Longevity of Sprint Fidelis Implantable Cardioverter-Defibrillator Leads and Risk Factors for Failure
Implications for Patient Management

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Background—Sprint Fidelis (Fidelis) implantable cardioverter-defibrillator leads are prone to fractures that have caused adverse events, primarily inappropriate shocks, and a few reported deaths. More than 100 000 patients have Fidelis leads. No independent multicenter long-term performance information exists for this lead, and single-center studies suggest that certain patients are at increased risk for Fidelis failure. Our aim was to assess the longevity of Fidelis leads and to evaluate clinical variables and adverse events associated with Fidelis failure. The results were compared with like data for Quattro Secure (Quattro) implantable cardioverter-defibrillator leads implanted at our centers.

Methods and Results—This 3-center study included adults ≥18 years of age who received Fidelis or Quatro leads for the prevention of sudden cardiac death. From November 2001 to January 2009,1023 Fidelis and 1668 Quattro leads were implanted and followed up. The failure rate for Fidelis leads was 2.81%/y compared with 0.43%/y for Quattro leads (P<0.0001). No deaths or injuries occurred as a result of lead failure, but 42% of fractures caused inappropriate shocks. The survival of Fidelis leads at 4 years was 87.0% (95% confidence interval, 83.6 to 90.1) compared with 98.7% (95% confidence interval, 97.9 to 99.4) for Quattro leads (P<0.0001). Multivariate predictors of Fidelis failure were younger age (hazard ratio, 0.98; 95% confidence interval, 0.96 to 0.99), female gender (hazard ratio, 0.61; 95% confidence interval, 0.40 to 1.00), and cardiac disease (P=0.041).

Conclusions—Compared with Quattro leads, the survival of Fidelis leads continues to decline, and Fidelis failure is notably higher in younger patients, women, individuals with hypertrophic cardiomyopathy, and patients with arrhythmogenic right ventricular dysplasia or channelopathies. These findings have significant implications for the management of patients who have Fidelis leads, and they demonstrate the importance of weighing clinical variables in assessments of implantable cardioverter-defibrillator lead performance. (Circulation. 2011;123:358-363.)

Key Words: channelopathies ■ cardiomyopathy, hypertrophic ■ implantable cardioverter-defibrillators

The Medtronic Sprint Fidelis (Fidelis) implantable cardioverter-defibrillator (ICD) transvenous high-voltage lead began to fracture soon after it was introduced in 2004.1 The manufacturer voluntarily removed Fidelis leads from the market in 2007 after 268 000 were implanted worldwide.2 Subsequently, the Fidelis fracture rate was observed to accelerate during the first 2 years after implantation,3-5 and leads in younger8 more active patients with less impairment of left ventricular function appeared to be more prone to failure.3

Editorial see p 353
Clinical Perspective on p 363

Approximately 100 000 patients continue to rely on Fidelis leads. Recently, Medtronic reported Fidelis model 6949 cumulative survivals of 94.2%/1.7/-2.3 at 4 years after implantation.6 However, there are no independent multicenter long-term performance data for this lead, and recent studies suggest that Medtronic’s estimates of Fidelis survival do not reflect the experience with this lead in other populations.4,5 Moreover, additional information is needed that may identify patients who are at greater risk for Fidelis failure. Such knowledge is important because it may affect Fidelis patient management and improve our understanding of lead failure mechanisms. Accordingly, we examined the longevity and clinical outcomes of Fidelis leads at our 3 centers and further assessed clinical variables associated with Fidelis failure. The results of these analyses were compared with similar data for Medtronic Quattro Secure (Quattro) ICD leads implanted at our hospitals.
Methods

Study Design
Patient information and lead data were collected routinely by each center and pooled and analyzed retrospectively for the purposes of this study.

Study Population
The study included adults ≥18 years of age who received a Fidelis (model 6931, 6949, and 6949) or Quattro (model 6947) lead and were followed up at the Minneapolis Heart Institute (Minneapolis, MN), Mayo Clinic (Rochester, MN), and Beth Israel Deaconess Medical Center (Boston, MA). The leads were implanted between November 2001 and January 2009, and follow-up was complete through June 2009.

