCR}}$ criteria for fracture were chosen from small samples and should be considered as values at or above which partial/complete fracture is present. However, occurrence of fracture at a lower $\sigma_{\text{DCR}}$ does not affect our main finding: early fracture-induced oversensing always corresponds to bending-induced DCR variations that are too small to be detected by present impedance diagnostics.

We tested only one manufacturer’s lead because only manufacturers own the necessary test apparatus, and the competitive corporate environment precludes testing of one manufacturer’s leads on another’s apparatus. However, all manufacturers have achieved equivalent results when performing the same bending test on identical conductor segments. To encourage reproducing our experiment with other leads, we provide detailed experimental methods. Further, our primary finding is independent of conductor type: For both pacing-coils and ring-cables, the onset of fracture-induced oversensing correlates with intermittent, bending-induced peaks in DCR that are too small to be detected clinically. Since
all multilumen ICD leads use pacing-coils and cables to the ring or integrated-bipolar sensing electrode, we expect this primary finding to apply generally.

Similarly, we tested only one manufacturer’s diagnostics. However, all manufacturers have similar impedance-threshold alerts and all manufacturers have oversensing diagnostics. LIA has been studied more extensively than any other oversensing diagnostic. The only other reports of another oversensing diagnostic or determination of oversensing using real time EGMs show earlier warning than impedance diagnostics before inappropriate VF detection.

We underestimate performance of oversensing alerts because continuous bending causes oversensed intervals to accumulate faster than intermittent bending. In contrast, we overestimate performance of impedance alerts because periodic impedance measurements are unlikely to identify the first transient DCR spike that exceeds the alert threshold. Thus, we underestimate the clinical superiority of oversensing alerts relative to impedance alerts.

We did not test passive-fixation ICD leads. However, they also have a pacing-coil ring-cable. So, it is likely that our findings apply to passive-fixation ICD leads. Our findings may not apply to leads with different constructions such as coaxial coils or individually-insulated, co-radial coils.

Conclusions

In developing ICD pace-sense conductor fracture, early oversensing correlates with bending-induced peaks in impedance that are too small to be detected by
clinical impedance diagnostics. Even with complete fracture, oversensing may stop and DCR/impedance may normalize when bending stops. Our findings provide direct evidence that fracture-induced signals are caused by make-break potentials, explain why clinical oversensing alerts are superior to clinical impedance alerts, and suggest opportunities for improving impedance diagnostics based on short-term variability.
Acknowledgments

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References


### Table 1

#### A. Direct Current Resistance Criteria (Ω) for Complete and Partial Fracture, Development Leads (N=22)

<table>
<thead>
<tr>
<th></th>
<th>Partial Fracture</th>
<th>Complete Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pacing-Coil (N=11)</strong></td>
<td>( \sigma_{\text{DCR}} \geq 0.5 \Omega )</td>
<td>( \sigma_{\text{DCR}} \geq 3000 \Omega )</td>
</tr>
<tr>
<td><strong>Ring-Cable (N=11)</strong></td>
<td>( \sigma_{\text{DCR}} \geq 0.0015 \Omega )</td>
<td>( \sigma_{\text{DCR}} \geq 0.5 \Omega )</td>
</tr>
</tbody>
</table>

DCR=direct current resistance; \( \sigma_{\text{DCR}} \) =standard deviation of DCR

#### B. Direct Current Resistance Mean and Standard Deviation (Ω), Test Leads (N=17)

<table>
<thead>
<tr>
<th></th>
<th>Test Onset</th>
<th>Partial Fracture</th>
<th>LIA (Pacing-Coil)</th>
<th>Complete Fracture</th>
<th>LIA (Ring-Cable)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fractured Conductor</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pacing-Coil (N=12)</strong></td>
<td>Mean DCR</td>
<td>40.7±2.1</td>
<td>*40.8±1.9</td>
<td>45.7±13.9</td>
<td>( \geq 3000 )</td>
</tr>
<tr>
<td></td>
<td>( \sigma_{\text{DCR}} )</td>
<td>*0.97±0.62</td>
<td>2.5±2.1</td>
<td>( \geq 10^{10} )</td>
<td></td>
</tr>
<tr>
<td><strong>Ring-Cable (N=5)</strong></td>
<td>Mean DCR</td>
<td>15.0±0.35</td>
<td>15.1±0.4</td>
<td>*16.1±0.6</td>
<td>17.4±2.1</td>
</tr>
<tr>
<td></td>
<td>( \sigma_{\text{DCR}} )</td>
<td>3.7±0.61x10^{-4}</td>
<td>18±1.8x10^{-4}</td>
<td>*1.1±0.9</td>
<td>2.5±2.4</td>
</tr>
</tbody>
</table>

