Prospective long-term follow-up of silicone-polyurethane–insulated implantable cardioverter-defibrillator leads

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BACKGROUND St Jude Medical (now Abbott) Optim-insulated implantable cardioverter-defibrillator (ICD) leads were expected to overcome problems with insulation abrasion and externalized conductors in earlier models. Long-term follow-up is essential to the evaluation of lead performance.

OBJECTIVE To determine, in a prospective cohort of Optim-insulated ICD leads, the rates of all-cause mechanical failure and its subtypes (conductor fracture, insulation abrasion, externalized conductors, and other mechanical failures) and electrical dysfunction adjudicated as nonmechanical failure.

METHODS Abbott established 3 prospective registries, enrolling 11,155 leads among 10,872 patients beginning in 2006. There was standardized baseline documentation, 6-monthly follow-up, adverse events reporting, and documentation of lead revision or inactivation, study withdrawal, and death or transplant. The Population Health Institute (McMaster University) reviewed database functions, adjudicated all potential mechanical lead failures, and conducted independent data analyses.

RESULTS During a median follow-up of 4.6 years, there were 171 mechanical failures (1.53%, 95.4% freedom from failure by 12 years). There were no significant differences in survival among Durata DF4 and DF1 and Riata ST Optim leads. The year-to-year rate of failure of leads increased over time. There were 69 electrical dysfunctions (0.62%, 98.8% freedom from failure by 12 years) adjudicated as nonmechanical failure.

CONCLUSION During follow-up as long as 12 years (median 4.6 years), Optim-insulated leads had low rates of mechanical failure and electrical dysfunction. Independent analyses provide reliable data on the long-term outcomes essential to analyzing ICD lead performance.

KEYWORDS ICD leads; Optim insulation; Mechanical lead failure; prospective cohort study; ICD lead registry

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Introduction

Use of the implantable cardioverter-defibrillator (ICD) has reduced mortality among patients at risk for fatal ventricular arrhythmias and these devices have been implanted in millions of patients worldwide.[1,2] Although advances in materials science, biomedical engineering, manufacturing, and long-term monitoring have gradually improved the reliability and durability of ICD leads, they remain the weakest link and their failure can result in structural and electrical malfunctions, with serious consequences.[3]

Conductor fracture was recognized in 2007 as a relatively common complication of the Sprint Fidelis ICD lead.[4] The Riata family of leads was first introduced in 2002 by St Jude Medical, Inc (acquired by Abbott in 2017 and hence-forth referred to as "Abbott" or the "manufacturer"). The Riata leads were reported to develop a new form of insulation abrasion, with protrusion of 1 or more cables beyond the lead body ("externalized conductors").[5] The US Food and Drug Administration issued a class I recall of the Sprint Fidelis lead in October 2007 and then for the Riata lead in December 2011.[4] Much-improved failure rates were observed with a new Sprint Quattro lead and design modifications of the Riata family of leads.[6]

The principal modification of the Riata leads (now designated as Riata ST Optim and Durata; Figure 1) was to coat the silicone insulation with Optim™, a tear- and abrasion-resistant silicone-polyurethane copolymer, and to increase the insulation thickness between the cables and the outer lead border by 50%.[7] Abbott established 3 prospective registries of Optim-insulated ICD leads at 295 sites, 98% in the United States and 2% in Europe. The Population Health Research Institute (PHRI) at McMaster University was

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KEY FINDINGS

- After follow-up of up to 12 years (54,677 lead-years), there was 95.4% freedom from mechanical failure and 94.2% freedom from the aggregate of mechanical failure or electrical dysfunction.
- Younger age was independently predictive of mechanical failure.
- The annual rate of mechanical failure increased over time.

contracted by the manufacturer to review processes for data collection and validation and to conduct independent analyses of the follow-up data on these leads. All the data analyses and designations of lead failures were done independently by PHRI, using database versions transferred every 6 months. The first author vouches for the fidelity of the analyses based upon the data received. A draft of the manuscript was provided to Abbott to allow for correction of any errors in description of their relevant systems and processes.

