Original Research

Detailed Electrical Analysis of Lead Failures in a Small-Scaled Right Ventricular Defibrillator Lead: Reality of Sprint Fidelis Medical Device Recalls

Jens Kreuz[1], Osman Balta[1], Sebastian Zimmer[1], Rolf Fimmers[2], Lars Lickfett[1], Fritz Mellert[3], Georg Nickenig[1], Joerg Otto Schwab[1]

[1]*Department of Medicine-Cardiology,* [2]*Department of Medical Biometry, Informatics and Epidemiology,* [3]*Department of Cardiac Surgery, University of Bonn, Bonn, Germany*

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Introduction: This paper illustrates our experience with the Sprint Fidelis® lead (SF, single coil model 6931). We investigated lead failure incidence, analysed for possible predictive factors and examined the efficacy of integrated early ICD warning systems.

Methods: We analysed 181 consecutive patients with SF (follow up: 406 ± 250 days). Left ventricular ejection fraction, age, gender, follow up, ICD indication, type of device, duration of implantation, and target vein used for implantation were evaluated as potential predictive factors of lead failure. Additionally, the predictive value of recommended impedance alert adaptations, the potential effects of the sensing integrity counter (SIC), and of the new lead integrity alert (LIA)® were studied.

Results: Nine lead failures were identified. Lead failure occurred significantly more often in patients with single- and dual-chamber devices. None of the patients under cardiac resynchronisation therapy (CRT) had a lead failure (p=0.04). Seven failures (78%) became apparent through inappropriate shock interventions. Impedance alert adaptations did not prevent any inappropriate shock intervention, but the SIC and the activation of the LIA might have prevented inappropriate interventions. A fractured pace/sense ring conductor was identified as the most vulnerable part of the SF lead (in 7 failures, 78%).

Conclusion: We verified an increased failure rate in patients with the SF lead. Only patients with CRT devices were free from lead failure, suggesting a correlation with increased physical activity. The impedance alert reprogramming did not predict any inadequate shock interventions but LIA may become a new valuable tool for the early detection of lead failure signs.

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Address:
Jens Kreuz

Department of Medicine – Cardiology
University of Bonn
Sigmund-Freud-Str. 25
53105 Bonn
Germany
e-mail:
jens.kreuz@ukb.uni-bonn.de

Technical complications are a profound problem in the therapy of patients with an implantable cardioverter/defibrillator (ICD). Often, mechanical defects result in inappropriate ICD shocks or the need for surgical interventions, both of which present a substantial physical and psychological burden. ICD manufacturers are constantly working on the development of new and the improvement of established products. The Medtronic Sprint Fidelis® (SF: Medtronic Inc., Minneapolis, MN, USA) was advertised as an amazingly thin but stable lead. Unfortunately, the SF had to be withdrawn from the market after reports of increased mechanical failure.[1-7] Since then, Medtronic has released a lead failure report comparing SF with Sprint Quattro leads, documenting a significantly worse outcome for SF after 36 months (survival 98.7% vs. 96.7%, p<0.03).[8] We have now investigated the failure rate of 181 consecutive patients who received an SF lead, analysed for possible predictive factors, and examined the efficacy of early general warning systems.

Independently of the "SF problem", Medtonic launched the promising new lead integrity alert (LIA®) algorithm, which was designed to identify ongoing lead failures and to prevent inappropriate ICD therapies.[9-11] The LIA is designed to alert the patient acoustically if the device detects one of the following abnormalities: an abnormally high lead impedance measurement, or the combination of two non-sustained ventricular arrhythmias exceeding 220 bpm and >30 ventricular intervals with a cycle length ≤140 ms. These abnormalities indicate non-physiological oversensing and are highly suggestive of a lead fracture.

Methods

The goal of this investigation was to detect patterns, individual characteristics, and risk factors prior to an SF lead failure. The definition of lead failure was met if the following criteria were fulfilled: losing its electrical integrity followed by device alerts or, finally, initiating an ICD therapy of inadequate nature.