Implantation Techniques and Follow-Up
Leads were inserted via preferably a left- or alternatively a right-sided venous access by cephalic cut-down or via the axillary or subclavian vein using standard micropuncture and introducer sheath techniques. Leads were positioned in the right ventricular apex or ventricular septum. Defibrillation safety margins and pacing threshold and sensing measurements were obtained according to each center’s protocol to provide rate support and to ensure adequate detection and termination of ventricular fibrillation and ventricular tachycardia. Atrial and left ventricular pacing leads were added for multichamber therapy. Patients were followed up every 3 to 4 months in the clinic and/or by remote monitoring (Medtronic Carelink). Approximately 65% of patients were followed up by remote monitoring, which was implemented with a home monitor that interrogated the ICD and transmitted a rhythm electrogram and all data within the device memory via telephone to a secure Carelink network server. The information was subsequently reviewed by our centers on the Carelink Web site. Remote monitoring with the Carelink methodology has been shown to be comparable to clinic visits for identifying clinically important device issues.

Definitions
A lead was considered implanted after it was tested and connected to the ICD pulse generator and the incision was closed. A lead malfunctioned if it did not meet its performance specifications or otherwise perform as intended. A lead failed if it exhibited abnormal impedance; if it exhibited electrical noise as manifested by nonphysiological signals on the electrogram or by pulse generator diagnostic data suggesting rapid oversensing (e.g., nonphysiological short intervals and/or recurrent nonsustained ventricular tachycardia with intervals usually <220 milliseconds); or if it could not sense R waves and/or provide effective electrical therapy as a result of an apparent structural defect such as a conductor fracture or insulation breach. Functional abnormalities, including exit block and physiological oversensing in the presence of an electrically intact lead, were not failures. Lead dislodgement was not a lead failure unless a fixation mechanism defect was identified. Leads removed from service were classified according to the Heart Rhythm Society’s recommendations. Lead failures were reviewed and adjudicated by a co-investigator at each center. Pseudoabnormalities caused by header or connector problems were identified at the time of lead revision.

Statistical Analysis
Survival probabilities were estimated by the Kaplan-Meier method with 95% confidence bounds (95% confidence interval [CI]) computed with the effective sample size method of Dorey and Korn. Survival curves were compared by use of the log-rank test. Investigation of clinical predictors of lead failure was carried out via Cox proportional hazards regression. Tests of the proportional hazards assumption were conducted on the Schoenfeld residuals with the method of Grambsch and Therneau. The ability of models to predict failures was measured by the C-index of Harrell. Between-group comparison of quantities not based on time-to-event was carried out via t tests (continuous variables), χ² tests (categorical variables), or the uniformly most powerful unbiased approach (ratios of Poisson rates). All P values are 2 sided.

Results
From November 2001 to January 2009, 1023 Fidelis (model 6949, n = 1,007; model 6931, n = 14; model 6948, n = 2) and 1668 Quattro (model 6947) leads were implanted and followed up at the 3 centers. The characteristics of the patients who received these leads are provided in Table 1. Compared with Fidelis patients, more Quattro patients were male and had ischemic heart disease; but fewer were implanted for primary prevention. No significant differences were found between lead models in the proportion of patients who had hypertrophic cardiomyopathy (HCM) or either arrhythmogenic right ventricular dysplasia (ARVD) or channelopathies.

The status of Fidelis and Quattro leads and their failure rates are shown in Table 2. A lower proportion of Fidelis leads were active and a higher percentage of Fidelis leads had failed than Quattro leads (P < 0.0001). No difference was found between Fidelis and Quattro leads in the percentage of leads removed from service as a result of patient death.
The failure rate for Fidelis leads was 2.81%/y compared with 0.43%/y for Quattro leads (P = 0.0001). Of the 80 Fidelis failures, 76 (95%) were pace-sense conductor fractures and 4 (5%) were breaks in the high-voltage conductor. Pace-sense conductor fractures affected 19 of 23 Quattro failures (83%), and 4 Quattro leads (17%) failed as a result of high-voltage conductor defects.

