

Externalized conductors and electrical dysfunction in transvenous ventricular leads: Results of the Cardiac Lead Assessment Study



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BACKGROUND The Cardiac Lead Assessment Study (CLAS) was a large prospective, multicenter, international postmarket surveillance study conducted at 45 sites.

OBJECTIVE The purpose of CLAS was to examine the prevalence and incidence of externalized conductors and electrical dysfunction in subjects with selected St. Jude Medical defibrillator and left ventricular leads.

METHODS Cinefluoroscopy was used to determine the presence of externalized conductors at enrollment and at 12-, 24-, and 36-month follow-up visits. Lead electrical measurements were collected systematically.

RESULTS The study enrolled 2216 subjects with a total of 2847 study leads. The prevalence of externalized conductors through 36 months for Riata leads was 30.9%, Riata ST leads 12.6%, Durata leads 0.5%, and QuickSite/QuickFlex leads 4.7%. The prevalence of electrical dysfunction through 36 months for Riata was 4.0%, Riata ST 3.3%, Durata 2.4%, and QuickSite/QuickFlex 0.3%. In Riata and Riata ST leads with externalized conductors, there was a low risk of

electrical dysfunction. None of the Durata or QuickSite/QuickFlex leads with externalized conductors developed electrical dysfunction. There was no evidence of an electrical short in a high-voltage shocking circuit leading to failed shock.

CONCLUSION A high prevalence of externalized conductors was found in Riata and Riata ST defibrillator leads, with a higher risk of externalization for 8F Riata leads than for 7F Riata ST leads. The 98% reduction in prevalence of externalized conductors in Durata leads compared to Riata/Riata ST leads confirms that the design improvements culminating in Durata leads significantly improved abrasion resistance and durability.

KEYWORDS Electrical dysfunction; Externalized conductor; High-voltage lead; Implantable cardioverter-defibrillator; Lead insulation

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Introduction

Transvenous pacemaker and defibrillator lead durability depends on multiple factors, including lead design, material, and mechanical stress. Silicone rubber, which represents the industry's most common pacemaker and defibrillation lead insulation material over the past 20 years, is vulnerable to abrasion,^{1,2} with a reported prevalence of 3%–10%.^{3,4} The St. Jude Medical (SJM), Los Angeles, CA, RiataTM and RiataTM ST family of leads are high-voltage defibrillator leads with silicone insulation. QuickSiteTM and QuickFlexTM left ventricular leads also utilize silicone rubber for insulation.

A different mechanism, known as inside–out abrasion with externalized conductors (each leading either to the proximal pacing ring or to one of the shocking coils) initially was reported in 2010 with Riata and Riata ST leads.⁵ This abrasion mechanism results in the presence of conductors outside the lead body as detected by radiography or post-plant visual inspection (Figure 1). The externalization does not consistently cause electrical dysfunction because the conductors themselves are insulated with a layer of ethylene tetrafluoroethylene (ETFE).⁶ However, some cases of externalized conductors accompanied by electrical noise, inappropriate shocks, oversensing, and increased pacing impedance and thresholds have been reported.^{7,8} Furthermore, there are reports of failure to deliver appropriate shocks due to short-circuiting between high-voltage components in patients with Riata and Riata ST leads.^{9–11}

The DurataTM family of defibrillator leads utilizes a silicone polyurethane copolymer insulation (OptimTM), which

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KEY FINDINGS

- The prevalence of externalized conductors in Riata and Riata ST leads is substantial, with 8F Riata leads being about twice as likely to show externalized conductors as 7F Riata ST leads.
- Externalized conductors are rarely seen in Durata leads.
- Survival free of electrical dysfunction is excellent among all 3 defibrillator lead groups (Riata, Riata ST, Durata).
- Although Riata and Riata ST leads with externalized conductors are more likely to show electrical dysfunction than those without, the vast majority of these leads with externalized conductors did not demonstrate electrical dysfunction.
- There was no documented occurrence of a failed shock due to a short-circuit between the high-voltage components of the defibrillator system.

is associated with a significant reduction in abrasion compared to Riata and Riata ST silicone-insulated leads. The Cardiac Lead Assessment Study (CLAS) prospectively examined the prevalence of externalized conductors and electrical dysfunction in subjects with Riata, Riata ST, Durata, and QuickSite/QuickFlex leads.

