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CLINICAL RESEARCH
Leads and lead extraction

Failure of a novel silicone–polyurethane copolymer (Optim™) to prevent implantable cardioverter-defibrillator lead insulation abrasions

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Aim The purpose of this study was to determine if Optim™, a unique copolymer of silicone and polyurethane, protects Riata ST Optim and Durata implantable cardioverter-defibrillator (ICD) leads (SJM, St Jude Medical Inc., Sylmar, CA, USA) from abrasions that cause lead failure.

Methods and results We searched the US Food and Drug Administration's (FDA's) Manufacturers and User Device Experience (MAUDE) database on 13 April 2012 using the simple search terms 'Riata ST Optim™ abrasion analysis' and 'Durata abrasion analysis'. Lead implant time was estimated by subtracting 3 months from the reported lead age. The MAUDE search returned 15 reports for Riata ST Optim™ and 37 reports for Durata leads, which were submitted by SJM based on its analyses of returned leads for clinical events that occurred between December 2007 and January 2012. Riata ST Optim™ leads had been implanted 29.1 $\pm$ 11.7 months. Eight of 15 leads had can abrasions and three abrasions were caused by friction with another device, most likely another lead. Four of these abrasions resulted in high-voltage failures and one death. One failure was caused by an internal insulation defect. Durata leads had been implanted 22.2 $\pm$ 10.6 months. Twelve Durata leads had can abrasions, and six leads had abrasions caused by friction with another device. Of these 18 can and other device abrasions, 13 (72%) had electrical abnormalities. Low impedances identified three internal insulation abrasions.

Conclusions Riata ST Optim™ and Durata ICD leads have failed due to insulation abrasions. Optim™ did not prevent these abrasions, which developed $\leq$4 years after implant. Studies are needed to determine the incidence of these failures and their clinical implications.

Keywords Implantable cardioverter-defibrillator • Lead • Insulation • Complications • Failure

Insulation abrasion has been a common problem affecting silicone implantable cardioverter-defibrillator (ICD) leads.[1–4] Abrasions may occur when a lead is in contact with the pulse generator in the pocket (can abrasion), other leads (lead-to-lead abrasion), and other devices (annuloplasty ring) or anatomic structures (clavicle, rib). Since abrasions may result in lead failure, the manufacturers have developed a number of abrasion-resistant coatings that protect the silicone insulation. One such material is a proprietary silicone–polyurethane copolymer trademarked as Optim™, which St Jude Medical (Sylmar, CA, USA) licensed in 2006 and applied as an overlay to its Riata ST Optim™ and Durata ICD leads. According to St Jude Medical (SJM), Optim is 50 times more abrasion-resistant than silicone[5] and, after >5 years experience with >278 000 Optim™-covered leads, 99.9% of leads are free from abrasion of any type.[6]

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What's New?

- Optim™, a novel copolymer of silicone and polyurethane, does not prevent insulation abrasions in Riata ST Optim™ and Durata ICD leads (St Jude Medical, Inc., Sylmar, CA, USA).
- These insulation abrasions often occur due to friction with the ICD can or other leads and they may result in lead failure and serious adverse clinical events.
- This is a new and unexpected finding. Additional studies are needed to determine the incidence of these failures and their clinical implications.

Recently, we reported deaths that were due to the failure of SJM Riata and Riata ST leads:[7] seven of these deaths were caused by can abrasions that resulted in high-voltage shorts during shock delivery. We found no deaths caused by a can abrasion in patients who had Quattro Secure ICD leads (Medtronic, Inc., Minneapolis, MN, USA), which are covered with abrasion-resistant polyurethane. Therefore, we queried the US Food and Drug Administration's (FDA's) Manufacturers and User Facility Device Experience (MAUDE) database to identify insulation abrasions that SJM has reported for its Riata ST Optim™ and Durata leads. The purpose was to determine if Optim™ protects these devices from abrasions that could cause lead failure, including can and lead-to-lead abrasions that may result in short circuiting during high-voltage shock delivery.

Methods

Riata ST Optim™ and Durata Leads

The 7 French Riata ST Optim™ and Durata single and dual coil ICD leads were approved by the FDA in 2006 and 2007 respectively. The Durata DF4 with a new in-line connector pin was approved in 2009. Approximately 21 000 Riata ST Optim™ and 114 000 Durata leads had been sold in the USA by July 2011.[8] The multilumen construction includes redundant high voltage and pace-sense cables, which are extruded with ethylene-tetrafluoroethylene (ETFE); the pace-sense conductor coil is strung through a tube of polytetrafluoroethylene. The flat wire shock coils are completely back filled with silicone. The thin (0.09 mm) Optim™ overlay covers the exposed outer silicone body but not beneath the shocking coils. The silicone body of Riata ST Optim™ leads are covered by Optim™ to a point near the distal right ventricular (RV) shocking coil. Optim™ covers all Durata silicone surfaces.