During the study, no deaths occurred as the result of lead failure. Overall, 42% of lead failures (42 of 103) were associated with inappropriate shocks, including 37 Fidelis pace-sense conductor fractures.

The Kaplan-Meier survivals for Fidelis and Quattro leads are shown in Figure 1. The survival of Fidelis leads at 4 years was 87.0% (95% CI, 83.6 to 90.1) compared with 98.7% (95% CI, 97.9 to 99.4) for Quattro leads (P < 0.0001). Lead survivals for each of the 3 study centers are available in the online-only Data Supplement. Lead survival differences were highly significant at all centers (P < 0.0001).

Univariate predictors of lead failure are given in Table 3. For Fidelis leads, age, gender, underlying cardiac disease, and left ventricular ejection fraction were significantly associated with lead failure, whereas none of the variables were significant for the comparatively small number of Quattro lead failures. The hazard ratios for Fidelis lead failure are shown in Table 4. Tests for hazard disproportionality were all nonsignificant (smallest P = 0.14). The hazard of Fidelis lead failure decreased 3% for every 1-year increase in age and increased 2% for every 1% increase in ejection fraction. With age grouped into tertiles (<60, 60 to 73, or >73 years; n = 341 per group), the hazard ratios for Fidelis failure were 0.885 (95% CI, 0.55 to 1.43) for the middle age group to the youngest age group and 0.451 (95% CI, 0.24 to 0.84) for the oldest age group to the youngest age group; the linear trend was significant (P = 0.015). C indexes for the univariate models in Table 4 were between 0.53 and 0.60.

A Cox proportional hazards multiple regression model was fitted using the 4 variables that were significant in univariate analysis. Left ventricular ejection fraction was the least significant (P = 0.60) and was removed from the model. Age, gender, and cardiac disease remained significant independent predictive factors after accounting for the other 2 variables in the model (Table 5). Interactions between these predictors were not significant. The C index for this model was 0.65. The multiple regression model (Table 5) yielded no evidence of hazard disproportionality (P = 0.52). The failure rates according to cardiac disease for Fidelis and Quattro leads are shown in Table 6.

### Discussion

**Principal Findings**

The results of this large retrospective multicenter study show that the survival of Fidelis leads continues to decline and that
the risk of Fidelis failure is notably higher in younger patients, women, individuals with HCM, and patients who have ARVD or channelopathies. In contrast, Quattro leads exhibited a failure rate well below the suggested benchmark of 0.6%/y, and none of the clinical variables studied appeared to affect Quattro survival. Except for inappropriate shocks, we did not observe major adverse clinical events in our patients who experienced either Fidelis or Quattro lead failure. These findings have significant implications for the management of the >100,000 patients who have Fidelis leads, and they underscore the importance of weighing clinical variables in assessments of ICD lead performance.

We believe this is the first study to show that age, gender, and cardiac disease are independent risk factors for the failure of Fidelis or any ICD lead model. A multicenter study of ICD lead performance in 324 HCM patients (some of whom were included in this study) found that certain models, including Fidelis, had higher failure rates. Although lead failure caused inappropriate shocks in some patients, no HCM patient died or suffered a serious injury as the result of lead failure. Compared with patients without lead defects, Kleeman et al reported that patients with lead defects (defined as severe lead failure requiring surgical correction) more often were women, were younger, and had other cardiac diseases, including HCM, ARVD, and long-QT syndrome. Long-term studies have shown that lead complications have been relatively high in patients who receive ICD therapy for Brugada and congenital long-QT syndromes.

