

Time course of oversensing and impedance changes in developing implantable cardioverter-defibrillator lead fracture



Adam Himes, MS,* Scott Hoium, AA,* Charles D. Swerdlow, MD[†]

From the *Medtronic, Mounds View, Minnesota, and [†]Smidt Heart Center, Cedars Sinai Medical Center, Los Angeles, California.

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 To 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 minutes; electrograms were telemetered continuously. Twenty-two leads were tested to develop partial or complete fracture criteria confirmed by imaging, using DCR or DCR variability measured by standard deviation (σ_{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 σ_{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 more frequently than impedance alerts (94% vs 17%; $P = .00002$).

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 ventricular fibrillation 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

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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 nonphysiologic 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.

Address reprint requests and correspondence: Dr Charles D. Swerdlow, 414 North Camden Drive, Suite 1100, Beverly Hills, CA 90210. E-mail address: swerdlow@ucla.edu.

Methods

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

ICD System

The ICD system comprised a Medtronic Cobalt generator attached to Medtronic Sprint Quattro RV leads (Medtronic, Minneapolis, MN). The multilumen 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 an 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 of 40 with a VF detection interval of 320 ms.

KEY FINDINGS

- In developing implantable cardioverter-defibrillator 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 than present diagnostics based on relative or absolute thresholds.

Test Apparatus and Procedure

Leads were subjected to continuous, cyclic bending in a fatigue tester (Model 3230; Bose, Eden Prairie, MN) at 1.3 Hz (Figure 1).⁸ 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,⁹ increasing the likelihood that 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

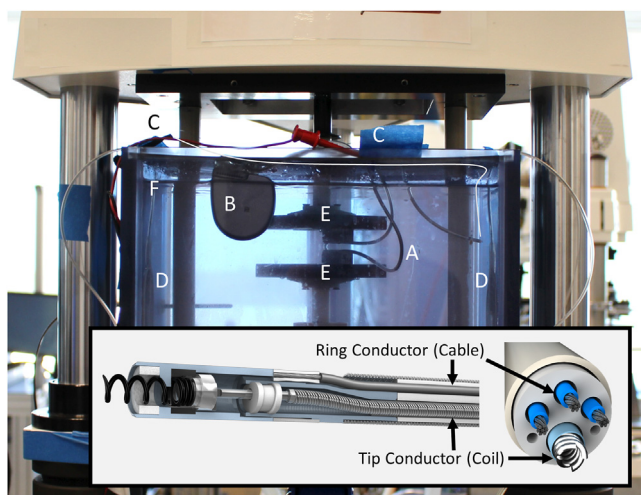


Figure 1 Test apparatus. **A:** Defibrillation lead. **B:** Implantable cardioverter-defibrillator generator. **C:** Proximal and distal connections for measurement of direct current resistance. **D:** Patch electrodes to input simulated electrogram signal. **E:** Upper and lower fatigue tester fixtures. **F:** Saline fluid level. The inset shows transverse and longitudinal lead cross-sections.

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 minutes using a digital multimeter (Model 3458A; range, 10^{-5} to 10^{38} Ω ; Agilent, Santa Rosa, CA). We used custom LabVIEW software (Version 2012, National Instruments, Austin, TX) to pause or end testing based on DCR or its standard deviation (σ_{DCR}), which were determined in near real time.

Each lead was imaged at the completion of testing. High-resolution radiographs (Model M50; North Star Imaging, 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 σ_{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 or σ_{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 previously. See the [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 1](#) shows the partial or complete fracture criteria determined in development experiments.