Methods

CLAS was a large prospective, international, multicenter study. Human Research Ethics Committee review and approval were required for participating study centers. Participating study sites obtained written informed consent from all enrolled study subjects. The research reported herein adhered to the guidelines outlined in the Declaration of Helsinki.

Patient enrollment and study protocol

Inclusion criteria included (1) implanted with market-released SJM implantable cardioverter-defibrillator, cardiac resynchronization therapy-defibrillator, or cardiac resynchronization therapy-pacemaker; and (2) at least 1 implanted Riata, Riata ST, Durata, or QuickSite or QuickFlex lead (for details, see [Supplemental Table 1](#)).

Lead measurements were obtained at enrollment and at 6, 12, 18, 24, 30, and 36 months. Cinefluoroscopy was performed at enrollment and at 12, 24, and 36 months. [Supplemental Figure 1](#) details the study flow diagram.

Determination of externalized conductors and electrical dysfunction

Cinefluoroscopic images of each lead were obtained in the posteroanterior, 45° left, and 45° right anterior oblique views. Images were reviewed by a committee of experienced electrophysiologists. Criteria for externalized conductors were (1) a conductor cable outside the body of the lead (defined



Figure 1 Externalized conductor in Riata lead postexplant.

by the shock coil electrode shadow) or (2) change in the curvature of the conductors of the lead in the region of the suspected externalized conductor compared with the remainder of the lead body ([Figure 2](#)).

Subjects were evaluated for electrical dysfunction based on device interrogation and session records. Cases that met any of the following criteria were adjudicated by 3 cardiac electrophysiologists to confirm electrical dysfunction: (1) presence of noise not due to external interference; (2) rise in pacing impedance to $>2000 \Omega$ or $>200 \Omega$ over the previous 6 months or $>400 \Omega$ over any time period; (3) decrease in pacing impedance $>200 \Omega$ over the previous 6 months or a value $<200 \Omega$ from a baseline impedance $>300 \Omega$ or a decrease of 400Ω over any period of time; (4) change in shocking impedance $>25 \Omega$ or to $>125 \Omega$ or to $<20 \Omega$; or (5) capture threshold $>5 \text{ V}$ or an increase $\geq 2 \text{ V}$ from baseline.

Deaths and adverse events

Subject deaths and adverse events were adjudicated by an independent clinical events committee for defibrillator system relatedness.

Statistical analysis

The prevalence of externalized conductors or electrical dysfunction was calculated as the number of leads with the respective anomaly during the 36-month study follow-up period divided by the total number of leads in each of the 4 lead groups. Annual hazard rates were calculated as percentages using the ratio of the number of respective lead anomalies divided by the total lead implant years.

Survival curves for freedom from externalized conductors and electrical dysfunction from lead implantation were estimated using interval-censored survival analysis.¹²

The likelihood of externalized conductors in the right ventricular leads was compared among different grades of slack using the Cochran-Armitage trend test (slack determined as described by Ha et al¹³). Mean time to electrical dysfunction was compared for leads with and those without externalized conductors (for Riata and Riata ST leads only) using the Wilcoxon test.

Results

The first subject enrolled in this study in March 2013. Enrollment was completed in June 2016, with the last follow-up

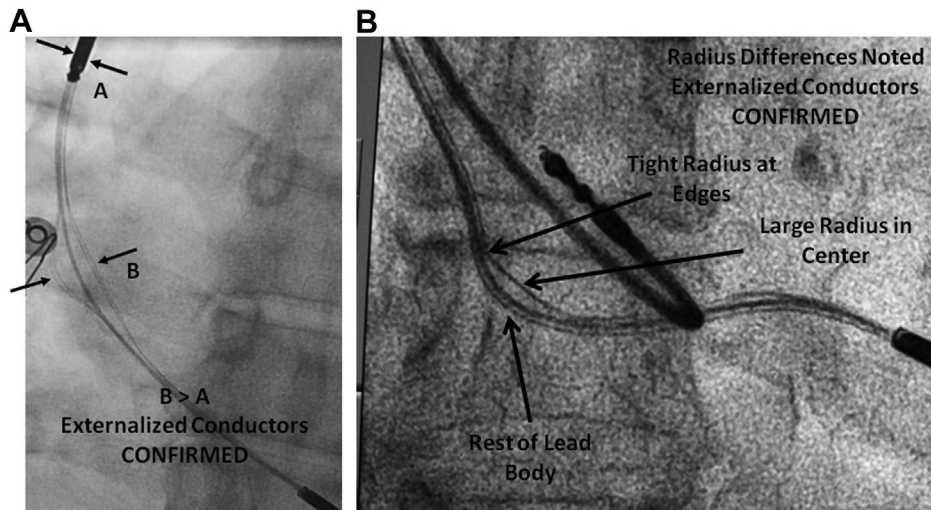


Figure 2 Examples of externalized conductors that meet the 2 criteria: (1) appearance of a conductor cable outside of the lead body as defined by the coil electrode shadow (A) and (2) change in the radius of curvature of the suspected externalized conductor compared with the remainder of the lead body (B).