Definitions

A *high-voltage conductor short circuit* occurs if the silicone and ETFE insulation break down and there is contact between the conductive metal surfaces of the high-voltage cables, a high-voltage and low-voltage conductor, or a high-voltage cable and a shocking coil or pulse generator can; these may be manifested by melted conductors or an arc mark that is visible on the pulse generator can. *Outside-in abrasions* include defects caused by friction or contact with another device or anatomic structure and include: (i) *can abrasion* caused by contact in the pocket between the lead and the pulse generator can; (ii) *lead-to-lead abrasion* due to contact with another lead or leads, often in the right atrium; (iii) anatomic abrasions due to contact with the clavicle, rib, or tricuspid annulus. *Inside-out abrasion* is an insulation defect caused by motion of the cables within the lead insulation lumen.

FDA MAUDE database

The MAUDE database contains reports of adverse events involving medical devices that are reported to the US manufacturers by users worldwide. The FDA requires the manufacturers to report adverse events that are communicated to them verbally or in writing, and they must report the results of investigations into the causes of device malfunctions. MAUDE reports are available online at www.fda.gov/cdrh/maude.html. The MAUDE report for each table entry in this study can be accessed by entering the MDR Report Key into the simple search field at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm and selecting 'all years' for 'date report received by FDA'. Since MAUDE does not include data for all leads of a particular model at any point in time, it is not possible to determine the incidence of a particular defect or failure mode.

We searched the MAUDE database on 13 April 2012 using the simple search terms 'Riata ST Optim™ abrasion analysis' and 'Durata abrasion analysis'. Lead implant time was estimated by subtracting three months from the lead 'age', which is the date the lead was manufactured or shipped.

Results

The MAUDE search returned 15 reports for 'Riata ST Optim abrasion analysis' and 37 reports for 'Durata abrasion analysis'. All MAUDE reports were submitted by SJM based on its analyses of returned leads for events that occurred between December 2007 and January 2012.

Riata ST Optim Leads

Table 1 summarizes SJM's findings for Riata ST Optim™ leads; these leads had been implanted an average of 29.1 ± 11.7 months (range: 9–49 months). Eight of the 15 leads (53%) had can abrasions and three abrasions (20%) were caused by friction with another device, most likely another lead. Four high-voltage failures were associated with two can abrasions and two abrasions that were due to friction with another device. One high-voltage failure (case # 6) resulted in a death when the shock was truncated. One failure (case #7) was caused by an internal insulation defect that was manifested by oversensing and the loss of the RV coil electrogram.

Durata leads

Table 2 summarizes the findings for Durata leads; these leads had been implanted an average of 22.2 ± 10.6 months (range: 3–48 months). Twelve of the 37 leads (32%) had can abrasions, and 6 leads (16%) had abrasions caused by friction with another device, including a tricuspid valve annuloplasty ring. Of these 18 can and other device abrasions, 13 (72%) had electrical abnormalities signified by abnormal impedance, noise, threshold changes, or damaged conductors. Another three malfunctioning leads had abrasions that may have been due to friction with the can but such contact was not specified in the reports.

Three internal insulation abrasions were identified. Case #1 presented with low impedance 48 months after implant; the cause was an internal abrasion that uncovered the RV conductor that