All test leads were cycled to $\text{DCR} \geq 3000$ Ω (open circuit) for the conductor under study. This permitted correlation of EGM characteristics with impedance ($\text{DCR}/\sigma_{\text{DCR}}$) changes over the entire course of developing fracture. We paid special attention to EGM characteristics at the earliest $\text{DCR}/\sigma_{\text{DCR}}$ 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 nonphysiologic short ventricular intervals ≤ 130 ms within 3 days and occurrence of ≥ 2 rapid

Table 1 DCR criteria for complete and partial fracture (development leads) and DCR mean and standard deviation (test leads)

| DCR criteria for complete and partial fracture, development leads (n = 22) | | Partial fracture (Ω) | | Complete fracture (Ω) | |
|--|-----------------------|-----------------------------------|-------------------------------|--------------------------------|--------------------------------|
| Pacing coil (n = 11) | | $\sigma_{\text{DCR}} \geq 0.5$ | | DCR ≥ 3000 | |
| Ring cable (n = 11) | | $\sigma_{\text{DCR}} \geq 0.0015$ | | $\sigma_{\text{DCR}} \geq 0.5$ | |
| DCR mean and standard deviation, test leads (n = 17) | | | | | |
| Fractured conductor | Mean DCR | Test onset (Ω) | Partial fracture (Ω) | LIA (pacing coil) (Ω) | Complete fracture (Ω) |
| Pacing coil (n = 12) | 40.7 \pm 2.1 | 40.7 \pm 2.1 | 40.8 \pm 1.9* | 45.7 \pm 13.9 | ≥ 3000 |
| Ring cable (n = 5) | 15.0 \pm 0.35 | 15.0 \pm 0.35 | 0.97 \pm 0.62* | 2.5 \pm 2.1 | $\geq 10^{10}$ |
| | σ_{DCR} | $3.7 \pm 0.61 \times 10^{-4}$ | 15.1 \pm 0.4 | | 16.1 \pm 0.6* |
| | | | 18 \pm 1.8 $\times 10^{-4}$ | | 1.1 \pm 0.9* |

Values are mean \pm SD, unless otherwise indicated.

DCR = direct current resistance; LIA = Lead Integrity Alert; σ_{DCR} = standard deviation of direct current resistance.

*First oversensing.

nonsustained tachycardia (NST) episodes (<220 ms) 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 2 components.

First oversensing was defined as the first V-V interval <1000 ms 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 $\geq 2000 \Omega$.

Events defined by DCR or σ_{DCR} comprised partial fracture, complete fracture, LIA relative impedance criterion, nominal pacing impedance alert, and DCR $\geq 3000 \Omega$.

Because DCR was recorded every 3 minutes, 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 months) of clinical service. This is conservative based on clinical median time from implantation to LIA oversensing alerts for conductor fracture of 118 months.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 <.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 (DCR/ σ_{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 the [Supplemental Results, Supplemental Tables, and Supplemental Figures 5 to 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

[Figure 3](#) shows the progression of DCR and EGM changes in a representative pacing coil fracture. [Figure 4](#) shows the corresponding progression in a representative ring cable

