Prospective long-term evaluation of Optim-insulated (Riata ST Optim and Durata) implantable cardioverter-defibrillator leads

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BACKGROUND St Jude Medical Optim-insulated implantable cardioverter-defibrillator leads were designed to impart lubricity, strength, and abrasion resistance while maintaining flexibility and biostability. No long-term prospective follow-up data have been published.

OBJECTIVE The objective of this study was to determine the rates of all-cause mechanical failure and its subtypes (conductor fracture, insulation abrasion, externalized conductors, and other mechanical failures) in a prospective cohort of Optim-insulated implantable cardioverter-defibrillator leads.

METHODS St Jude Medical established 3 prospective registries and enrolled 11,016 leads implanted in 10,835 patients beginning in 2006. There was standardized baseline documentation, 6-monthly follow-up, adverse events reports (verified by expert staff using detailed algorithms), and documentation of lead revisions or inactivation, study withdrawal, and death. The Population Health Research Institute (McMaster University) was engaged to review database functions, adjudicate all potential mechanical lead failures, and conduct independent analyses of the data.

RESULTS During a median follow-up of 3.2 years, there were 51 mechanical failures (0.46%), with 99.0% survival free of this outcome by 5 years of follow-up. Freedom from conductor fracture was identified in 99.4% and from all-cause abrasion in 99.8% of the leads, and there were no reports of externalized conductors. There were no significant differences in survival among Durata DF4, Durata DF1, and Riata ST Optim leads.

CONCLUSION Over a mean follow-up of 3.2 years, Optim-insulated leads have low rates of all-cause mechanical failure and no observed externalized conductors. Independent analyses of these registries are designed to provide reliable long-term follow-up information and are ongoing.

KEYWORDS ICD leads; Optim insulation; Mechanical lead failure; Prospective cohort study; Prospective registries

ABBREVIATIONS **CI** = confidence interval; **ICD** = implantable cardioverter-defibrillator; **IQR** = interquartile range; **MAUDE** = Manufacturer and User Facility Device Experience; **PHRI** = Population Health Research Institute; **SJM** = St Jude Medical

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Introduction

Implantable cardioverter-defibrillator (ICD) leads are highly functional electrophysiological devices with advanced engineering design and manufacturing sophistication that must function over long periods within the human intravascular space.[1] These leads are fundamental components of ICD systems that have markedly reduced mortality among patients at risk of fatal ventricular arrhythmias.[2]

Under the terms of a contract with the Population Health Research Institute of McMaster University and Hamilton Health Sciences, St Jude Medical paid all costs of independent analyses of their databases. Dr Cairns, Dr Connolly, Dr Buller, Dr Epstein, and Dr Healey have received compensation from St Jude Medical (SJM) for time spent on independent reviews and analyses of prospective registries of Optim-insulated leads. In addition, Dr Cairns is a coinvestigator on clinical trials supported by Medtronic and Boston Scientific. Dr Buller has provided consultation to Boston Scientific and has received fellowship support from Boston Scientific. Dr Connolly has provided consultation to SJM. Dr Epstein has received research grants from Biotronik, Boston Scientific, Medtronic, and SJM; honoraria from Boston Scientific, Medtronic, and SJM; and fellowship support from Boston Scientific, Medtronic, and SJM. Dr Healey has received research grants from Medtronic, SJM, and Boston Scientific. Dr Wilkoff serves on the physician advisory board of Medtronic, SJM, and Spectranetics and is a principal investigator or coinvestigator of trials supported by Medtronic, SJM, and Boston Scientific. **Address reprint requests and correspondence:** Dr John A. Cairns, Division of Cardiology, University of British Columbia, Room 9113, GLD Health Care Centre, 2775 Laurel St, Vancouver, British Columbia, Canada V5Z 1M9. E-mail address: john.cairns@ubc.ca.