We analysed the incidence of lead failures in 181 consecutive patients implanted with an SF (solely model 6931) from June 2005 to October 2007. All patients were followed on a quarterly basis at our university hospital. After two lead failures had occurred, all patient's ICDs were reprogrammed for early detection of an SF lead problem, according to the manufacturer's recommendations.[12] We evaluated left ventricular ejection fraction, age, gender, follow up, ICD indication, type of device (single vs. dual vs. triple chamber), duration of implantation procedure, and vein used for implantation, as potential predictive factors of SF lead failure. In addition, we investigated whether the above-mentioned reprogramming of alarm thresholds resulted in an earlier detection of a lead failure. This study also examined the potential effects of the sensing integrity counter (SIC), and prospectively the LIA algorithm (Table 3).

The SIC is the predecessor of the above-mentioned LIA algorithm.[13,14] It was invented, in addition to the conventional automated daily lead-impedance monitoring, to detect clinically silent lead dysfunctions associated with persistent or intermittent oversensing in any ICD lead. This algorithm records non-physiological fast ventricular intervals (≤140 ms). The accumulation of such fast intervals (>300) is highly suggestive of an imminent lead failure creating ventricular oversensing and noise. A high SIC counter is indicated during the interrogation of the device but, in contrast to the new LIA algorithm, the SIC is not linked with an acoustic patient alert and the reaction to an abnormal result depends on the interrogator of the device.

Statistical analysis

We used a two sample t-test and Fisher's exact test (two-tailed) to analyse SF lead failure incidence. A Wilcoxon signed rank test was implemented to generate a Kaplan-Meier curve comparing the type of implanted ICD device and lead failure. Here, the incidence of a lead failure was defined as a crucial event with respect to the device type. A p-value ≤0.05 was considered statistically significant. Statistical analysis was performed using the SPSS 12.0 statistical package (SPSS Inc., Chicago, IL, USA).

Results

Lead failures were detected in nine patients (5%) after an average of 17 months (range 2-50 months). Demographics are shown in Table 1. Table 2 provides a short summary of each case. Seven patients (78%) were identified as suffering from inappropriate shock interventions, one lead failure was revealed by an acoustic alarm, and one patient had recurrent syncope due to pacing defects (Figures 1, 2). Unfortunately, no early detection of a lead failure was realised after the general implementation of the alert adaptations. The only lead failure revealed by an acoustic alarm was prior to the general adaptations. It is worth mentioning however, that only four patients with SF lead failure were implanted with a Medtronic device capable of emitting an acoustic impedance alarm. In two patients a pathological SIC was documented at least two days prior to the first inadequate shock intervention. Table 3 shows a comparison of the impedance alert statistics and the SIC in patients with SF lead failure. In one additional patient the SF was explanted because of a lead dislocation. This patient presented with deteriorated right ventricular sensing (1 mV at first follow up vs. 4.1 mV after implantation) and a distinct increase in the right ventricular pacing threshold from implantation to first follow up (3.5 V/0.5 ms at follow up vs. 1.0 V/0.5 ms at implantation).

Of all the possible predictive parameters investigated, only device type showed a significant correlation with SF lead failure (Table 1). None of the 49 patients with a cardiac resynchronisation device had an SF lead failure, whereas 3 of 72 (4%) patients with single-chamber devices and 6 of 60 (10%) patients

Table 1. Demographics of patients with and without lead failure (LF).

	Patients with LF (n=9)	Patients without LF (n= 172)	p
Age	62.9 ± 11.6	65 ± 12.9	0.41
Men (%)	6 (66)	138 (80)	0.97
Indication	6 PP vs. 3 SP	84 PP vs. 88 SP	0.20
Follow up (days)	555 ± 456	434 ± 252	0.16
EF (%)	36.1 ± 14	33.9 ± 15.4	0.40
Prior LF (%)	0	26 (15.1%)	0.28
Device	3 SC + 6 DC	69 SC + 54 DC + 49 TC	0.04
Venous access	8 cep/ 1 sub	139 cep/ 33 sub	0.82
Implantation time (min)	81 ± 76	82 ± 54	0.67

cep – cephalic vein; DC – dual chamber; LF – lead failure; PP – primary prevention indication; SC – single chamber; SP – secondary prevention indication, sub – subclavian vein; TC – triple chamber.

Table 2. Key data for each patient with lead failure.