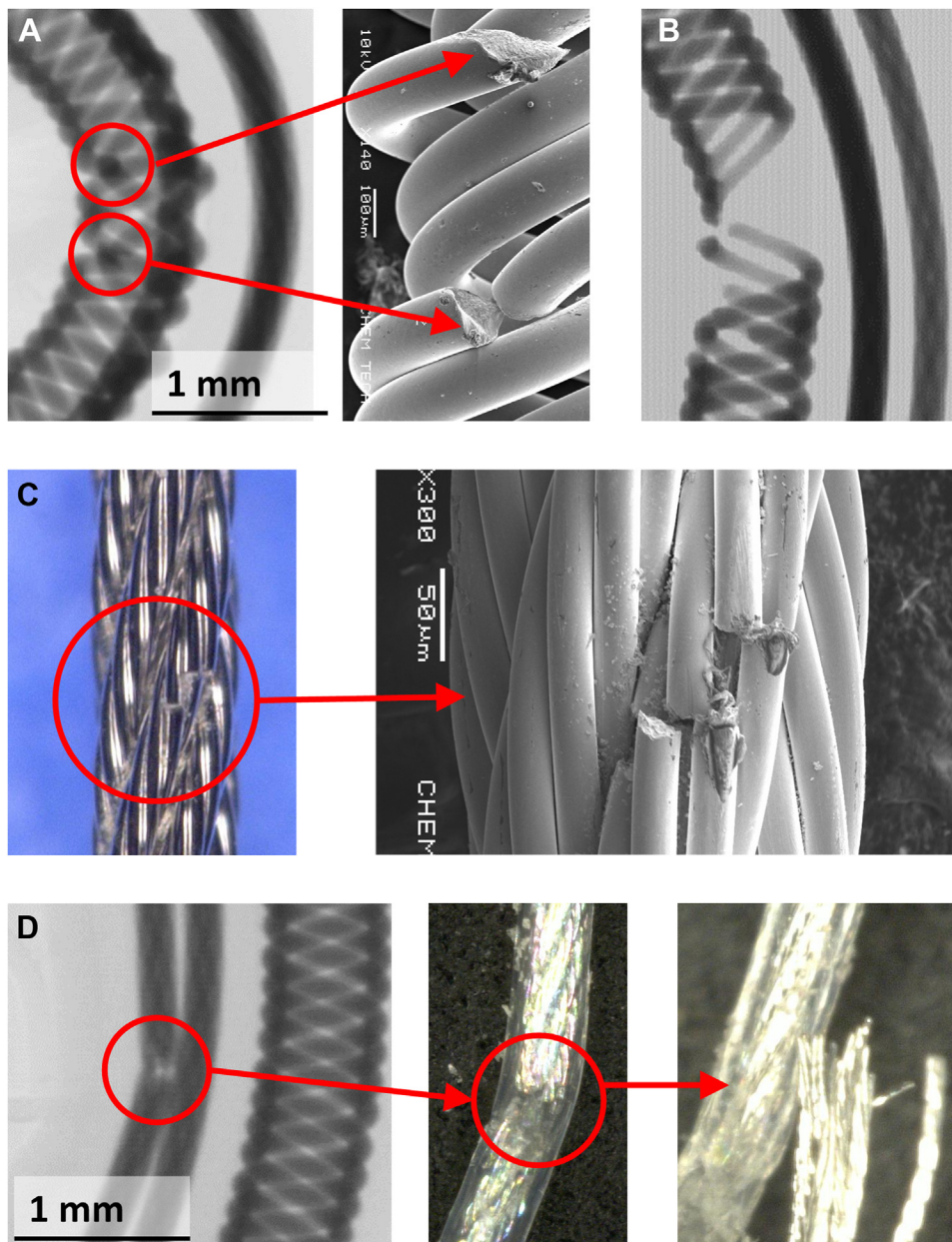


Figure 2 Radiographs and microscopy at direct current resistance (DCR) criteria for partial or complete fracture. **A:** Partial pacing coil fracture (standard deviation of DCR [s_{DCR}] $\geq 0.5 \Omega$) with scanning electron micrograph. **B:** Complete pacing coil fracture (DCR $\geq 3000 \Omega$). **C:** Partial ring cable fracture ($\sigma_{\text{DCR}} \geq 0.0015 \Omega$) with scanning electron micrograph. **D:** Complete ring cable fracture ($\sigma_{\text{DCR}} \geq 0.5 \Omega$) with photomicrograph.

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 (Figure 3B and 3C), but neither the relative nor the 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 s_{DCR} increased abruptly near the onset of oversensing (pacing coil partial fracture and ring cable complete fracture).