completed in June 2019. A total of 2216 subjects, including 779 carried over from the Riata Lead Evaluation Study,¹⁴ were enrolled at 45 sites. [Supplemental Figure 2](#) and [Supplemental Table 2](#) detail subject disposition and demographics.

A total of 2847 leads were studied, including 670 Riata, 458 Riata ST, 982 Durata, and 737 QuickSite/QuickFlex leads. Of the Riata leads, 64 were single coil and 606 were dual coil; of the Riata ST leads, 83 were single coil and 375 had dual coils; and of the Durata leads, 173 were single coil and 809 were dual coil. [Table 1](#) summarizes study leads and implant durations at enrollment and end of study. Mean implant durations at enrollment ranged from 4.5 years for Durata leads to 6.8 years for Riata leads, and mean implant durations at the end of the study ranged from 7.0 years for Durata leads to 8.9 years for Riata leads.

Externalized conductors

The externalized conductor prevalence and annual hazard rates are listed in [Table 2](#) and survival curves free of externalized conductors are shown in [Figure 3](#). The prevalence and annual hazard rate of externalized conductors were much greater for Riata and Riata ST leads than for Durata or QuickSite/QuickFlex leads. Among the Riata and Riata ST leads, the original Riata leads with an 8F diameter showed more

than double the prevalence and annual hazard rate of externalized conductors than the subsequently introduced Riata ST leads with a 7F diameter ($P < .05$). There was no significant difference in the prevalence of externalized conductors between single-coil and dual-coil Riata and Riata ST models. The Optim-insulated Durata leads had a 96% reduction in the prevalence and annual hazard rate of externalized conductors compared to 7F Riata ST leads and a 98% reduction compared to 8F Riata leads.

For Durata leads, externalized conductors not only were much less frequent (5 cases total), but the mechanism sometimes was different from the typical inside-out abrasion of Riata and Riata ST leads.¹⁵ Two Durata leads had *external* abrasion: subclavian crush in one case and abrasion from a tricuspid valve ring in the other. In another Durata lead, externalized conductors were visible in a short region just proximal to the right ventricular coil unprotected by Optim insulation. In the other 2 Durata leads, externalization was similar to that typically seen with Riata and Riata ST leads.

There was no significant difference in demographics and other characteristics of subjects with externalized conductors compared to those without ([Supplemental Table 3](#)). However, an increasing degree of lead slack was associated with an increasing likelihood of externalized conductors ($P < .0001$) ([Supplemental Table 4](#)).

Table 1 Lead enrollment and 36-month follow-up

Lead family	Total leads enrolled (N)	Lead implant date	Lead implant duration at enrollment (y)	36-month follow-up completed (N)	Lead implant duration at end of study (y)
Riata	670	2002–2009	6.8 ± 1.6	336	8.9 ± 1.9
Riata ST	458	2006–2009	5.6 ± 1.4	249	7.9 ± 1.7
Durata	982	2008–2010	4.5 ± 1.1	618	7.0 ± 1.3
QuickSite/QuickFlex	737	2006–2010	5.3 ± 1.5	430	7.7 ± 1.8

Data are given as mean ± SD.

Table 2 Externalized conductor prevalence and annual hazard rate

Lead family	Prevalence (total no. of externalized conductors/total no. of leads) *	Annual hazard rate from implant (no. of events/lead-year) *
Riata	30.9% (204/660)	3.46% (204/5899)
Riata ST	12.6% (57/452)	1.61% (57/3551)
Durata	0.5% (5/973)	0.07% (5/6811)
QuickSite/QuickFlex	4.7% (34/723)	0.61% (34/5586)

*Prevalence and annual hazard rate of externalized conductors were significantly lower for Riata ST than Riata leads ($P < .001$) and significantly lower for Durata than either Riata or Riata ST leads ($P < .001$).