Patient	Index event	Follow up (days)*	Device	Resolution	Impedance alert (prevention of IS)
1	IS (6)	347	Med	SF ex	No
2	High RV-Imp	884	Med	SF ex	Yes (yes)
3	IS (2)	647	Bio	SF ex	No
4	IS (5)	317	Bio	SF ex	No
5	Pacing inability in a PM-dependent patient	67	Med	SF ex	No
6	IS (3) high RV-Imp	298	Med	SF ex	No
7	IS (3)	1479	Bio additional RV lead	No SF ex	No
8	IS (8)	1035	Sorin	SF ex	No
9	IS (24)	431	SJM	SF ex	No

*Time between lead implantation and the occurrence of lead failure.
Bio – Biotronik; Imp – Impedance; IS – inappropriate shock (number of cumulative inappropriate shocks before SF explantation); Med – Medtronic; No SF ex – SF explantation not possible, implantation of an additional RV shock lead; RV – right ventricular; SF – Sprint Fidelis; SF ex – explantation of SF and implantation of a new RV shock lead; SJM – St. Jude Medical.

with dual-chamber devices developed a lead failure (p=0.04, Figure 3).

Analysis of explanted leads

Of the 9 identified SF lead failures, we received 8 definite damage reports. One lead had to be explanted because of substantial venous adhesions. Because of the short follow-up period after implantation, all leads could be extracted very easily after the device pocket had been prepared carefully and the lead disconnected from the header. For the final extraction procedure, the surgeon pulled the proximal lead connector with caution. All SF leads were explanted in total and sent for intensive examinations to the Medtronic lead analysis experts. Based on their final damage report, we documented the individual failure mechanism for each explanted lead.

All explanted SF underwent a detailed visual and electrical inspection by the manufacturer. Patients 1 to 4 and 6 to 9 had a fractured pace/sense ring conductor (Figure 4), while the SF explanted from patient 5 revealed a fracture of the lead's tip conductor (Figure 4). Electrical testing of the SF explanted from the additional patient with a dislocated lead showed normal visual and electrical parameters.

Discussion

Inappropriate ICD interventions represent a common problem that significantly affects patients' quality of life and even their prognosis.[15,16] It is therefore critical to develop effective early warning systems for imminent technical complications[17] and to identify mechanical components susceptible to failure. Here we describe a single-centre experience of patients im-

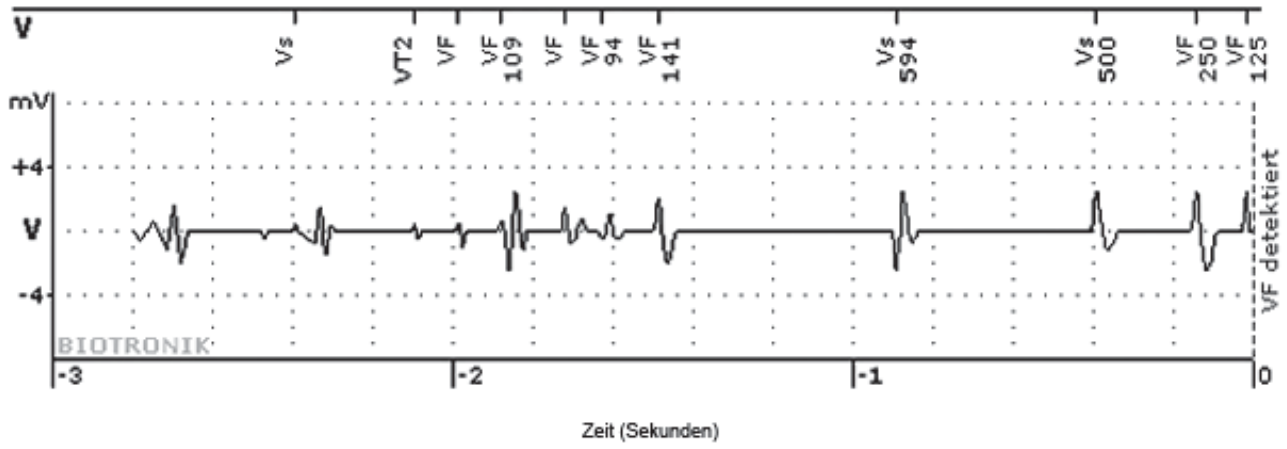

Figure 1. Signs of lead failure in remote follow-up technology. y-axis – amplitude in mV; x-axis – time before detection of arrhythmia in s. V – marker channel; Vs – ventricular sensing; VT2 – arrhythmia in the VT2 zone; VF – ventricular fibrillation; numbers (e.g. 109) time in ms.