In Figures 3 and 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

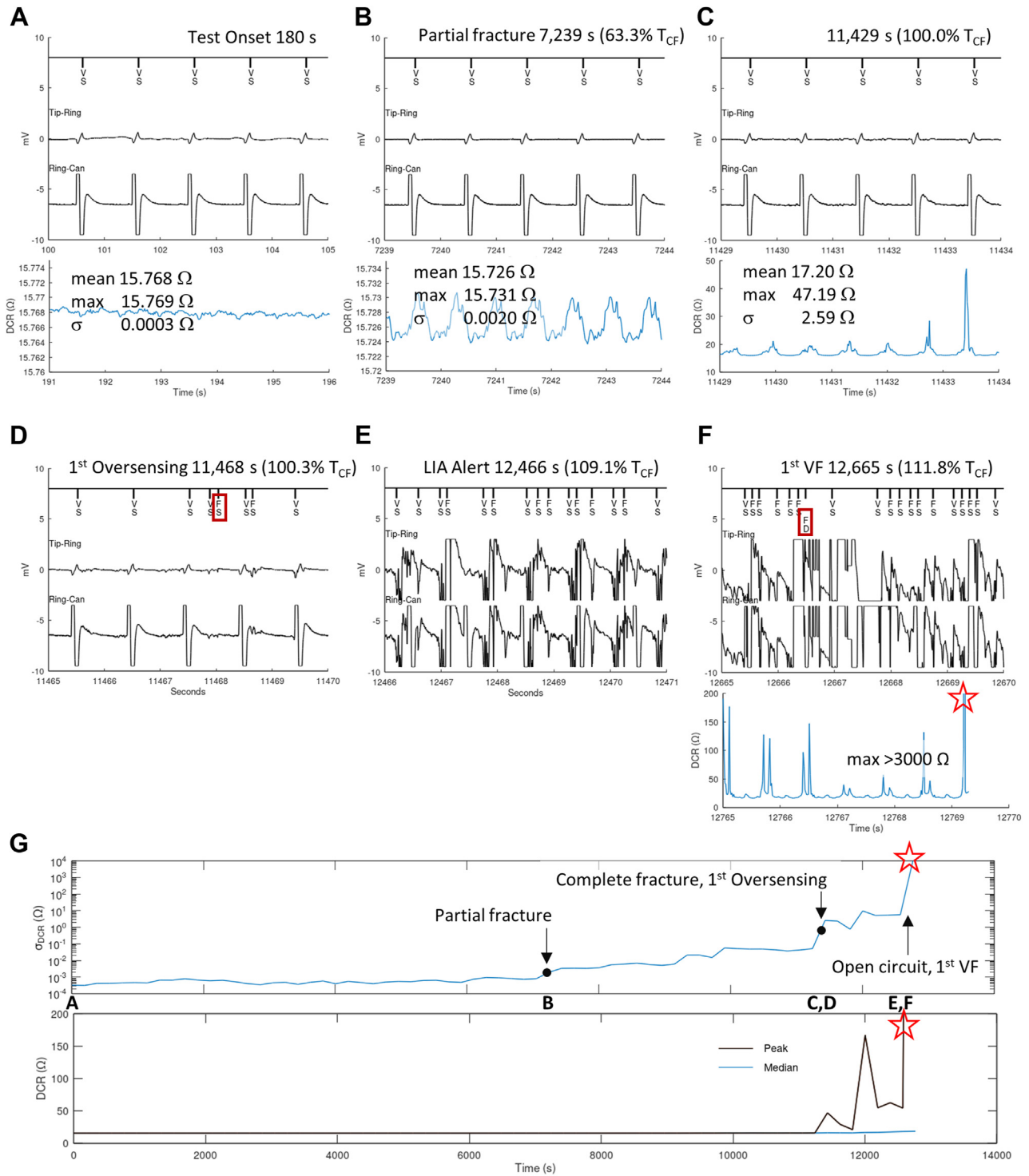


Figure 4 Sequence of direct current resistance (DCR) and electrogram (EGM) changes in ring cable fracture. The format is identical to [Figure 3](#), except that the bottom telemetered EGM is the Ring-Can channel and that panels C–F display test time in percentage of time to complete fracture (T_{CF}). **A**: Baseline. **B**: At time to partial fracture, variations in DCR are numerically tiny (peak–trough = ~0.005 Ω) but distinctly different from baseline; the EGM shows no fracture-induced signals. **C**: At T_{CF}, variations in DCR increase (peak–trough = ~30 Ω). Low-amplitude fracture-induced signals appear, too small to cause oversensing. **D**: Thirty-nine seconds later, these signals first cause oversensing at the bending frequency. **E**: The second nonsustained tachycardia triggers the Lead Integrity Alert (LIA) oversensing alert. **F**: First inappropriate detection of ventricular fibrillation (VF), just before open circuit, which triggers impedance alerts. **G**: Plot of standard deviation of DCR (σ_{DCR}) (log scale) and median DCR through the test. In contrast to the pacing coil tracing in [Figure 3G](#), ring cable median σ_{DCR} barely increases until complete fracture.