Electrical dysfunction

Of the 2847 study leads, 68 (2.4%) showed electrical dysfunction. The prevalence and rates of electrical dysfunction are listed in Table 3, and the corresponding event-free survival curves are shown in Figure 4. For the 3 defibrillator lead groups, the likelihood of survival free of electrical dysfunction at 8 years ranged from 96.6% to 97.7%, with no difference among the groups. QuickSite/QuickFlex leads had significantly less electrical dysfunction than the 3 defibrillator leads ($P < .0001$).

Only a single lead was adjudicated to have electrical dysfunction on the basis of abnormally low shocking impedance. This Riata lead was capped and abandoned, and it was not returned for analysis. This study subject had no additional lead-related complications.

Relationship of electrical dysfunction to externalized conductors

Riata and Riata ST lead groups combined showed a higher likelihood of electrical dysfunction in leads with externalized conductors than in those without (6.1% vs 3.0%, respectively; $P = .039$) (Table 4). No Durata or QuickSite/QuickFlex leads showed both externalized conductors and electrical dysfunction.

In all Riata and Riata ST leads with both externalized conductors and electrical dysfunction, the detection of externalized conductors preceded development of electrical dysfunction with a mean delay of 0.8 years. There was no significant difference in implant duration at the time of electrical dysfunction in leads with antecedent externalized conductors (7.6 years) compared to those without (7.1 years) ($P = .58$).

Deaths and adverse events

A total of 321 subjects (14.5%) died during study follow-up. Only 1 death was adjudicated as being related to the defibrillator system. This subject died during attempted extraction of a dual-coil Durata lead that had not shown externalized conductors. Thirty-five deaths (1.6%) were adjudicated as sudden and cardiac related, of which 29 were not device related and 6 had unknown relatedness.

Eighty-three adverse events were adjudicated to be related to the defibrillator system. These include the 68 leads with electrical dysfunction as well as reports of lead dislodgment, phrenic nerve stimulation, and defibrillator shock for atrial

fibrillation. No adverse events were adjudicated as a failure to deliver an appropriate defibrillator shock, and there was no other evidence of an electrical short in a high-voltage shocking circuit.