Methods

There were only minor differences in eligibility criteria and protocols among the 3 registries. Each registry required informed consent or patient authorization, adhered to relevant ethical guidelines, and received Institutional Review Board approval before implementation at any given clinical site. Eligible patients had received an Optim-coated high-voltage right ventricular lead. Those ineligible were participating in a clinical trial with an active treatment arm, had life expectancy <6 or 24 months (registry-specific) or were age <18 years. Informed consent or patient authorization was required. Demographic, clinical, and implant procedure data were recorded at baseline; all these and subsequent patient data were de-identified. Semi-annual standard device follow-up visits were recommended. Electrical testing was encouraged but routine fluoroscopy was not required. About half the patients were also followed by using the Merlin™ remote monitoring system.[8] Adverse events were documented by the study site on formal case report forms (CRFs), as were the following events: revision of the ICD system, lead taken out of service, patient withdrawal from follow-up, and death or transplantation.

Site-reported adverse events that had resulted in lead inactivation in a living patient of a lead that had been implanted for more than 30 days were classified by the sponsor as being due to either mechanical lead failure or nonmechanical failure. A mechanical lead failure was designated if any of the following occurred: (1) a returned product analysis (RPA) had been performed by the sponsor and confirmed mechanical lead failure; or (2) there was no RPA but the lead was reported to have been "taken out of service" (extracted or capped and electrically abandoned) and (a) the site reported either lead fracture or all-cause insulation abrasion (including externalized conductor) or (b) the site reported (i) noise artefact, abnormal pacing impedance ($\leq$100 Ω or $\geq$2000 Ω), or abnormal high-voltage lead impedance ($\leq$20 Ω or $\geq$200 Ω); or (ii) a large impedance change coupled with any of elevated pacing threshold, loss of sensing, loss of capture, oversensing, or undersensing. The following subtypes of mechanical failure were designated: (1) conductor fracture; (2) all-cause insulation abrasion or externalized conductor; (3) miscellaneous mechanical failure (failure at a crimp, bond, or weld); (4) unclassified mechanical failure (apparent mechanical failure that could not be further subtyped). Any inactivated lead that did not meet the above criteria was designated as a nonmechanical failure. On some occasions, an RPA became available after a lead failure had been classified as mechanical or nonmechanical using the algorithms; if the RPA designation differed from the original, the database entry was revised accordingly.

PHRI reviewed the documentation and CRFs of the 3 registries, Abbott's formal definitions of all-cause mechanical failure and its subtypes, and their protocols for assignment of these types of lead failure from adverse events reported from the study sites.

PHRI established a data handling plan, performed test analyses, compared results to those from previous analyses by Abbott, and resolved differences. The most up-to-date

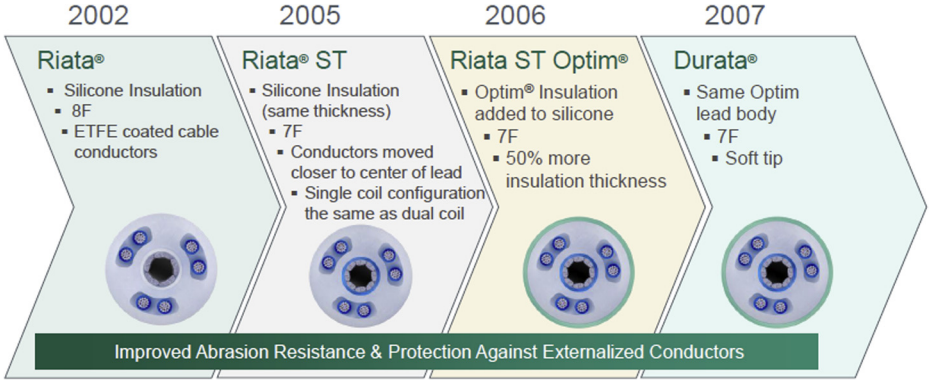

Figure 1 Design evolution of Riata and Optim leads.