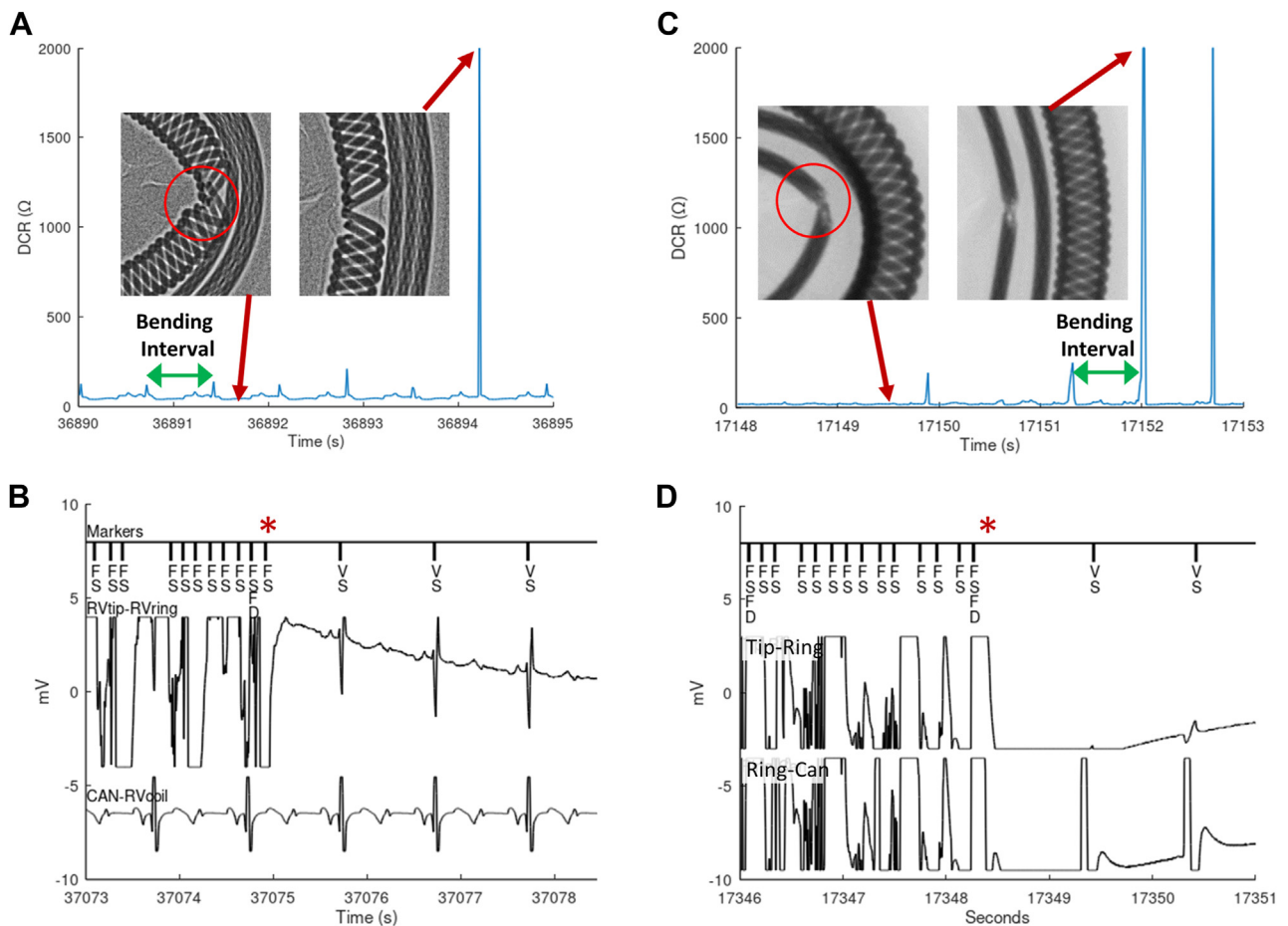


Figure 5 Radiographs, direct current resistance (DCR) plot, and electrograms at test end for pacing coil fracture (A, B) and ring cable fracture (C, D). A, C: Radiographs and last recorded DCR plots. Transient DCR spikes $\geq 3000 \Omega$ synchronized to the bending cycle trigger the controlling software to end the test. Panels B, D: Electrograms. See text for details. Red asterisks denote test end. See text for explanation.

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 1 shows the values of mean DCR/ σ_{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 $3.6 \pm 2.5 \Omega$, ring cable peak at complete fracture $8.9 \pm 9.4 \Omega$).

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 (94%) of 17 test leads. Figure 6 summarizes the relationship between structural changes, oversensing, and DCR or 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 minute before inappropriate VF detection in 14 (82%) leads. With a median time to oversensing alert of 401 minutes, 1 minute 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 (94%) leads ($P = .0005$). 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 (18%) leads ($P = .00002$ vs LIA oversensing alert).