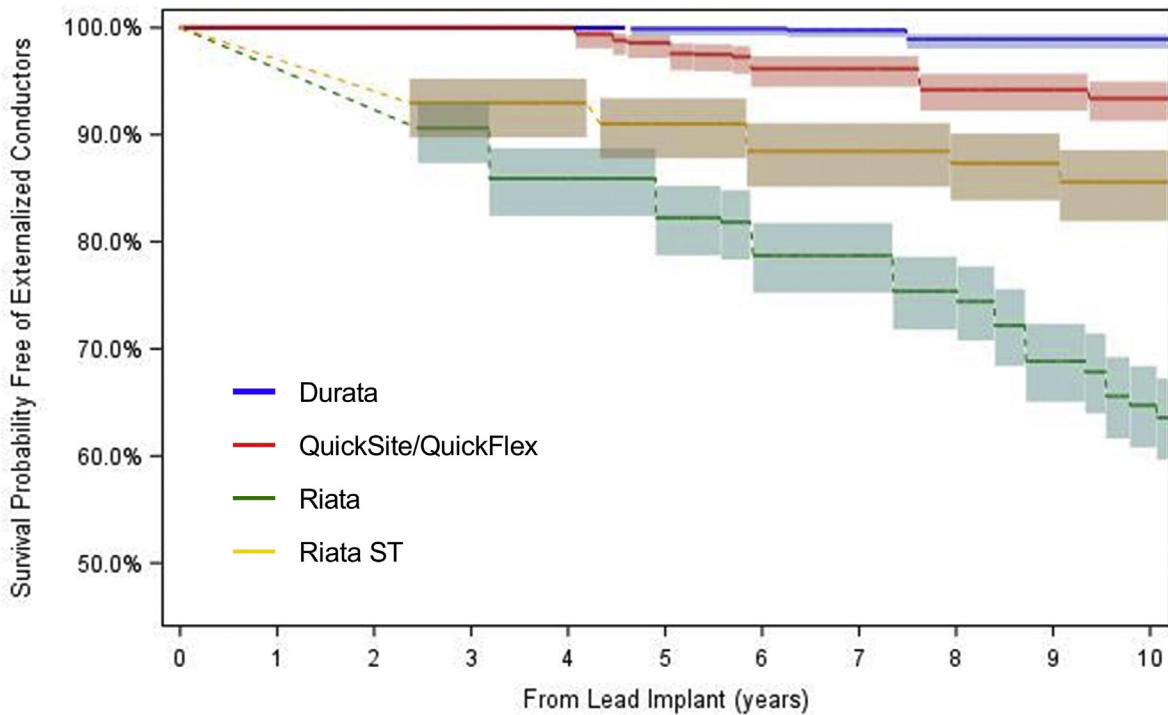
Discussion

This multicenter prospective study is the largest and most extensive investigation of the incidence of externalized conductors and electrical dysfunction in SJM Riata, Riata ST, Durata, and QuickSite/QuickFlex pacemaker and defibrillator leads. The principal findings of this report are as follows. (1) The prevalence of externalized conductors in Riata and Riata ST leads is substantial, with 8F Riata leads being about twice as likely to show externalized conductors as 7F Riata ST leads. (2) Externalized conductors are rarely seen in Durata leads. (3) Survival free of electrical dysfunction is excellent among all 3 defibrillator lead groups. (4) Although Riata and Riata ST leads with externalized conductors are more likely to show electrical dysfunction than those without, the vast majority of these leads with externalized conductors did not demonstrate electrical dysfunction. (5) There was no documented occurrence of a failed shock due to a short-circuit between high-voltage components of the defibrillator system.

Riata and Riata ST externalized conductors

The overall prevalence of externalized conductors we found in Riata and Riata ST leads (30.9% and 12.6%, respectively) was higher than that found by Theuns et al¹⁶ (21.4% and 8.0%, respectively) but more similar to that reported in the meta-analysis of Zeitler et al¹⁷ (30.5% and 9.6%, respectively). Importantly, we found that the risk of developing externalized conductors was ongoing through 8–10 years postimplant.

Differences in design between the 8F Riata leads and the 7F Riata ST leads probably account for the lower prevalence of externalized conductors in the latter compared to the former. A major difference is that the conductor cables in 7F Riata ST leads are closer to the center of the lead body (Supplemental Figure 3), resulting in reduced tension on the cable and reduced forces on the silicone insulation during bending of the lead (unpublished data; Abbott engineering report).



Lead Family	Surviving Leads from Time of Implant (Survival Probability)										
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Durata	973 (100%)	973 (100%)	973 (100%)	972 (100%)	951 (100%)	907 (99.9%)	772 (99.9%)	486 (99.8%)	225 (98.9%)	39 (98.9%)	8 (98.9%)
QuickSite/ Quickflex	723 (100%)	723 (100%)	723 (100%)	722 (100%)	708 (100%)	666 (98.6%)	588 (96.2%)	445 (96.2%)	323 (94.2%)	158 (94.2%)	63 (93.2%)
Riata	660 (100%)	660 (100%)	660 (100%)	659 (90.6%)	653 (85.9%)	634 (82.2%)	592 (78.7%)	501 (78.7%)	388 (75.4%)	257 (68.8%)	139 (64.7%)
Riata ST	452 (100%)	452 (100%)	452 (100%)	450 (93.0%)	444 (93.0%)	425 (91.0%)	368 (88.5%)	285 (89%)	189 (87.3%)	85 (87.3%)	48 (85.6%)

The total number of leads for each year was counted based on the implant time and follow-up time. Leads were censored based on when externalized conductor was first identified or when the follow-up period ended (whichever happened)

Figure 3 Estimated survival from externalized conductors with 95% confidence limits for each lead family as a function of time from lead implant. Dashed lines indicate time-points for which data are not available.

Reduction of risk of externalized conductors in Durata leads

The 96%–98% reduction in externalized conductors in Durata leads compared to Riata/Riata ST leads is attributable to the design changes in the Durata lead, including a 50% increase in the insulation thickness from the inner cables to the outer edge of the lead and the addition of the Optim insulation layer, which results in a 50-fold improvement in abrasion resistance.¹⁸ Our finding of only rare instances of externalized conductors in the Durata leads is consistent with an independent analysis of 11,155 Optim-insulated Durata leads

and the similarly constructed Riata ST Optim leads enrolled in prospective, multicenter registries of Optim-insulated leads, which demonstrated 100% freedom from externalized conductors and 99.7% freedom from all-cause insulation abrasion through 4.6 years implant duration.¹⁹

Risk of developing electrical dysfunction in Riata and Riata ST leads with externalized conductors