Table 1 Baseline patient characteristics

	All Optim leads		Durata		Riata ST Optim		
	N	%	N	%	N	%	*P* value
Total enrolled	10,872		8086		2786		
Male	7910	72.8	5844	72.3	2066	74.2	.06
Ethnicity available	9949		7289		2660		<.01
Black	1329	13.4	952	13.1	377	14.2	
White	8011	80.5	5888	80.8	2123	79.8	
Other	531	5.3	386	5.3	145	5.5	
NYHA class available	7420		5325		2095	74.5	<.01
I or II	3451	46.4	2323	43.4	1128	54.3	
III	3744	50.5	2841	53.4	903	43.1	
IV	232	3.1	174	3.3	58	2.8	
Mean (SD) age, y	65.9 (12.9)		65.8 (13.0)		66.4 (12.7)		.03
Mean (SD) EF	29.3 (11.5)		29.3 (11.6)		29.2 (11.1)		.67
Mean (SD) BMI	29.8 (13.4)		30.1 (15.0)		29.5 (11.1)		.11

BMI = body mass index; EF = ejection fraction; NYHA = New York Heart Association; SD = standard deviation.

version of the database was transferred to PHRI every 6 months. Using all relevant CRFs, an electrophysiologist member of the steering committee (J.H. or A.E.) independently adjudicated each inactivated lead that had been designated by Abbott as being due to (1) mechanical failure or (2) nonmechanical failure, but with some features suggestive of mechanical failure (noise, altered impedance, or inappropriate shocks) mandating adjudication. Clinical data and all relevant CRFs for each Abbott-recorded lead failure were reviewed for conformance with Abbott's algorithms for designation of type of lead failure to arrive at a consensus designation by PHRI. When there was disagreement with the Abbott designation, the result was discussed with Abbott personnel; if it appeared that relevant data were missing, Abbott attempted retrieval from the clinical study sites and any received were further discussed. Study procedures stated that the final designations of mechanical or nonmechanical failure or no lead malfunction would be made by PHRI; Abbott representatives accepted all final PHRI designations. As appropriate, Abbott then edited the relevant registry databases, which were then used for all analyses The kappa for agreement on confirmed inactivations was 0.96.

The demographic and clinical profiles of registry participants were summarized as counts and percentages for binary characteristics and as means and standard deviations for continuous variables. All leads contributed to follow-up from the time of implantation to August 31, 2019 or were censored on the date of lead inactivation, withdrawal from the study, last documented follow-up, or death/transplantation.

All event rates are presented in relation to total right ventricular leads enrolled, rather than registry participants, since an individual could have multiple Abbott right ventricular leads over time. Rates for each type of lead failure were defined as the number of failures divided by either the total leads (percentages) or total lead years at risk (rates per 100 person-years) within the registry.

Survival curves for time to lead failure were plotted using the Kaplan-Meier method with 95% confidence intervals (95% CI) estimated as suggested by Peto and colleagues.[9] Comparisons of mechanical failure rates between Durata overall and Riata ST Optim leads and among the Durata DF-1, Durata DF-4, and Riata ST Optim leads was done using log-rank tests, with hazard ratios estimated from a Cox proportional hazards regression. To determine change in lead failure rate over time, a log-log plot of the cumulative hazard function was performed (ie, the logarithm of the hazard was plotted against the logarithm of time) to yield a visual and quantitative depiction of the changing instantaneous rate of mechanical failure over time.[10] If the cumulative hazard (H) of lead failure at time t is defined by the function $H(t) = at^n$, where a and n are constants, then the relationship may be expressed as $\log H(t) = \log a + n \log t$. Linear regression analysis of the log H – log t plot yielded the slope n and the constant log a. The slope parameter (n) provides an indication as to whether the rate of mechanical failure is increasing ($n > 1$), constant ($n = 1$), or decreasing ($n < 1$) over time.

The odds ratios for the outcome of mechanical failure were calculated by univariable and multivariable analyses for the baseline measures of ethnicity (white vs nonwhite), New York Heart Association (NYHA) functional class (I or II vs III or IV), ejection fraction (EF) (dichotomized at the median of 29.3%), age (dichotomized at the mean of 65.9), weight (continuous variable), body mass index (continuous variable), and sex (male vs female).