Precisely how these clinical variables affect the Fidelis pace-sense conductors is unknown. However, the pattern of Fidelis conductor fractures is consistent with a nonrandom time-dependent mechanical failure mode, and it is likely that young active adults with these inherited cardiac diseases mechanically stress Fidelis leads more vigorously than older sedentary patients who have severe ischemic cardiomyopathy and heart failure. The observation that patients who have higher left ventricular ejection fractions also experience higher Fidelis fracture rates further supports the notion that the Fidelis conductors are vulnerable to normal physiological stresses. The influence of gender is less clear, but women have had a higher early complication rate after de novo ICD implantation than men, and their vascular anatomy may subject leads to the aggressive bend conditions that have been shown to affect Fidelis more than Quattro leads. Whatever the mechanism(s), more research is needed to understand why these differences exist so that future ICD leads perform reliably in all patients.

**Comparison With Medtronic Data**

The survival of Fidelis leads in this and other investigations is lower than those Medtronic has reported from its postmarket studies. These studies include the CareLink, CareLink PLUS, and the System Longevity Study (SLS). Although the SLS study includes all lead-related complications, the CareLink PLUS numerator includes fractures determined by CareLink transmissions, analyses of returned leads, and interrogation of returned Medtronic ICD pulse generators that were used with Fidelis leads; the denominator is the number of active Fidelis leads in the CareLink cohort based on the Medtronic registry data. The survival data from this study and for CareLink PLUS Fidelis model 6949 leads are shown in Figure 2 and Table 7, together with Quattro survivals from this study and the Medtronic SLS. Although our survival probabilities for Fidelis leads in this study are consistently lower than CareLink PLUS, the survival probabilities for Quattro leads in the SLS and this study are nearly identical through 6 years of follow-up.

The difference in the survivals of Fidelis leads between our study and the Medtronic CareLink PLUS data may be partly methodological, but it is also possible that it is due to dissimilar patient populations, especially the proportion of

<table>
<thead>
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<th>Variable</th>
<th>Hazard Ratio (95% CI)</th>
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<tr>
<td>Age</td>
<td>0.98 (0.96–0.99)</td>
</tr>
<tr>
<td>Male gender</td>
<td>0.61 (0.40–1.00)</td>
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<tr>
<td>Cardiac disease</td>
<td>3.66 (1.62–8.31)</td>
</tr>
<tr>
<td>HCM</td>
<td>2.50 (0.91–6.88)</td>
</tr>
<tr>
<td>ARVD and channelopathies</td>
<td>2.08 (1.11–3.89)</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>1.97 (0.45–8.70)</td>
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</table>

C = 0.65 for this model.

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C = 0.65 for this model.

**Figure 2.** Sprint Fidelis and Quattro Secure lead survival probabilities for this study, Medtronic’s postmarket CareLink PLUS (+) study, and the Medtronic SLS.
Table 7. Fidelis and Quattro Lead Survival Probabilities From This Study, Medtronic’s Postmarket CareLink PLUS (+) Study,6 and the Medtronic SLS