We found the risk of electrical dysfunction among Riata and Riata ST leads with externalized conductors to be 6.1%, substantially less than the 10.9% reported by Theuns et al¹⁶ and

Table 3 Electrical dysfunction prevalence and annual hazard rate

Lead family	Prevalence (total no. of electrical dysfunction/total no. of leads)*	Annual hazard rate from implant (no. of events/lead-year)*
Riata	4.0% (27/670)	0.45% (27/5984)
Riata ST	3.3% (15/458)	0.42% (15/3598)
Durata	2.4% (24/982)	0.35% (24/6859)
QuickSite/QuickFlex	0.3% (2/737)	0.04% (2/5672)

*There was no significant difference in prevalence and annual hazard rate of electrical dysfunction among Riata, Riata ST, and Durata leads; however, QuickSite/QuickFlex leads had significantly lower prevalence and annual hazard rate ($P < .0001$).

the 17.3% reported in a meta-analysis by Zeitler et al.¹⁷ The present study confirms a statistically significant higher likelihood of electrical dysfunction among Riata/Riata ST leads with externalized conductors compared to those without externalized conductors, but the 2-fold increased risk we found is less striking than the 3-fold increased risk reported by Theuns et al¹⁶ and the 8-fold increased risk reported in the meta-analysis by Zeitler et al.¹⁷ Our findings are more consistent with the large Canadian survey reported by Parkash et al²⁰ showing a low concordance of electrical dysfunction and externalized conductors in Riata leads, with only 8% of Riata leads with electrical dysfunction showing externalized conductors.

In this study, mean time from implant to electrical dysfunction in Riata and Riata ST leads with and without externalized conductors was similar and relatively long at 7.6 and 7.1 years, respectively ($P = .104$). These results suggest that, apart from any causative role externalized conductors might play in electrical dysfunction, lead age is also a factor in the development of electrical dysfunction. The majority of leads showing externalized conductors do not show electrical dysfunction, which probably is attributable to the ETFE coating on the conductor cables. The ETFE coating has sufficient dielectric strength to maintain the functionality of the lead independent of the silicone insulation.⁶

Externalized conductors aside, survival free of electrical dysfunction of the defibrillator leads in this study was excellent: 96.6%–97.7% at 8 years. This survival is better than that based on reported rates of chronic complications and malfunctions for the array of the lead models included in this study, as detailed in a recent edition of the manufacturer's product performance report.²¹ The electrical performance of the defibrillator leads in this study also compares favorably with that of contemporaneous leads from other manufacturers.^{22,23} Of note, the chronic complications and malfunctions that contribute to lead survival rates in product performance reports include not only electrical dysfunction but also lead dislodgment, perforation, and extracardiac stimulation.

In this study, no subject death or adverse event was independently adjudicated to be related to a short-circuit between high-voltage components of the defibrillator system. Six subjects with sudden cardiac death were adjudicated to have unknown relatedness to the defibrillator system; the possibility that one or more of these subjects died of failure of a defibrillator shock cannot be ruled out.

Comparison to previous literature

The most comprehensive report before the current study pertaining to externalized conductors and electrical dysfunction in Riata and Riata ST leads is the meta-analysis of Zeitler et al.¹⁷ Our study differs from that of Zeitler et al with respect to both methodology and some findings. In contrast to Zeitler et al, who reported cross-sectional studies, our study was prospective and longitudinal. This longitudinal methodology allowed for detection of the ongoing incidence of conductor externalization and electrical dysfunction at 8–10 years of implant duration. The present study utilized uniform fluoroscopic imaging and criteria for detection of externalized conductors, and it utilized prospective and specific criteria for electrical dysfunction. The present study found a lower prevalence of electrical dysfunction in Riata and Riata ST leads at longer mean implant durations compared to that reported by Zeitler et al. Although both reports indicate that externalized conductors increase the probability of subsequent detection of electrical dysfunction, the magnitude of the increased risk is lower in the present study than in previous reports.