Results

Among the 3 registries, 10,872 patients received a total of 11,155 Optim-coated leads (8289 Durata [3210 DF4, 5079 DF1] and 2866 Riata ST Optim). Patients were 72.8% male, mean age was 65.9 years, 80.5% were white and 13.4% were black, mean body mass index was 29.8, mean left ventricular EF was 29.3%, and most were in NYHA functional class II or III (Table 1). The baseline characteristics of patients were generally similar among the 3 registries, with small differences reaching statistical significance for age

Table 2 Lead status by lead type, August 31, 2019

	Lead type					
	Durata or Riata ST Optim		Durata		Riata ST Optim	
	N	%	N	%	N	%
Total leads enrolled	11,155	100.0	8289	100.0	2866	100.0
Currently followed leads	2467	22.1	2029	24.5	438	15.3
Lead not currently followed	8688	77.9	6260	75.5	2428	84.7
Lead/system inactivated	852	7.6	685	8.3	167	5.8
Mechanical failure	171	1.5	116	1.4	55	1.9
Nonmechanical failure	735	6.6	555	6.7	180	6.2
Electrical dysfunction	69	0.6	53	0.6	16	0.6
Other	612	5.5	516	6.2	96	3.3
Death/transplant	3540	31.7	2468	30.0	966	33.7
Death	3486	31.3	2508	30.3	978	34.1
Transplant	54	0.5	49	0.6	10	0.3
Administrative withdrawal	4290	38.5	3017	36.4	1273	44.4
Patient/family request	1113	10.0	811	9.8	302	10.5
Investigator request	365	3.3	215	2.6	150	5.2
Sponsor request	55	0.5	46	0.6	9	0.3
Site or physician withdrawn from study	1185	10.6	867	10.5	317	11.1
Noncompliance	170	1.5	114	1.4	56	2.0
Lost to follow-up	1389	12.5	952	11.5	437	15.2
Other	13	0.1	11	0.1	2	0.1
Reason for withdrawal missing	6	0.1	6	0.1	0	0.0

and sex. Small differences, some statistically significant, were observed between patients receiving a Durata lead vs a Riata ST Optim lead, and between those receiving a DF-4 Durata lead or a DF-1 Durata lead. Median follow-up was 4.6 years (interquartile range 2.1–7.5) for all Optim leads. There were 7351 Optim-insulated leads followed for at least 3 years, 4928 for at least 5 years, 912 for at least 10 years, and 83 still under follow-up after 12 years. Total lead-years of follow-up was 54,677.

As of August 31, 2019, 22.1% of leads enrolled were still under active follow-up (Table 2). Major reasons for the 77.9% of leads that had been censored included lead inactivation 7.6% (either explanted or abandoned/capped), death or heart transplant 31.7%, administrative reason 38.5% (including requests by the patient, family, or investigator; no data obtained for $\geq$18 months; loss to follow-up; or noncompliance), and reason unknown 0.1%.

There were 852 leads inactivated in a living patient. Common reasons for lead inactivation in addition to either mechanical failure or nonmechanical failure with electrical dysfunction suggestive of mechanical failure ("electrical dysfunction") were apparent lead dislodgement, perforation, or migration; electrical dysfunction not suggestive of mechanical failure (eg, elevated pacing threshold, poor sensing, decreased R-wave amplitude infection); pulse generator malfunction; pulse generator pocket problems; or a variety of clinical events (eg, heart failure, myocardial infarction, thromboembolism).

Following adjudication, there were 171 inactivated leads designated as having all-cause mechanical failure (1.53% of enrolled leads) (Table 3). The specific types of mechanical failure were designated as conductor fracture in 120 leads (1.08%), insulation abrasion in 33 leads (0.30%), and miscellaneous or unclassifiable types of mechanical lead failure in 18 leads (0.16%). There were no externalized conductors. Estimated lead survival, free of any type of mechanical failure, was 95.4% (95% CI: 91.0%–96.2%) at 12 years (Figure 2), a loss of approximately 0.38% per year. Lead survival at 12 years with freedom from conductor fracture was 96.9% (95% CI: 93.3%–97.6%) and from insulation abrasion was 99.0% (95% CI: 96.8%–99.4%). Comparisons of survival free of all-cause mechanical failure between Durata and Riata ST Optim leads revealed no statistically significant difference (hazard ratio [HR] = 0.78 [95% CI: 0.56–1.07], P = .12), nor were there significant differences between DF-4 vs DF-1 (HR = 0.86, 95% CI = 0.58–1.28, P = .47) or between DF-4 vs Riata ST Optim (HR = 0.72, 95% CI = 0.46–1.08, P = .10) (Figure 3).