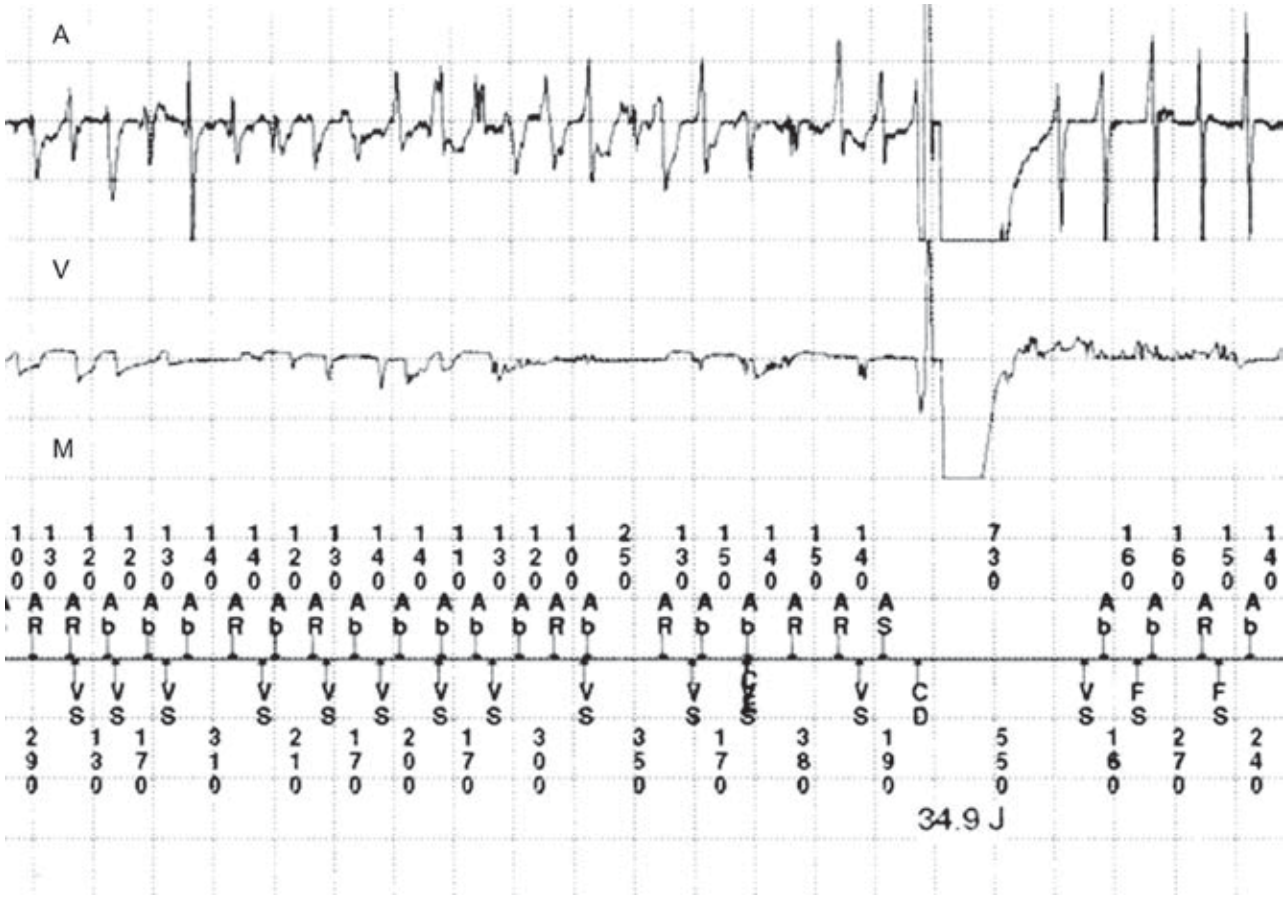

Figure 2. Inadequate shock intervention due to ongoing ventricular oversensing. IEGM – intracardiac electrogram; A – atrial IEGM (showing atrial fibrillation); V – ventricular IEGM (showing an ongoing oversensing); M – atrial and ventricular marker channel; AR – atrial refractory; Ab – atrial blank; AS – atrial sense; VS – ventricular sense; FS – fibrillation sense; CE – charge end; CD – ICD charge delivered (34.9 J); numbers (e.g. 130) time in ms.