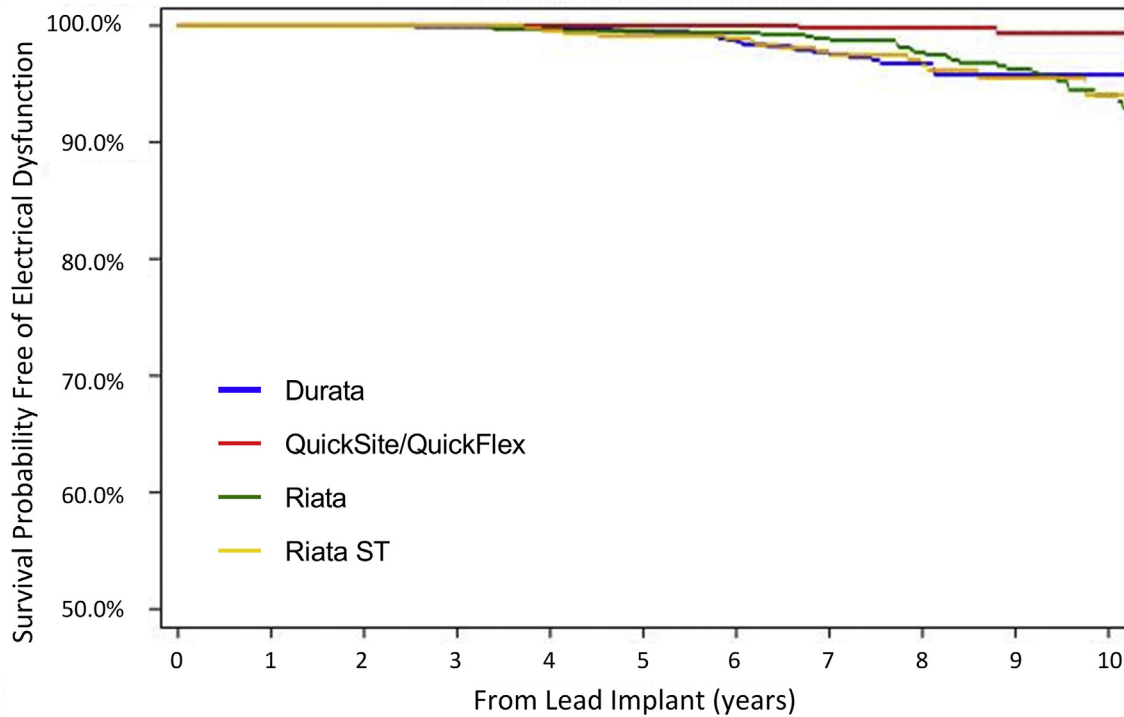
QuickSite and QuickFlex left ventricular leads

QuickSite and QuickFlex left ventricular leads were included in this prospective study because isolated cases of externalized conductors were previously reported in these lead models.²⁴ The present study demonstrates that externalized conductors are much less common in QuickSite and QuickFlex leads than in Riata or Riata ST leads, and that electrical dysfunction in QuickSite and QuickFlex leads is rare.

Clinical implications

This study has implications both for the specific lead models studied and for lead surveillance in general. There are a significant number of active Riata leads (approximately 15,000) and Riata ST leads (approximately 11,000) in the United States.²¹ Our results indicate that these leads have a substantial prevalence of externalized conductors and remain at risk for the development of externalized conductors even after 8–10 years of implant duration. Fortunately, the risk of electrical dysfunction in leads showing externalized conductors is low, approximately 6% after mean implant duration of 8.4 years. However, clinicians should be alert to the detection of an ongoing small incidence of electrical dysfunction.

Our results also demonstrate a very low incidence of externalized conductors in Durata leads. The progressive lead



Lead Family	Surviving Leads from Time of Implant (Survival Probability)										
	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Durata	982 (100%)	982 (100%)	982 (99.9%)	979 (99.9%)	958 (99.9%)	910 (99.5%)	772 (98.6%)	484 (97.5%)	226 (96.8%)	39 (95.8%)	8 (95.8%)
QuickSite/QuickFlex	737 (100%)	737 (100%)	737 (100%)	735 (100%)	721 (100%)	682 (100%)	607 (100%)	463 (99.8%)	340 (99.8%)	174 (99.4%)	67 (99.4%)
Riata	670 (100%)	670 (100%)	670 (100%)	670 (100%)	666 (99.7%)	653 (99.6%)	628 (99.4%)	568 (98.9%)	460 (97.7%)	332 (96.3%)	185 (94.0%)
Riata ST	458 (100%)	458 (100%)	458 (100%)	457 (100%)	451 (99.6%)	441 (99.1%)	395 (98.9%)	316 (97.5%)	217 (96.6%)	98 (95.5%)	54 (94.0%)

The total number of leads for each year was counted based on the implant time and follow-up time. Leads were censored based on when electrical dysfunction was first identified or when the follow-up period ended (whichever happened first)

Figure 4 Estimated survival from electrical dysfunction. Survival curves for each lead family as a function of time from lead implant.

design modifications from Riata to Riata ST to Durata models seem to have successfully mitigated the risk of externalized conductors. Importantly, there was no evidence of a short-circuit between the high-voltage components of the defibrillator system leading to a failed shock in subjects with Durata, Riata, or Riata ST leads.

