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 ± 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 ± 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 ≤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 silicone5 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 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...
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.

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 presum-ably 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 unexpect-ed 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 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 | Can abrasion |
| 5 | 7022/65 | 2242754 | 33 | Inappropriate shocks | Can abrasion |
| 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 |
| 11 | 7022/65 | 1411014 | 21 | Low impedance | Can abrasion |
| 12 | 7070/65 | 1411029 | 16 | High impedance | Pacing coil fracture; clavicular crush |
| 13 | 7020/60 | 1337721 | 20 | HV short during VF | Incidental connector insulation abrasion |
| 14 | 7021/65 | 1337731 | 19 | Noise | Can abrasion;
| 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.
## 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 | 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 | Can abrasion |
| 10       | 7170/65 | 2084197       | 30       | Oversensing | Can abrasion |
| 11       | 7120/65 | 2333118       | 29       | Inappropriate shocks | SVC cable abraded |
| 12       | 7120/65 | 1954890       | 27       | Inappropriate shocks | Analysis found insulation abrasion in unspecified location |
| 13       | 7120/65 | 2015091       | 26       | Oversensing | Analysis found insulation abrasion in unspecified location |
| 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 |
| 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 |
| 28       | 7120/65 | 2332800       | 16       | Unspecified | Failure due to fracture. |
| 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 | Failure due to fracture. |
| 32       | 7121Q/58 | 2084058      | 9        | Noise | Abrasion at 44.1–45 cm from connector pin due to friction with another device |
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 SPCTM) 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 Jenney13 reported that Optim™ lead insulation material was significantly more biostable in animal tests than the polyurethanes Pellathane 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

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**Table 2 Continued**

| Case no. | Model     | MDR event key | Lead age | Sign          | Analysis                                                                 |
|---------|-----------|---------------|----------|---------------|---------------------------------------------------------------------------|
| 33      | 7121Q/58  | 2015064       | 6        | Low R-wave    | 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        | Break         | Can abrasion. Cables exposed.                                              |
| 35      | 7122Q/65  | 2084562       | 5        | Inappropriate shocks | Abrasion caused by clavicular crush                                          |
| 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               |                       |                   |                      | DF-1 cable and SVC coil melted           |
| High-voltage short during VF          |                 |                       |                   |                      |                                          |
| Low impedance                         | 5               | 3                     | 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’                               |                 |                       |                   |                      | Clavicle-1                               |
| High impedance                        |                 |                       |                   |                      | Clavicle-1                               |
| Loss of capture, rising threshold      | 1               |                       |                   |                      | Annuloplasty ring-1                       |
| Unspecified                           | 4               | 3                     |                   | 3                    |                                          |
96,000 Durata leads; the Kaplan–Meier probability of abrasion failure (defined as a full thickness outer insulation abrasion) for OptimTM covered Durata leads was lower than that for silicone defibrillation leads (0.045 vs. 0.27%; \( P < 0.0001 \)). The authors concluded that OptimTM 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 custom- er reported data, confirmed by returned product analysis, had found a total of 21 insulation breaches in 10 Durata and 11 Riata ST OptimTM leads; these included six can abrasions (Durata-3, Riata ST OptimTM-3) and seven lead-to-lead abrasions (Durata-4, Riata ST OptimTM-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 monitor- ing and importantly that the available patient alerts be activated. At the time of pulse generator change, these leads should be evalu- ated visually and with high-resolution fluoroscopy; the potential for short circuiting should be assessed by impedance measure- ments 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 OptimTM or Durata leads. Likewise our data must be considered preliminary, or hypothesis generating, and additional studies of Riata ST OptimTM 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 OptimTM 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. OptimTM 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.

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