<table>
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<tr>
<th></th>
<th>0 Years</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
<th>6 Years</th>
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<tbody>
<tr>
<td><strong>Fidelis: this study</strong></td>
<td>1023</td>
<td>922</td>
<td>771</td>
<td>498</td>
<td>148</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
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<tr>
<td>%</td>
<td>99.8</td>
<td>97.4</td>
<td>92.6</td>
<td>87.0</td>
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<tr>
<td>CI</td>
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<td>96.3–98.4</td>
<td>90.8–94.6</td>
<td>83.6–90.1</td>
<td></td>
<td></td>
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<tr>
<td><strong>Fidelis: Medtronic CareLink PLUS</strong></td>
<td>21 500</td>
<td>21 231</td>
<td>20 099</td>
<td>12 709</td>
<td>2039</td>
<td></td>
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<tr>
<td>%</td>
<td>99.8</td>
<td>98.9</td>
<td>96.5</td>
<td>93.8</td>
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<tr>
<td>CI</td>
<td>99.7–99.9</td>
<td>98.8–99.0</td>
<td>96.2–96.7</td>
<td>93.3–94.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quattro: this study</strong></td>
<td>1668</td>
<td>1385</td>
<td>1014</td>
<td>774</td>
<td>614</td>
<td>425</td>
<td>254</td>
</tr>
<tr>
<td>n</td>
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<td>%</td>
<td>99.8</td>
<td>99.4</td>
<td>98.8</td>
<td>98.7</td>
<td>98.3</td>
<td>97.4</td>
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<tr>
<td>CI</td>
<td>99.6–100</td>
<td>99.0–99.8</td>
<td>98.1–99.5</td>
<td>97.9–99.4</td>
<td>97.3–99.2</td>
<td>96.0–98.7</td>
<td></td>
</tr>
<tr>
<td><strong>Quattro: Medtronic SLS</strong></td>
<td>2634</td>
<td>1298</td>
<td>1020</td>
<td>871</td>
<td>704</td>
<td>531</td>
<td>282</td>
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<td>n</td>
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<td>%</td>
<td>99.4</td>
<td>99.2</td>
<td>98.9</td>
<td>98.5</td>
<td>98.2</td>
<td>97.9</td>
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<tr>
<td>CI</td>
<td>99.0–99.7</td>
<td>98.6–99.8</td>
<td>98.5–99.6</td>
<td>97.6–99.1</td>
<td>97.1–98.9</td>
<td>96.7–98.7</td>
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n=number exposed; survival probability±95% CI.

patients at higher risk for Fidelis fracture (Table 4). This hypothesis is supported by the observation that our survivals for Quattro leads were similar to the Medtronic SLS data and further that Quattro leads were unaffected by clinical variables. This observation implies that future premarket and postmarket studies of ICD leads should include statistically representative samples of these high-risk patients and that analyses for these higher-risk groups should be reported separately.

Limitations
The results of this study are subject to the usual limitations of a retrospective analysis. The cause of most lead failures was not verified by returned product analyses. This occurred because some leads were abandoned or extracted in fragments; in other cases, the analyses were incomplete or unavailable. The diagnosis of lead failure was made at each center, not by an independent panel. However, the criteria for lead fracture were identical at each center and defined before database review.

Conclusions
The survival of Fidelis leads continues to decline. Although Quattro leads appeared to perform well in all patient subgroups, the risk of Fidelis fracture was notably higher in younger patients, women, HCM patients, and patients who have ARVD or channelopathies. Except for inappropriate shocks, we did not observe major adverse clinical events in patients whose Fidelis leads failed. Our findings have significant implications for the management of patients who have Fidelis leads. Clinical variables should be assessed in evaluations of ICD lead performance.

Sources of Funding
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Disclosures
Dr Mugglin is a statistical consultant for Medtronic and St. Jude Medical. Dr Hayes is a speaker with honoraria for Medtronic, Boston Scientific, St. Jude Medical, Biotronik, and Sorin; he serves on advisory boards for Boston Scientific, St. Jude Medical, and Pixel Velocity; and he is on a steering committee or study advisory committee for Medtronic and St. Jude Medical. Dr Friedman is a speaker or consultant with honoraria for Medtronic, Boston Scientific, St. Jude Medical, and Bard; he receives significant research support from Medtronic and Pfizer; and he has intellectual property rights with Bard EP, Hewlett Packard, Medical Positioning Inc, Aegis Medical, and NeoChord. The other authors report no conflicts.

References
The main findings in this study are that Sprint Fidelis implantable cardioverter-defibrillator leads continue to fail and that younger patients, women, and patients with certain cardiovascular diseases are more likely to suffer Fidelis fractures than patients who are older and have ischemic or nonischemic cardiomyopathy. Except for inappropriate shocks, there were no deaths or serious injuries associated with Fidelis failure in this large multicenter study. Thus, these data suggest that most Fidelis patients can be managed with careful monitoring using algorithms that mitigate inappropriate shocks. Quattro Secure implantable cardioverter-defibrillator leads performed well (failure rate <0.5%/y) in all patient subgroups during 7 years of follow-up.
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Hauser et al
Supplemental Figure Legend

Survival of Sprint Fidelis and Quattro Secure leads at the 3 centers.
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