\*First oversensing

LIA=LIA oversensing alert. Other abbreviations as in Table 1A.
Figure 1. Test Apparatus. A. Defibrillation lead. B. Implantable-cardioverter defibrillator (ICD) generator. C. Proximal and distal connections for measurement of direct-current resistance (DCR). D. Patch electrodes to input simulated electrogram (EGM) signal. E. Upper and lower fatigue tester fixtures. F. Saline fluid level. Inset shows transverse and longitudinal lead cross-sections.
Figure 2:
**Figure 2.** Radiographs and microscopy at DCR Criteria for Partial/Complete Fracture. **A.** Partial pacing-coil fracture \( (\sigma_{\text{DCR}} \geq 0.5 \Omega) \) with scanning-electron micrograph (SEM). **B.** Complete pacing-coil fracture \( (\text{DCR} \geq 3000 \Omega) \). **C.** Partial ring-cable fracture \( (\sigma_{\text{DCR}} \geq 0.0015 \Omega) \) with SEM. **D.** Complete ring-cable fracture \( (\sigma_{\text{DCR}} \geq 0.5 \Omega) \) with photomicrograph.
Figure 3:

A. Test Onset 0 s

- Mean: 40.27 Ω
- Max: 40.30 Ω
- σ: 0.08 Ω

B. 1st Oversensing 19,616 s (99.7% T_{PP})

- Mean: 39.99 Ω
- Max: 43.57 Ω
- σ: 0.85 Ω

C. 19,629 s (100.3% T_{PP})

D. 1st NST 25,445 s (129.6% T_{PP})

- Mean: 40.75 Ω
- Max: 48.82 Ω
- σ: 1.89 Ω

E. LIA Alert 26,533 s (155.2% T_{PP})

- Mean: 41.63 Ω
- Max: 55.59 Ω
- σ: 3.29 Ω

F. 1st VF 27,956 s (142.0% T_{PP})

- Max > 3000 Ω

G. Partial fracture, 1st Oversensing → Complete fracture, 1st VF

- Log Scale
- DCR (Ω)
- Time (s)
**Figure 3.** Sequence of EGM and DCR changes in pacing-coil fracture. Each panel shows test time in s and percentage of time to partial fracture ($T_{PF}$). Upper panels show telemetered ICD signals: marker channel, RVtip-RVring pace-sense channel, and Can-RVcoil shock channel. Throughout, the filtered pace-sense EGM shows a 3mV base-peak signal at 1Hz. Lower panels show simultaneous (or closest in time) DCR recordings. The vertical DCR scale varies as peak impedance increases. Numerical values denote DCR mean, maximum (max), and standard deviation ($\sigma$).

**A.** Baseline. **B.** Initial oversensed signals at the bending frequency. **C.** DCR measured 13s later meets the partial-fracture criterion. For each bending cycle, there is one fracture-induced, double-peak electrical signal and one corresponding double-peak DCR spike. However, the maximum, cyclical DCR increase is only 4Ω.

**D.** Occurrence of a second DCR spike per bending cycle corresponds to the first device-detected NST. **E.** Longer bursts of oversensed signals saturate the sensing amplifier and are detected as the second NST, triggering LIA. **F.** First inappropriate detection of VF, 2 min after DCR reaches alert thresholds for both relative and fixed impedance-thresholds. **G.** Plot of $\sigma_{DCR}$ (log scale) and median DCR through the test. $\sigma_{DCR}$ shows a discrete step at $T_{PF}$ and both $\sigma_{DCR}$ and median DCR shows an abrupt, large increase at $T_{CF}$. In Panel G, labels A-F correspond to Panels A-F. VS and VF markers denote sensed intervals in sinus and VF zone, respectively. Red box (B): first oversensed event. Red oval (C): first repetitive oversensing. Red box (F): first VF detection (FD). Red stars (G) indicate values that exceed graph limits.
Figure 4:

A. Test Onset 180 s
- Tip-Ring: mean 15.768 Ω, max 15.769 Ω, σ 0.0003 Ω
- Ring-Can:

B. Partial fracture 7,239 s (63.3% T_{c})
- Tip-Ring: mean 15.726 Ω, max 15.731 Ω, σ 0.0020 Ω
- Ring-Can:

C. 11,429 s (100.0% T_{c})
- Tip-Ring: mean 17.20 Ω, max 47.19 Ω, σ 2.59 Ω
- Ring-Can:

D. 1st Oversensing 11,468 s (100.3% T_{c})

E. LIA Alert 12,466 s (109.1% T_{c})

F. 1st VF 12,665 s (111.8% T_{c})
- max >3000 Ω

G. Graph showing:
- Partial fracture
- Complete fracture, 1st Oversensing
- Open circuit, 1st VF
**Figure 4.** Sequence of DCR and EGM changes in ring-cable fracture. Format is identical to **Figure 3** except that the bottom telemetered EGM is the Ring-Can channel and that **Figures 4C-F** display test time in percentage of time to complete fracture ($T_{CF}$). **A.** Baseline. **B.** At $T_{PF}$, variations in DCR are numerically tiny (peak-trough $\sim 0.005\Omega$) but distinctly different from baseline; EGM shows no fracture-induced signals. **C.** At $T_{CF}$, variations in DCR increase (peak-trough $\sim 30\Omega$). Low-amplitude fracture-induced signals appear, too small to cause oversensing. **D.** Thirty-nine s later, these signals first cause oversensing at the bending frequency. **E.** The second NST triggers the LIA oversensing alert. **F.** First inappropriate detection of VF, just before open circuit, which triggers impedance alerts. **G.** Plot of $\sigma_{DCR}$ (log scale) and median DCR through the test. In contrast to the pacing-coil tracing in **Figure 3G**, ring-cable median $\sigma_{DCR}$ barely increases until complete fracture. Abbreviations as in **Figure 3**.
Figure 5: Radiographs, DCR plot and EGMs at test end for pacing-coil fracture (A-B) and ring-cable fracture (C-D). Panels A,C: Radiographs and last recorded DCR plots. Transient DCR spikes $\geq 3000\Omega$ synchronized to the bending cycle trigger the controlling software to end the test. Panels B,D: EGMs. See text for details. Red asterisks denote test end. Abbreviations as in Figures 3-4. See text for explanation.
### Figure 6:

<table>
<thead>
<tr>
<th></th>
<th><strong>Partial Fracture</strong></th>
<th><strong>Complete Fracture</strong></th>
<th><strong>Complete Separation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ring Cable</strong></td>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td>No clinical sensing or impedance signal</td>
<td>Oversensing → Alert → VF Impedance undetectable</td>
<td>Oversensing Alert, VF Impedance alert</td>
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<td><strong>Conductor Coil</strong></td>
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<td><img src="image5" alt="Image" /></td>
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<td></td>
<td>Oversensing → Alert → VF Impedance undetectable</td>
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**Figure 6.** Central Figure shows oversensing, impedance/DCR, and clinical diagnostic events at progressive stages of developing fracture for ring-cable (A-C) and pacing-coil (D-E). From top to bottom, each panel shows representative structural image of conductor (either optical or scanning-electron microscopy), corresponding EGM and DCR recordings, and presence (+) or absence (0) of oversensing and impedance alerts. Star indicates impedance alert. EGM format and abbreviations as in Figure 3. See text for details.
Figure 7:

Percentage of Time to Fracture

1st OS  1st NST  LIA OS  1st VF  Impedance Alert

Coil fractured first (N=12)  ○
Ring-cable fractured first (N=5)  △

Coil partial fracture  Ring-cable complete fracture  Coil and ring-cable separation
Figure 7. Correlation of Oversensing and Impedance Changes with Lead Integrity in Developing Conductor Fracture. **Upper panel:** For all 17 test leads, ordinate displays percentage of time to index event ($T_{PF}$ for pacing-coil fractures, circles; $T_{CF}$ for ring-cable fractures, triangles). Blue boxes represent 25th-75th percentile. Horizontal line denotes median. OS=oversensing; NST=high-rate, nonsustained tachycardia; LIA OS=Lead Integrity Alert triggered by 2 oversensing criteria; VF=inappropriate device-detected ventricular fibrillation; Impedance Alerts=simultaneous occurrence of LIA relative-impedance trigger and pacing-impedance alert. **Lower Panel:** Radiographs illustrate that the index oversensing event corresponds to $T_{PF}$ for pacing-coil and $T_{CF}$ for ring-cable. Impedance alerts correspond to complete separation for both conductors, resulting in open circuit. See text for details.
Figure 1:
Figure 2:
Figure 3:

A. Test Onset 0 s

B. 1st Oversensing 19,616 s (99.7% $T_{pf}$)

C. 19,629 s (100.0% $T_{pf}$)

D. 1st NST 25,445 s (129.6% $T_{pf}$)

E. LIA Alert 26,533 s (135.2% $T_{pf}$)

F. 1st VF 27,936 s (142.0% $T_{pf}$)

G. Partial fracture, 1st Oversensing

Complete fracture, 1st VF
Figure 4:

A. Test Onset 180 s
- Tip-Ring
- Ring-Cen
- Mean: 15.768 Ω
- Max: 15.769 Ω
- Std.Dev: 0.003 Ω

B. Partial fracture 7,239 s (63.3% T_{CF})
- Tip-Ring
- Ring-Cen
- Mean: 15.726 Ω
- Max: 15.731 Ω
- Std.Dev: 0.002 Ω

C. 11,429 s (100.0% T_{CF})
- Tip-Ring
- Ring-Cen
- Mean: 17.20 Ω
- Max: 47.18 Ω
- Std.Dev: 2.59 Ω

D. 1st Oversensing 11,468 s (100.3% T_{CF})
- Tip-Ring
- Ring-Cen
- Mean: 15.726 Ω
- Max: 15.731 Ω
- Std.Dev: 0.002 Ω

E. LIA Alert 12,466 s (109.1% T_{CF})
- Tip-Ring
- Ring-Cen
- Mean: 15.726 Ω
- Max: 15.731 Ω
- Std.Dev: 0.002 Ω

F. 1st VF 12,665 s (111.8% T_{CF})
- Tip-Ring
- Ring-Cen
- Max: >3000 Ω

G. Complete fracture, 1st Oversensing
- Tip-Ring
- Ring-Cen
- Mean: 15.726 Ω
- Max: 15.731 Ω
- Std.Dev: 0.002 Ω

Legend:
- Peak
- Median
Figure 5:
### Figure 6:

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<td><img src="imageB.png" alt="Image B" /></td>
<td><img src="imageC.png" alt="Image C" /></td>
</tr>
<tr>
<td>No clinical sensing or</td>
<td>Oversensing → Alert → VF</td>
<td>Oversensing Alert, VF</td>
</tr>
<tr>
<td>impedance abnormality</td>
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<td><img src="graphB.png" alt="Graph B" /></td>
<td><img src="graphC.png" alt="Graph C" /></td>
</tr>
</tbody>
</table>

| Conductor Coil            |                            |                              |
| ![Image D](imageD.png)    | ![Image E](imageE.png)     |                              |
| Oversensing → Alert → VF  | Oversensing Alert, VF      |                              |
| Impedance normal          | Impedance alert            |                              |
| ![Graph D](graphD.png)    | ![Graph E](graphE.png)     |                              |
Figure 7:

- **Coil fractured first (N=12)**
- **Ring-cable fractured first (N=5)**

Percentage of Time to Fracture (Conductor-coil %T_{FF}, Ring-Cable %T_{Gr})

- **1st OS**
- **1st NST**
- **LIA OS**
- **1st VF**
- **Impedance Alert**

- **Coil partial fracture**
- **Ring-cable complete fracture**
- **Coil and ring-cable separation**
Key Findings

- In developing ICD pace-sense conductor fracture, early oversensing correlates with bending-induced peaks in impedance that are too small to be detected by clinical impedance diagnostics.
- These results provide the mechanistic basis for the clinical observation that oversensing alerts are superior to clinical impedance alerts.
- Even with complete fracture, oversensing may stop and impedance may normalize when bending stops.
- This study provides the first direct evidence that fracture-induced oversensed signals are caused by make-break potentials.
- Impedance diagnostics based on short-term variability are predicted to be more sensitive to conductor fracture that present diagnostics based on relative or absolute thresholds.