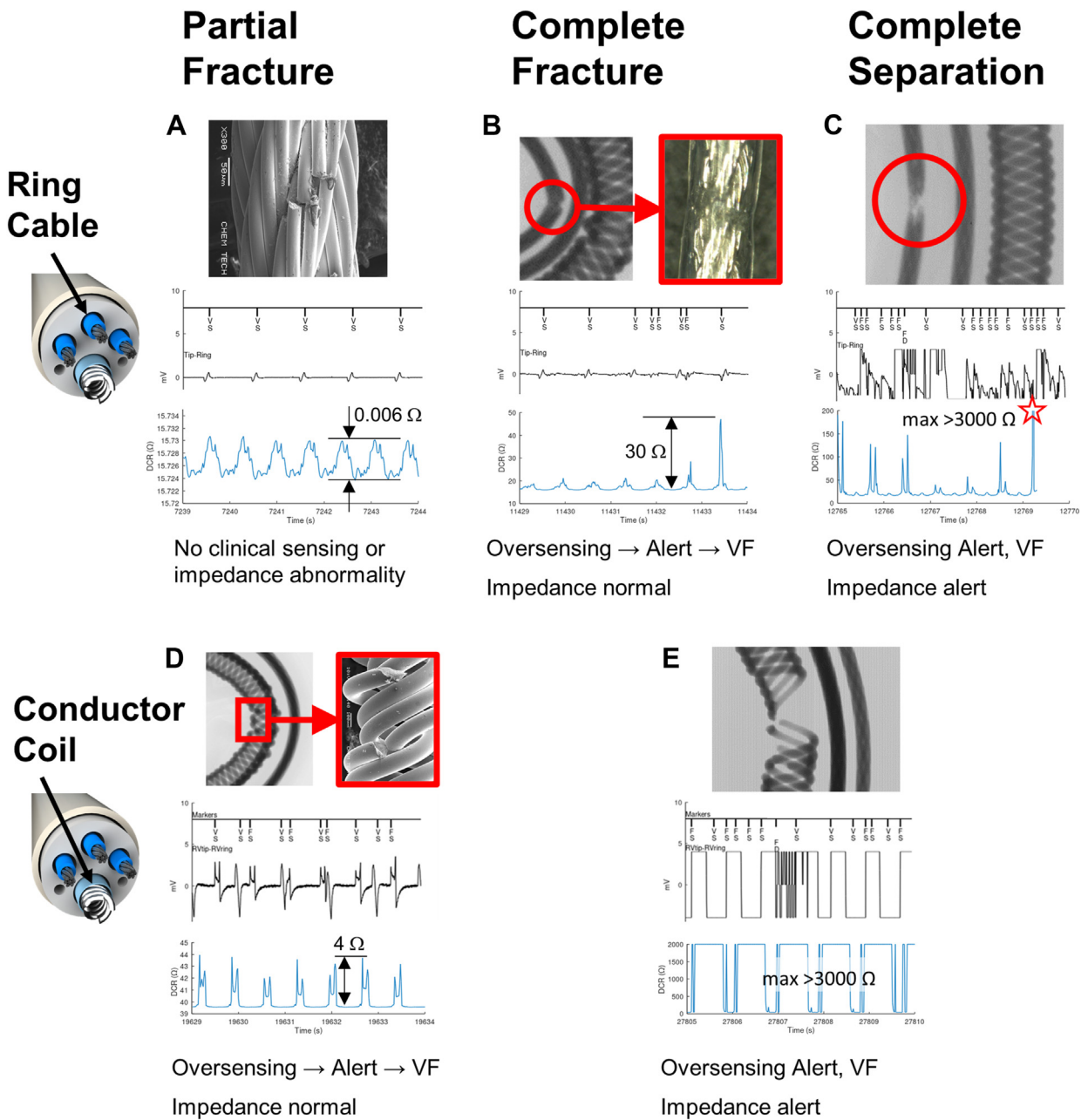


Figure 6 Oversensing, impedance or direct current resistance (DCR), and clinical diagnostic events at progressive stages of developing fracture for ring cable (A–C) and pacing coil (D, E). From top to bottom, each panel shows representative structural image of conductor (either optical or scanning electron microscopy), corresponding electrogram and DCR recordings, and presence (+) or absence (0) of oversensing and impedance alerts. Star indicates impedance alert. Electrogram format as in Figure 3. See text for details. VF = ventricular fibrillation.

Oversensing began later in the course of ring cable fractures than pacing coil fractures, and the LIA oversensing alert triggered correspondingly later (Table 1). However, once oversensing started, it progressed faster to inappropriate VF detection for ring cables than pacing coils ($1.08 T_{CF}$ vs $1.27 T_{PF}$; $P = .012$) (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, nonphysiologic 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 (94%) of 17 leads 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 tests⁸ show that small