The percent of leads free of mechanical failure decreased with each year of follow-up (Figure 2). During years 1–4, the mean decrease was 0.2% per year. During years 5–12, the mean decrease was 0.55% per year. The plot of the logarithm of the cumulative hazard of mechanical failure against the log of time yielded a line with excellent fit (R^2 = 0.97) with a slope of 1.16, indicative of an increasing rate of failure over time (Figure 4).

On univariable analysis, the outcome of mechanical failure was significantly more common among patients who were younger, had a higher ejection fraction, and were in NYHA functional class I or II vs III or IV. After multivariable analysis, only younger age (under vs over 65.9 years) was predictive (OR = 4.06, 95% CI 1.79–9.21, P = .0008).

Table 3 All-cause mechanical failures and subtypes, overall and annualized percentages

	Durata or Riata ST Optim			Durata			Riata ST Optim		
	N	%[†] (95% CI)	%/y[‡] (95% CI)	N	% (95% CI)	%/y (95% CI)	N	% (95% CI)	%/y (95% CI)
Total leads enrolled	11,155			8289			2866		
All-cause mechanical failure	171	1.53 (1.31–1.77)	0.31 (0.27–0.36)	116	1.40 (1.16–1.67)	0.29 (0.24–0.34)	55	1.92 (1.45–2.46)	0.38 (0.29–0.49)
Lead fracture	120	1.08 (0.89–1.28)	0.22 (0.18–0.26)	83	1.00 (0.80–1.23)	0.21 (0.165–0.25)	37	1.29 (0.91–1.74)	0.13 (0.07–0.21)
Lead abrasion	33	0.30 (0.20–0.40)	0.06 (0.04–0.08)	19	0.23 (0.14–0.34)	0.03 (0.01–0.06)	14	0.49 (0.27–0.78)	0.04 (0.01–0.08)
Misc/uncertain type mechanical failure	18	0.16 (0.10–0.24)	0.03 (0.02–0.05)	14	0.17 (0.09–0.27)	0.01 (0.00–0.03)	4	0.14 (0.04–0.31)	0.03 (0.01–0.07)
Electrical dysfunction	69	0.62 (0.48–0.77)	0.13 (0.10–0.16)	53	0.64 (0.48–0.82)	0.13 (0.10–0.17)	16	0.56 (0.32–0.86)	0.11 (0.06–0.17)
Either mechanical failure or electrical dysfunction	240	2.15 (1.89–2.43)	0.44 (0.39–0.50)	169	2.04 (1.74–2.36)	0.42 (0.36–0.49)	71	2.48 (1.93–3.09)	0.49 (0.38–0.61)

[†]Failed leads as a % of total leads (numerator is number of leads with failure, denominator is total number of leads enrolled).
[‡]Annual % of failed leads (numerator is number of leads with failure, denominator is number of lead-years of follow-up).

Following adjudication, there were 69 leads designated as having electrical dysfunction with some features suggestive of but not satisfying the algorithms for mechanical failure (0.62% of enrolled leads) (Table 3). The estimated lead survival, free of any such electrical dysfunction, was 98.8% (95% CI 96.4%–99.2%) at 12 years, an annual loss of approximately 0.1%.

The aggregate of adjudicated mechanical failure or electrical dysfunction was the explanation for lead inactivation in 240 cases (2.15% of enrolled leads) (Table 3). The estimated lead survival, free of inactivation because of either mechanical failure or electrical dysfunction, was 94.2% (95% CI 89.2%–95.1%) at 12 years, an annual loss of approximately 0.48% (Figure 5). The baseline characteristics predictive of the outcome of mechanical or electrical dysfunction were the same as those for mechanical failure.

There were 1389 patients lost to follow-up; they were significantly more likely to be of nonwhite ethnicity, to be younger, and to have a lower EF, but the differences were small.