Table 3. Impedance alert and positive sensing integrity counter in patients with Sprint Fidelis lead failure and Medtronic ICD.

Impedance alert (days prior to IS)	Sensing integrity counter
No	Yes
Yes (this patient received no IS)	No
No	No
No	Yes

IS – inappropriate shock.

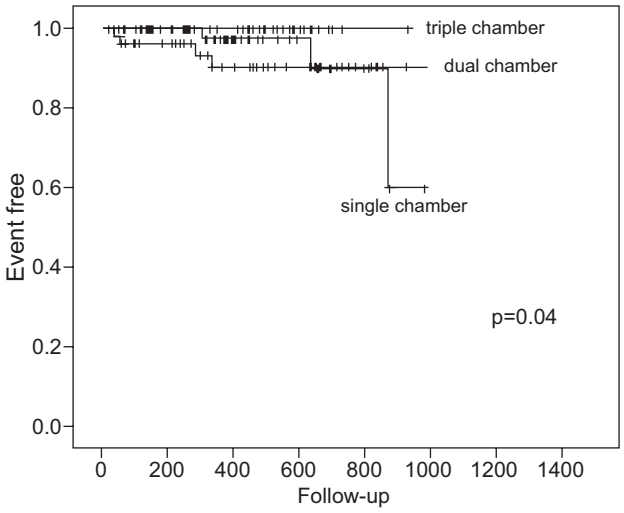

Figure 3. Kaplan Meier curve: events during follow up with respect to device type.

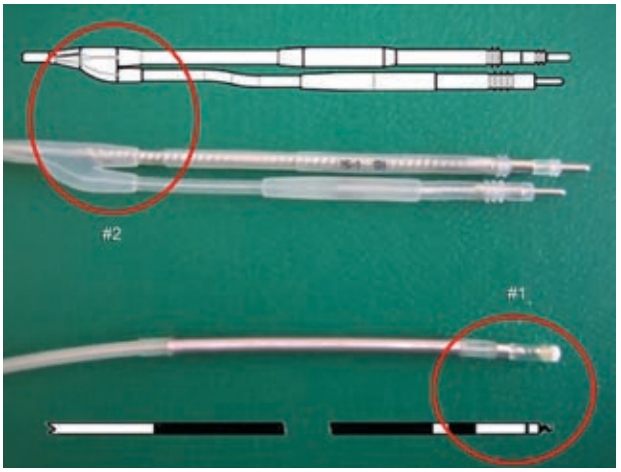

Figure 4. Schematic image and photography of an SF 6931 single coil electrode – vulnerable spots. #1 marks the tip conductor; #2 marks the pace sense ring conductor.

planted with SF leads, showing that a general adaptation of alert parameters is not effective in predicting or protecting from inadequate ICD interventions. We demonstrate, however, that the type of ICD device used significantly correlates with SF lead failure.

The incidence of lead failure in our patient population is higher than that published by Hauser et al.[3] They reported a failure rate of 1-2% during the first two years after implantation, while in the same time frame, 5% of patients included in our study suffered from lead failure. Hauser et al[18] reported an even higher SF lead failure incidence of 8.5% in a cohort of 848 SF leads. Fifty percent of those patients suffered from inappropriate shock interventions and the incidence of SF lead failure was significantly higher compared with any other ICD lead (estimated 3-year survival of SF 87.9% vs. 98.5% in the other ICD leads).

Ellenbogen and co-workers also found a lower failure rate of 2.8% during the first year of follow up.[4] The observed higher incidence of SF lead failure in our patients remains unclear, but could be due to different operating techniques, or to the type of ICD device and/or ICD device/lead combination used. In their study population the majority of patients with lead failure (80%) were identified because of low R-wave sensing, combined with an increased pacing threshold. Such a pattern in SF lead failure cannot be applied to the patients in our study.