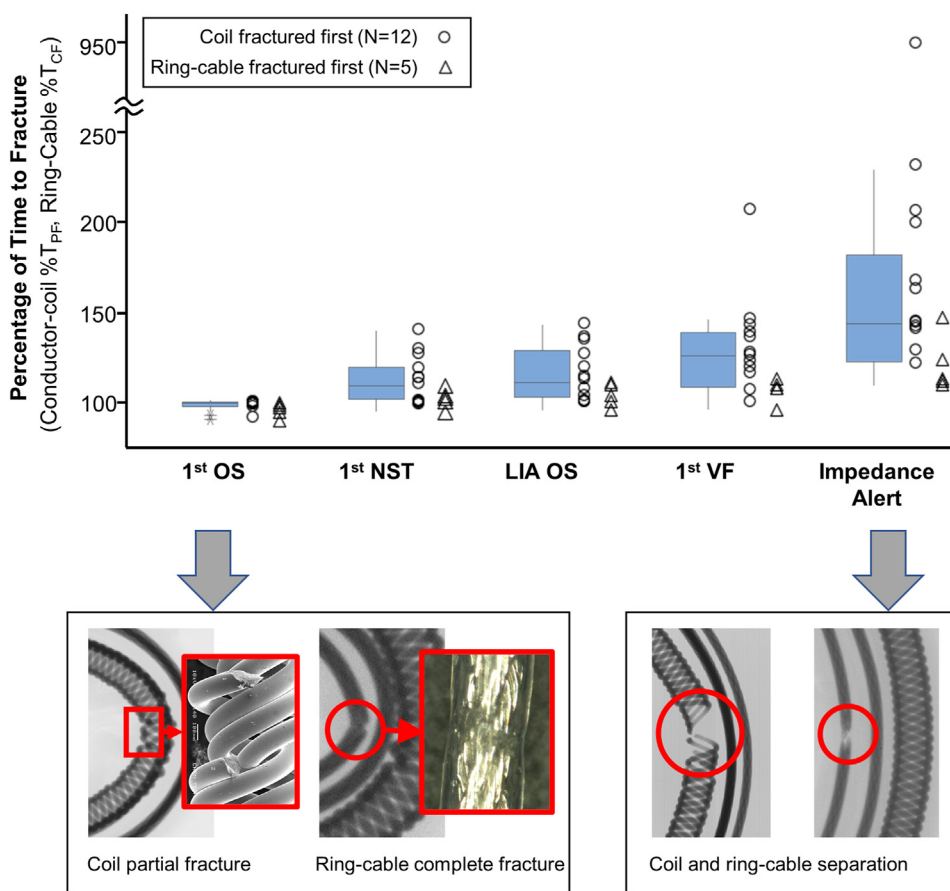


Figure 7 Correlation of oversensing and impedance changes with lead integrity in developing conductor fracture. **Upper panel:** For all 17 test leads, ordinate displays percentage of time to index event (time to partial fracture [T_{PF}] for pacing coil fractures [circles]; time to complete fracture [T_{CF}] for ring cable fractures, triangles). Blue boxes represent 25th to 75th percentile. Horizontal line denotes median. **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. The impedance alerts indicates a simultaneous occurrence of Lead Integrity Alert (LIA) relative impedance trigger and pacing impedance alert. NST = high-rate, nonsustained tachycardia; OS = oversensing; VF = inappropriate device-detected ventricular fibrillation.

changes in pacing impedance or DCR are sensitive for conductor fracture,² but clinical lead monitoring alerts that measure oversensing are more sensitive than those that measure impedance.^{3-6,10-12} Usually, bending tests are performed on short conductor segments, rather than on complete leads, continued to complete fracture so that the onset of partial fracture is not determined, and performed in air so that fracture-induced signals cannot be recorded.⁸ By testing complete leads connected to an ICD generator in saline, we determined the sequences of EGM and DCR or impedance changes and correlated them, both with each other and with structural changes in developing fractures.

Study Findings

Principal Findings

First, the onset of fracture-induced oversensing correlates with intermittent, bending-induced peaks in DCR. Second, for the pacing coil, oversensing begins at earliest partial fracture. In contrast, for the ring cable, oversensing does not begin until complete fracture. Third, as fractures progress, DCR or impedance varies cyclically with lead

bending, but mean and baseline values increase only minimally. Thus, measures of short-term DCR variability (eg, σ_{DCR}) are more sensitive than single measurements of DCR. Last, as oversensing progresses to device-detected VF, DCR or 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,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^{3,11,14,15}: intermittent occurrence, nonphysiologic 