Discussion

The algorithms used in the 3 registries upon which the present report is based were designed to provide data on the specific outcome of mechanical failure. There were 95.4% of leads free of mechanical failure over follow-up of up to 12 years. The annual increment of mechanical failure for any given lead was higher from years 5–12 than from years 1–4. Most published studies of ICD lead failure have reported all-cause failure (a lead inactivated in a living patient for either mechanical failure or electrical dysfunction with some features suggestive of mechanical failure and not because of infection, venous thrombosis, pulse generator problems, or other events not resulting from malfunction of the lead itself). Use of the outcome of all-cause failure reduces the subjectivity inherent in the algorithmic approach of defining mechanical failure, although it is less specific. In the present study there were 94.2% of leads free of this more inclusive outcome up to 12 years. An increase in the annual increment of all-cause failure was also observed beginning at about 5 years.

A meta-analysis of observational studies of ICD lead failure rates comparing at least 2 of the most commonly implanted leads reported much higher and statistically significant failure rates with the Sprint Fidelis (2.23%/year) and Riata (1.17%/year) leads of an earlier era with those of the Sprint Quattro (0.29%/year), Durata (0.45%/year) and Endotak Reliance (0.35%/year) leads currently in use, but there were no statistically significant differences among the latter 3 lead families.[6] Of the 17 studies summarized, only 6 were prospective. The follow-ups in most studies were for only 2–3 years; the longest median follow-up of 6.4 years involved only 304 leads. Lead failure was defined as a lead not performing according to its expected function and presenting a structural (externalization of conductors, insulation defect, or fracture) or electrical malfunction (excluding lead

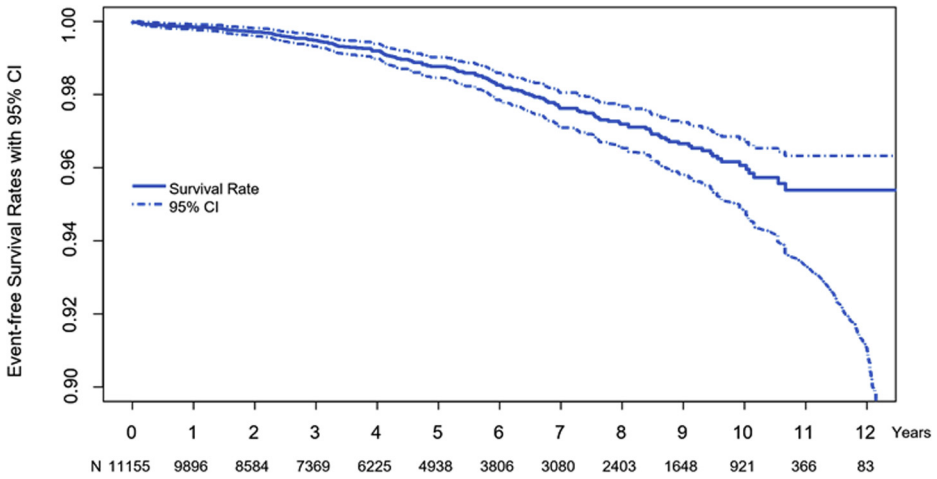

Figure 2 Freedom from mechanical failure: Optim-insulated leads. Kaplan-Meier estimates of freedom from mechanical failure with numbers at risk (N) on x-axis.

dislocation, perforation, or oversensing of noncardiac potentials).

The 4 studies of Optim-coated leads in the meta-analysis[6] had a mean annual failure rate of 0.45%. Additional follow-ups of Optim-coated leads have reported annual failure rates ranging from 0.15% (mechanical failures only)[11] to 0.25%[12] and 0.54%.[7] Outlying annual rates of failure of 1.2%[13] and 3.6%[14] have been reported from smaller and therefore less reliable studies.

The present study is distinguished from most prior studies by its prospective design and the engagement of an external academic group for adjudication of events and analyses of the data. The median follow-up of 4.6 years and the 54,677 lead-years of follow-up are additional features contributing to the validity of the results.

Prior studies have identified patient characteristics predictive of lead failure, including younger age,[15,16] female sex,[16–18] and higher ejection fraction.[19] In the present study only younger age was independently predictive of mechanical lead failure.