Table 1 Riata ST Optim leads

Case no.	Model	MDR event key	Lead age	Sign	Analysis
1	7020/65	2486749	44	Low impedance	Can abrasion
2	7022/65	2409042	48	Low R-wave	Outer insulation abrasion RV cable fracture
3	7020/65	2332700	49	High capture threshold	Can abrasion
4	7020/65	2332774	34	Noise Aborted therapy	Can abrasion
5	7022/65	2242754	33	Inappropriate shocks Arc on can	Can abrasion RV cable melted; HV failure
6	7020/60	1788235	37	Therapy truncated Patient died	Abrasion 52 cm from connector due to friction with another device; HV failure
7	7020/65	1627573	32	Oversensing; loss of RV coil EGM	Internal insulation abrasion 6. 7 cm from the distal tip. ETFE damaged
8	7020/60	1573108	30	Not specified	Can abrasion. Electrically intact
9	7020/60	1573109	28	Inappropriate shocks	Abrasion 50 cm from connector due to friction with another device. P/S cables exposed
10	7021/65	1524192	17	Inappropriate shocks	Can abrasion P/S cable melted; HV failure
11	7022/65	1411014	21	Low impedance	Can abrasion P/S cable exposed
12	7070/65	1411029	16	High impedance	Pacing coil fracture; clavicular crush Incidental connector insulation abrasion
13	7020/60	1337721	20	HV short during VF	Outer insulation abrasion; HV failure HV RV cables and SVC coil were melted
14	7021/65	1337731	19	Noise	Can abrasion P/S cable exposed
15	7022/60	1010619	9	Inappropriate shocks	Abrasion 52 cm from connector due to friction with another device

RV, right ventricle; SVC, superior vena cava; HV, high-voltage; P/S, pace/sense; EGM, electrogram; VF, ventricular fibrillation.

evidently shorted to the superior vena cava (SVC) shocking coil. Another internal abrasion (case #16) caused a low-voltage short circuit between the pace/sense conductor and inner coil; this abrasion was originally described as an inside-out abrasion but a subsequent MAUDE report clarification by SJM stated it was an internal abrasion. Case #20 also presented with low impedance; the returned lead analysis revealed an abrasion under the SVC coil that resulted in contact between the RV shock cables and SVC coil; originally this insulation defect was described as an abrasion from the inside out, but later SJM restated it as an abrasion at the proximal end of the svc coil.

Five reports did not specify the location or nature of the abrasions; however, two leads were associated with oversensing and inappropriate shocks, and one lead was removed after the patient received inappropriate shocks and the pulse generator reverted to a back-up mode. Clavicular crush caused four malfunctions and incidental abrasions, and four other abrasions were surface abrasions or abrasions associated with conductor fractures.

Signs of failure

The signs of Riata ST Optim™ and Durata failure are summarized in *Table 3*. The predominant signs of failure for can abrasions were oversensing, inappropriate shocks, and low impedance. Internal abrasions were characterized by low impedance. Abrasions due to clavicular crush were often associated with conductor fracture. When signs of failure were not provided, the abrasions were usually due to friction with the can or another device and presumably would have been signified by low impedance and/or noise.

Discussion

The results of this study suggest that Optim™, a proprietary copolymer of silicone and polyurethane, does not prevent critical insulation failures in Riata ST Optim™ and Durata leads that are caused by friction with the can or another device. Of equal concern is the fact that these failures occurred in leads that had only been implanted ≈4 years or less. This is a new and unexpected finding, since SJM has recently expressed confidence in the ability of Optim™ to prevent the insulation abrasions that have been observed in Riata, Riata ST, and other silicone leads.[9,10]

Most of the insulation defects were outside-in abrasions, namely those caused by contact with another device or anatomic structure; in these cases, Optim™ did not provide the abrasion resistance for which it is intended. The most common abrasions were those caused by friction with the pulse generator can and with another device, most likely another lead or leads. However, one