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Nevertheless, structural and electrical malfunctions may occur with potentially fatal consequences.[3,4]

St Jude Medical, Inc (SJM; St Paul, MN), introduced the Riata 8-F ICD lead in 2002 and the Riata ST 7-F lead in 2005. These leads contain 3 pairs of conductors each located in a hollow tunnel symmetrically arrayed around a central pace-sense spiral electrode, with the rest of the lead comprising insulating silicone. 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] A physician advisory letter was issued in November 2011, and the Food and Drug Administration classified this as a class 1 recall in December 2011.[6]

The SJM released a new family of leads (Riata ST Optim in 2006 and Durata in 2007 [DF1 in 2007 and DF4 in 2009]) in which the silicone insulation was coated with Optim, a tear- and abrasion-resistant silicone-polyurethane copolymer; the new leads also had a 50% increased insulation thickness.[7] With the addition of the Optim coating and other design features, Riata ST Optim and Durata leads are expected to have low rates of lead abrasion and conductor externalization; early clinical experience suggests that these problems are uncommon.[8] Long-term experience with these leads is limited, and there are no large, prospectively followed cohorts reported as yet.

To evaluate the long-term performance of the Riata ST Optim and Durata leads, at the time of their introduction, the SJM initiated prospective long-term observational studies of patients who received these leads. To provide an external and academic focus to the analysis of the information in these databases, the SJM subsequently contracted with the Population Health Research Institute (PHRI) at McMaster University to review processes for data collection and validation and to provide ongoing independent analysis of the follow-up data on these leads. This is the first article to report rates of mechanical lead failure in these prospective registries in which the follow-up is ongoing.

Methods

Beginning in 2006, the SJM established 3 prospective registries of Optim-insulated ICD leads (Table 1), with 6-monthly standard device follow-up visits recommended and electrical testing encouraged. No routine fluoroscopy was requested. About half the patients are also followed by using the Merlin remote monitoring system.[9] Patients were eligible for inclusion in 1 of the 3 registries if they had implantation of an SJM ICD or Cardiac Resynchronization Therapy-Defibrillator (CRT-D) with an Optim-insulated lead. Exclusion criteria were current participation in a clinical trial with an active treatment arm, life expectancy of <6 or 24 months (depending on registry), or age <18 years. Informed consent or patient authorization was required. Demographic, clinical, and implant procedure data were recorded at baseline. Adverse events were documented by the study site on formal case report forms requiring a conclusion about the type of adverse event and its resolution. The following events were also documented: any revision of the ICD system, any lead taken out of service, patient withdrawal from follow-up, and/or death.

The designation of the type of any adverse event is entered as reported by the site. Each adverse event is also classified by expert SJM personnel as being due to mechanical lead failure or nonmechanical lead failure, using detailed algorithms. All-cause mechanical lead failure was defined as any failure of the structural integrity of the lead with the following subtypes: (1) conductor fracture (conductor break with complete or intermittent loss of continuity that could interrupt current flow); (2) all-cause insulation abrasion (full-thickness breach in the insulation) or externalized conductor (protrusion of a conductor beyond the body of the lead); (3) miscellaneous mechanical failure (failure at a crimp, bond, or weld); and (4) unclassified mechanical failure (apparent mechanical failure that cannot be further subtyped). The designation of mechanical failure would be made only if the lead had been implanted for more than 30 days.

Table 1 The 3 SJM lead registries

Registry	Launch	ICD leads reported in the present study	Enrollment time after lead implant	Number of sites	Purpose
OPTIMUM	August 2006	Optim-insulated: 6047 Riata ST Optim: 2481 Durata: 3566 DF4: 244 DF1: 3322	$\leq$180 d	216	Prospective, multicenter, actively monitored registry to evaluate the long-term performance of all Optim insulated leads
SCORE	September 2007	Optim-insulated: 3458 Riata ST Optim: 388 Durata: 3070 DF4: 1327 DF1: 1743	$\leq$90 d	58	Prospective, multicenter, actively monitored, long-term data collection and evaluation registry to evaluate the long-term performance of cardiac rhythm management devices
SJ4 PAS	June 2009	Optim-insulated: 1511 Riata ST Optim: 0 Durata: 1511 DF4: 1511 DF1: 0	Date of lead implant	58	Prospective, multicenter, actively monitored study to characterize the chronic performance of the SJM SJ4 connector and right ventricular high-voltage SJ4 leads

ICD = implantable cardioverter-defibrillator; SJM = St Jude Medical.