This study has a number of limitations. Lead failure is designated only when a lead has been inactivated in a living patient, ensuring that a clinically important threshold for likelihood of lead malfunction has been reached and the algorithms used to define mechanical failure bring a degree of precision to decisions as to whether or not lead fracture or

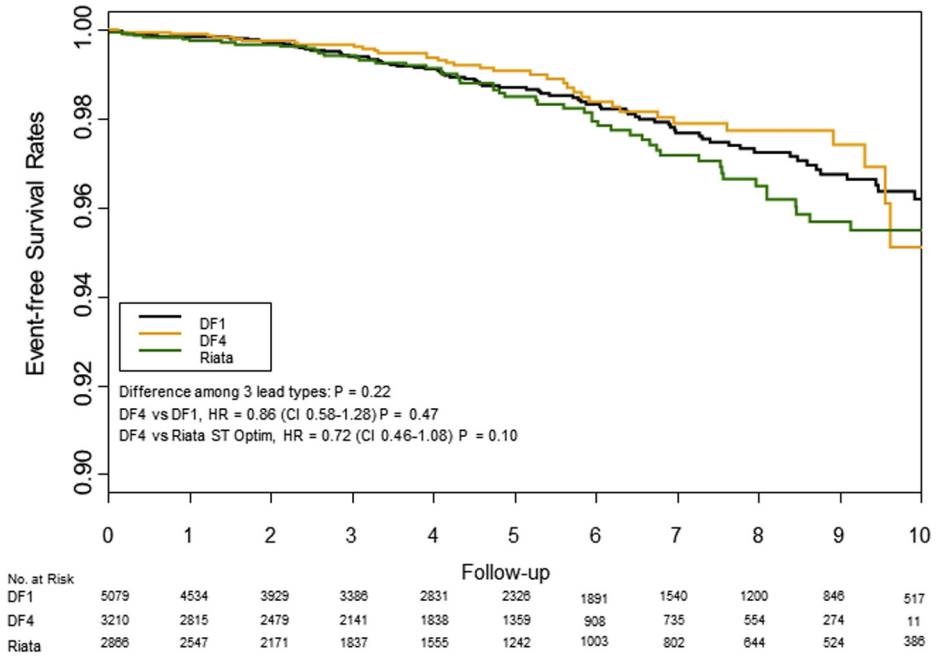

Figure 3 Freedom from mechanical failure; DF4 vs DF1 vs Riata ST Optim. Kaplan-Meier estimates of freedom from mechanical failure with numbers at risk on x-axis.

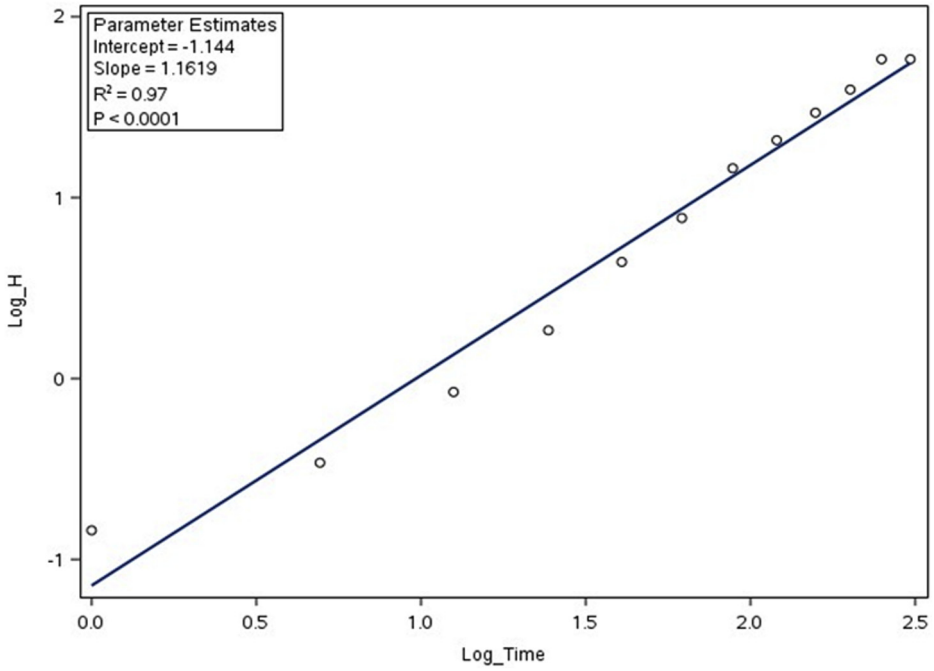

Figure 4 Log cumulative hazard vs log time for mechanical failure.