Table 2 Durata leads

Case no.	Model	MDR event key	Lead age	Sign	Analysis
1	7120/65	2487350	48	Low impedance	Internal abrasion 23 cm from distal tip. RV conductor abraded: 'This could cause the reported low impedance when in contact with the SVC shock coil'.
2	7120/65	2332798	38	Low impedance	Insulation abrasion near connector pin
3	7120/65	2409021	36	Insulation break near yolk	Analysis found insulation abrasion in unspecified location
4	7120/65	2463178	35	Intermittent loss of capture	Abrasion adjacent to proximal end of RV coil; friction with annuloplasty ring
5	7120/65	2409091	35	Low impedance	Can abrasion RV cables exposed
6	7122/65	2409053	33	Oversensing	Analysis found insulation abrasion in unspecified location
7	7170/65	2332939	33	Oversensing Inappropriate shocks	Analysis found insulation abrasion in unspecified location
8	7120/65	2084498	33	Low impedance	Can abrasion RV cables exposed; ETFE compromised
9	7121/65	2084194	31	Oversensing Inappropriate shocks	Can abrasion SVC cable abraded
10	7170/65	2084197	30	Oversensing Inappropriate shocks	Can abrasion Sensing cable exposed
11	7120/65	2333118	29	Inappropriate shocks PG in back-up mode	Analysis found insulation abrasion in unspecified location
12	7120/65	1954890	27	Inappropriate shocks	Analysis found insulation abrasion in unspecified location
13	7120/65	2015091	26	Oversensing	Can abrasion or friction with another lead Sensing coil flattened
14	7121/65	2487053	25	Unspecified	Abrasion 27 cm from connector Caused by friction with another device
15	7120/60	2014710	25	Unspecified	Abrasion 53 cm from connector exposing HV RV cables due to friction with another device
16	7170/65	2157205	24	Low impedance	Internal abrasion between 7 and 8 cm from the lead tip causing short circuit between the sensing and pacing conductor
17	7120/65	1955135	24	Abnormal sensing	Can abrasion affecting sensing cable insulation
18	7120/60	1679666	24	Inappropriate shocks	Abrasion at proximal end of RV shock coil due to friction with another device
19	7122/65	2487319	22	Unspecified	Can abrasion Coil melted
20	7120/65	1679680	22	Low impedance	Abrasion under the proximal end of the SVC coil. Intermittent contact between the RV shock cables and SVC coil
21	7122/65	1376803	22	Noise	Abrasion was observed on the lead at 14. 8–15. 2 cm from the connector pin
22	7122Q/65	2332898	20	Break	Abrasion probably due to clavicular crush
23	7122/65	2015063	20	Unspecified	Abrasion at 57. 7–58 cm at the proximal end of the RV shock coil due to friction with another device
24	7120/65	1895671	20	Inappropriate shocks	Failure due to sensing coil fracture. Incidental connector abrasion
25	7122Q/58	2242920	19	Unspecified	Can abrasion. RV cables exposed. Electrically normal
26	7122/65	1896015	19	Low impedance	Can abrasion. RV cable exposed.
27	7121/65	1679744	17	High impedance	Can abrasion Failure due to fracture.
28	7120/65	2332800	16	Unspecified	Abrasion in unspecified location
29	7121/65	1752115	15	Low impedance	Partial lead surface abrasion
30	7122/65	2409093	10	Low impedance	Abrasion was found between 38. 8 and 40. 9 cm from connector pin
31	7121/65	1830483	10	High impedance Oversensing	Failure due to fracture. Incidental connector abrasion
32	7121Q/58	2084058	9	Noise	Abrasion at 44. 1–45 cm from connector pin due to friction with another device

Continued

Table 2 *Continued*

Case no.	Model	MDR event key	Lead age	Sign	Analysis
				Low R-wave	
33	7121Q/58	2015064	6	Break	Abrasion at 22 cm from the connector pin. The ETFE insulation of the svc cable and proximal cable were abraded due to clavicular crush
34	7122/60	1411082	6	Noise	Can abrasion. Cables exposed.
35	7122Q/65	2084562	5	Inappropriate shocks	Abrasion caused by clavicular crush
				Low impedance	
36	7120Q/65	2242898	4	Unspecified	Surface abrasion 22 cm from connector
37	7120/60	1627605	3	Unspecified	Can abrasion exposing the RV and SVC cables

RV, right ventricle; SVC, superior vena cava; ETFE, ethylene-tetrafluoroethylene.

Table 3 **Signs of Riata ST Optim and Durata failure. A lead may have had more than one sign of failure**

Sign	PG can abrasion	Other device abrasion	Internal abrasion	Unspecified abrasion	Other abrasion
Death, truncated shock		1			
High-voltage short during VF					DF-1 cable and SVC coil melted
Low impedance	5		3	3	Clavicle-2
Inappropriate shocks	4	3		3	Clavicle-1
Oversensing, noise	6	1	2	4	Fracture-1
Low R-wave	1	1		1	
'Break'				1	Clavicle-1
High impedance					Clavicle-1
Loss of capture, rising threshold	1				Annuloplasty ring-1
Unspecified	4	3		3	

Riata ST Optim™ lead failure and three Durata lead failures were internal abrasions, which appear to be similar to the inside-out abrasions that have been reported for Riata and Riata ST leads. Indeed SJM originally described case #16 as an inside-out abrasion but subsequently edited its MAUDE report. These internal abrasions were manifested by low impedance, which is the harbinger of short circuiting. Internal abrasions should not be related to Optim™ performance; rather, we speculate that these abrasions, like Riata and Riata ST, are the result of cable movement within the lumens of the lead. The failure mode of Durata case #1 (*Table 2*), specifically contact between a bare RV high-voltage cable and proximal shocking coil, is typical of the short circuiting that has occurred with leads that are prone to inside-out abrasion.[11]