In 2011, the SJM (now Abbott) Medical Advisory Board, the United States Food and Drug Administration, and the

Heart Rhythm Society recommended against prophylactic explant or replacement of electrically functioning Riata or Riata ST leads with or without externalized conductors. The results of this study support this recommendation.

This study is the first to prospectively and systematically study implanted pacemaker or defibrillator leads fluoroscopically and to correlate abnormal fluoroscopic findings with electrical dysfunction. By comparison, when the problem

Table 4 Correlation of externalized conductors and electrical dysfunction prevalence in Riata and Riata ST leads

	With electrical dysfunction	Without electrical dysfunction	Total
With externalized conductor	16	245	261
Without externalized conductor	26	825	851

There was a statistically significant higher rate of electrical dysfunction in Riata/Riata ST leads with externalized conductors (6.1%) than without (3.0%) ($P = .039$).

Sixteen subjects with Riata or Riata ST leads did not have adjudication of externalized conductors and were excluded from this table.

of “subclavian crush” (disruption of pacemaker lead conductor in the region of the clavicle and first rib) was prevalent years ago, there was no study that comprehensively compared the prevalence of fluoroscopic and electrical abnormalities among different lead models. There was a report of serial cinefluoroscopic imaging of the Telectronics Accu-fix atrial pacemaker lead, whose retention wire was subject to fracture and then extrusion through the outer lead insulation; however, subjects in this study had just 2 fluoroscopic imaging sessions separated by <6 months, no change was detected in any subject between the 2 sessions, and as the retention wire was not electrically active there was no correlation with lead electrical dysfunction.²⁵ Despite lessons learned from the design of Riata and Riata ST leads, it is not unlikely that future pacemaker or defibrillator lead models will show abnormalities detectable by fluoroscopy, and the present study sets a standard for prospective fluoroscopic lead evaluation.

Study limitations

Although externalized conductors and electrical dysfunction were not exclusion criteria for enrollment into this study, it is possible that investigators were less likely to enroll patients known to have either of these findings, leading to an underestimate of the prevalence of these lead defects. We are unable to quantitate the magnitude of any such underestimations.

Failure to defibrillate due to a high-energy short-circuit in patients with a Riata or Riata ST lead without antecedent electrical dysfunction or fluoroscopic lead abnormality has been reported.⁵ Therefore, the absence of detectable electrical and fluoroscopic abnormalities does not protect against the possibility of high-energy short-circuit during delivery of a shock and failure of shock energy delivery. An algorithm to automatically detect and instantaneously redirect shock current in order to mitigate this risk has been developed.²⁶

Conclusion

There is a significant prevalence of externalized conductors in Riata and Riata ST leads, and the risk of developing externalized conductors persists at 8–10 years after lead implantation. In contrast, electrical dysfunction was uncommon in

Riata and Riata ST leads, and the vast majority of these leads with externalized conductors showed no electrical abnormality during mean follow-up of 8.4 years post-implant. Durata leads demonstrated a 96%–98% reduction in the prevalence of externalized conductors compared to Riata and Riata ST leads and showed excellent electrical performance throughout the course of the study. The experience with Riata, Riata ST, and Durata leads illustrates how aspects of lead design can predispose to and mitigate specific lead failure modes.

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Disclosures: Dr Freedman is a consultant for Cook Medical, Merit Medical, and Abbott; has received honoraria for speaking for Cook Medical; and serves on the advisory board for Abbott. Dr Curtis serves on the advisory board for Janssen Pharmaceuticals, Medtronic, Inc., Abbott, Sanofi Aventis, and Milestone Pharmaceuticals; and has received honoraria for speaking for Medtronic, Inc., Abbott, and Zoll. Dr Delgado is employed by Abbott (formerly St. Jude Medical). Dr Lee was formerly employed by Abbott.

Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent: Participating study sites obtained written informed consent from all enrolled study subjects.

Ethics Statement: The research reported herein adhered to the guidelines outlined in the Declaration of Helsinki. Human Research Ethics Committee review and approval were required for participating study centers.

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