abrasion is likely.[20] However, a definitive diagnosis of either of these outcomes requires visualization of an extracted lead and RPA by the company. In the present study, only 31% of leads judged to have either mechanical failure or electrical dysfunction underwent RPA. The algorithms used for detection of mechanical failure are likely very sensitive, but relatively nonspecific, and the designation of subtypes (fracture, abrasion, other mechanical failure) is only an approximation of the true designations that could be made from RPA. Most published reports of lead failures provide data for only the aggregate of mechanical failure or electrical dysfunction. Accordingly, we have provided data for this aggregate outcome to allow comparisons with other reports.

Among the lead failures attributed to abrasion, there were no externalized conductors documented. However, externalized conductors often show no electrical abnormality and reliable determination of the incidence is available only from studies employing routine radiography or fluoroscopy,[20] neither required by the registries analyzed for the present report. There were 12.5% of leads lost to follow-up. Using the Kaplan-Meier approach a lead lost to follow-up is censored at the time of last clinic visit or Merlin transmission. In contrast to studies of survival experience in clinical trials with clinical events as the outcome, where loss to follow-up could well result from the occurrence of a clinical event, we believe there is no reason to expect a greater likelihood

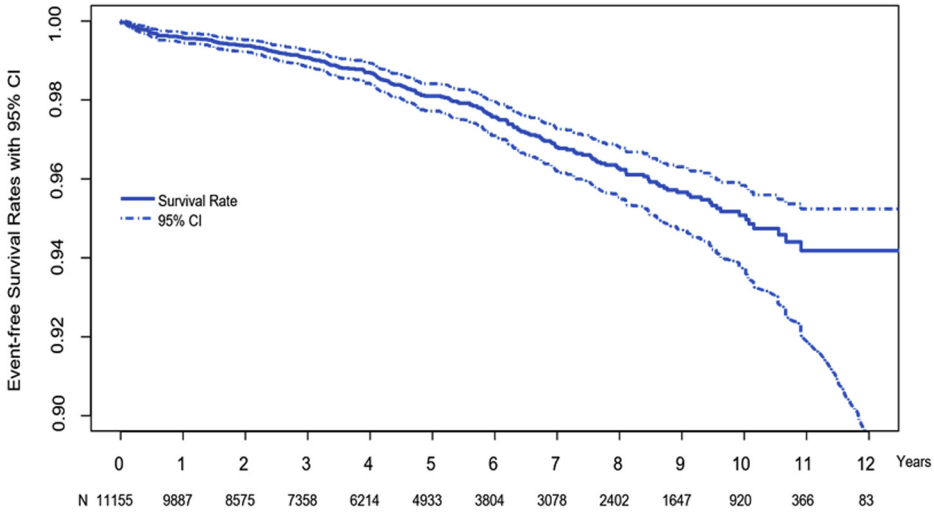

Figure 5 Freedom from mechanical failure or electrical dysfunction: Optim-insulated leads. Kaplan-Meier estimates of freedom from mechanical failure or electrical dysfunction with numbers at risk (N) on x-axis.

of lead failure among patients lost to follow-up than among those continuing under active follow-up. There were no important differences in baseline characteristics between patients lost to follow-up and those not.

Conclusion

This cohort study of Optim family leads followed for up to 12 years provides more extensive prospective follow-up data than previously reported. There were low rates of all-cause mechanical failure and of the aggregate of mechanical failure or electrical dysfunction adjudicated as nonmechanical failure. The annual failure rate of mechanical failure appeared to increase 2-fold from the first 4 years to the latter 8 years of follow-up. Prospective, observational studies initiated at the time of introduction of a new ICD lead and sustained over several years provide reliable data regarding lead survival and are essential to define its performance.

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Patient Consent: Each registry required informed consent or patient authorization.

Ethics Statement: Each registry adhered to relevant ethical guidelines and received Institutional Review Board approval before implementation at any given clinical site.

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