The characteristics and incidence of lead insulation failure varies according to application, technique, and materials. The challenge for manufacturers has been to identify a material that combines the biostability and flexibility of silicone and the strength and abrasion resistance of polyurethane. Optim™ is a novel copolymer that was developed by AorTech International, Inc. (Rogers, MN, USA) and licensed to SJM for use in pacemaker and ICD leads. Optim™'s long-term biostability was suggested by a 2-year ovine *in vivo* study by Simmons *et al.*[12] who implanted Elaston-Eon™ 2 80A samples and compared them with similar samples of Pellathane 55D, Pellathane 80A, and Bionate 55D. Their results encouraged the development of Optim™ (also known as SJM SPC™) for cardiovascular applications. In 2005, Jenney *et al.*[5] reported that Optim had an abrasion resistance >2 500 000 cycles to failure on a custom bench test compared with >125 000 cycles to failure for high-performance silicone; similarly, Optim™'s tear and tensile strengths were found to be much greater than high-performance silicone. The following year, Tan and Jenney[13] reported that Optim™ lead insulation material was significantly more biostable in animal tests than the polyurethanes Pellethane 55D and Pellathane 80A; the investigators predicted that the use of Optim™ lead insulation material would result in more reliable insulation. The FDA approved Optim in 2006 as a pre-market approval supplement for use in Riata ST Optim™; Optim™-covered Durata leads were approved in 2007.

In 2009 Epstein *et al.*[14] reported no insulation adverse events for 1092 patients (median follow-up 7 months) who received an Optim™ covered lead. Subsequently, Wilkoff *et al.*[15] reported the results of a 3-year prospective SJM multicenter study of

96 000 Durata leads; the Kaplan–Meier probability of abrasion failure (defined as a full thickness outer insulation abrasion) for Optim™ covered Durata leads was lower than that for silicone defibrillation leads (0.045 vs. 0.27%; $P < 0.0001$). The authors concluded that Optim™ insulation was associated with a markedly lower incidence of defibrillation lead abrasion than silicone ICD leads. Nonetheless, despite these favourable studies, the SJM November 2011 product performance report[8] stated that customer reported data, confirmed by returned product analysis, had found a total of 21 insulation breaches in 10 Durata and 11 Riata ST Optim™ leads; these included six can abrasions (Durata-3, Riata ST Optim™-3) and seven lead-to-lead abrasions (Durata-4, Riata ST Optim™-3). These totals may be less than those reported in our study because the SJM November 2011 product performance report contained data that were complete through June 2011.

Our study has certain clinical implications. Lead-to-can abrasions may be mitigated by dressing the lead in the pocket to minimize contact with the pulse generator. Lead-to-lead abrasions pose a difficult challenge; studies are needed to determine if it is feasible to adjust leads at the time of implant using multiple fluoroscopic views in order to reduce intracardiac lead-to-lead contact. We suggest that regular follow-up be combined with remote monitoring and importantly that the available patient alerts be activated. At the time of pulse generator change, these leads should be evaluated visually and with high-resolution fluoroscopy; the potential for short circuiting should be assessed by impedance measurements and a high-voltage shock. It is important to emphasize that systematic, manufacturer-independent data collection of ICD lead performance is warranted to ensure patient safety.

The results of this study do not support the prophylactic replacement of Riata ST Optim™ or Durata leads. Likewise our data must be considered preliminary, or hypothesis generating, and additional studies of Riata ST Optim™ and Durata leads are needed to determine the incidence of outside-in and internal insulation abrasions. Physicians and hospitals should return explanted leads to SJM for analysis accompanied by detailed clinical information and diagnostic data, including stored electrograms.

This study has limitations. Post-market surveillance in the USA relies on a passive reporting system, and thus adverse events are under-reported, particularly by physicians and hospitals. Therefore, the number of lead failures in this study likely underestimates the actual number that has occurred. Since MAUDE does not contain denominator data, we do not know the incidence of these insulation failures. Clinical information for some of the failures was incomplete or missing.

Conclusions

Riata ST Optim™ and Durata ICD leads have failed due to outside-in insulation abrasions caused by friction with the pulse generator can and other devices, most likely leads. Optim™ did not prevent these abrasions, which developed ≤4 years after implant. In addition, the manufacturer has reported a few internal insulation abrasions that may be similar to the inside-out abrasions found in Riata leads. Studies are needed to determine the incidence of these failures and their clinical implications.

Conflict of interest: none declared.

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