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 fractures 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 DCR/σ_{DCR} changes and oversensing in ring cable vs pacing coil fractures. The much greater number of filars in ring cables ($n = 49$) vs pacing coils ($n = 4$) determines both why fracture of one or a few filars causes a smaller increase in DCR/σ_{DCR} for the ring cable vs pacing coil and why, as individual filars break, σ_{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 DCR/σ_{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.¹⁶ 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.^{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. Interpatient differences in lead bending also contribute. Because 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 cinefluoroscopic images.⁹ Based on a preliminary report,¹⁷ 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 σ_{DCR} criteria for fracture were chosen from small samples and should be considered as values at or above which partial or complete fracture is present. However, occurrence of fracture at a lower σ_{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 1 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.⁸ 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. Because 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 1 manufacturer's diagnostics. However, all manufacturers have similar impedance threshold alerts and all manufacturers have oversensing diagnostics.⁷ LIA has been studied more extensively than any other oversensing diagnostic.^{3–5,10,12} The only other reports of another oversensing diagnostic⁶ or determination of oversensing using real time EGMs¹¹ showed 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 and 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, coradial coils.

Conclusion

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 or 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.

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Ethics Statement: The CareLink database referenced in methods supplement contains fully deidentified data and therefore was not classified as human participant research. Accordingly, institutional review board approval was not required.

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