Summarising the results of previous publications dealing with the incidence of SF lead failure, one can state that SF showed significantly inferior longevity compared with other high voltage ventricular ICD leads, while a high percentage of lead failures manifested with inappropriate shock interventions, although the observed manifestations of these findings may vary in each cohort.

Three different strategies are used to identify imminent technical complications: first, the ICD can complete self-checks and subsequently alert the patients with an acoustic signal in the event of a test error; second, the ICD can send system parameters and test results via a telecommunication system to the physician to be analysed; and third, the responsible physician can manually perform ICD checks. Unfortunately, two recent independent publications show that reprogramming the impedance alarms, as recommended by the Heart Rhythm Society, European Society of Cardiology, and German Cardiac Society, is not suitable for reducing inappropriate shock interventions in patients with a failing SF.[6,7] Our study is in accordance with these findings, although the data of the current study have to be carefully interpreted because only a few patients with SF lead failure received a Medtronic device equipped with the LIA algorithm.

From the authors' point of view, the usefulness of the SIC, but also its limitations – given the absence of the possibility to alert the patient acoustically in case of an imminent lead failure – is documented in the results of this study (Table 3). Therefore, the LIA algorithm, capable of generating an acoustic alert, might have prevented inappropriate shock interventions in a failing SF. Although this assumption is to some extent speculative, the beneficial value of the LIA is indicated by a pathological SIC in 50% of failing SF lead equipped with Medtronic devices in this cohort. These patients would have been alerted by the LIA algorithm and inappropriate therapies might have been prevented.

Prospectively, SF patients should, wherever possible, be followed up using advanced remote monitoring technologies, which might be able to identify unusual impedance measurements early on. The LIA algorithm, if available, should be activated. Considering the results of Farwell et al, and the data of this manuscript, this technology might be able to prevent inadequate shock interventions in patients with any kind of lead failure. Unfortunately, the efficacy of the LIA in preventing inappropriate shock interventions in SF patients cannot not be proven in our cohort, because all described lead failures occurred before the LIA algorithm was available. On the other hand, the evaluation of the SIC algorithm (Table 3) indicates that activation of the LIA could have prevented inappropriate ICD shocks in at least two SF lead failures.

Importantly, lead failure was significantly more frequent in patients with single- or dual-chamber devices than in patients with CRT. In our population, no CRT patient suffered from a lead failure. This finding may be explained by either the reduced daily activity of patients with end-stage congestive heart failure, the different intra-operative lead handling, or perhaps a different mechanical stress at critical lead junctions. Supporting this, Farwell et al[6] identified a higher left ventricular ejection fraction, associated with increased daily activity, as an independent risk factor for the incidence of SF lead failure. Further studies are required to fully understand the mechanisms of lead failure and to identify predictive parameters, but the ICD type involved is an extremely important component as it affects all of the above-mentioned aspects. Interestingly, no previous publications reveal any comparable data concerning the association of a failing SF and type of ICD device.

The reason for the enhanced failure rate of SF leads is still unknown and a matter of discussion. Lead implantation in our centre was performed by one of four experienced cardiac surgeons through an operative exposure of the subclavian or cephalic vein. No venous punctures were performed. Farwell reported that non-cephalic access is an independent predictor of SF lead failure, but we cannot confirm this finding in our cohort.[6] One could assume that the small lead diameter increases vulnerability to mechanical stress, which regularly occurs during implantation, and even more commonly during everyday life. In our study the pace/sense ring conductor was the main site of lead dysfunction, but further investigations are required to reveal whether design or constructional flaws are responsible for lead failure.

Conclusions

Based on the literature and our single-centre experience, routine lead explantation in patients with SF is not indicated or recommended. Furthermore, impedance alert reprogramming does not avoid inappropriate shock interventions and is therefore an inadequate tool for early detection of SF lead failure. The new LIA, on the other hand, may represent a valuable tool in the prevention of inappropriate shock interventions and the early diagnosis of any kind of lead failure. The pace/sense ring conductor appears to be the most vulnerable part of the SF lead and increased physical activity seems to be a substantial risk factor for the incidence of an SF lead failure. The documented lower incidence of SF lead failures in CRT patients needs validation in greater patient populations.

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