How to Manage the Faulty ICD Lead

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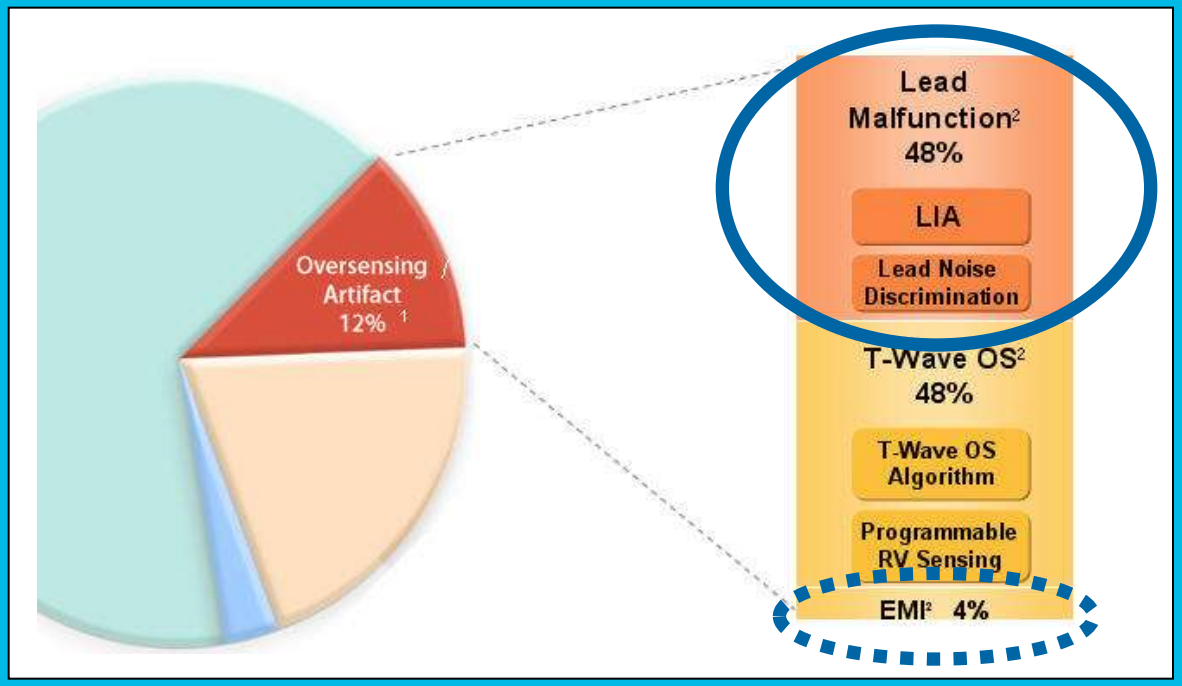
Not All Implants Work Well Long-Term

Inappropriate Shocks Occur Frequently and Lead Failure is a Common Cause

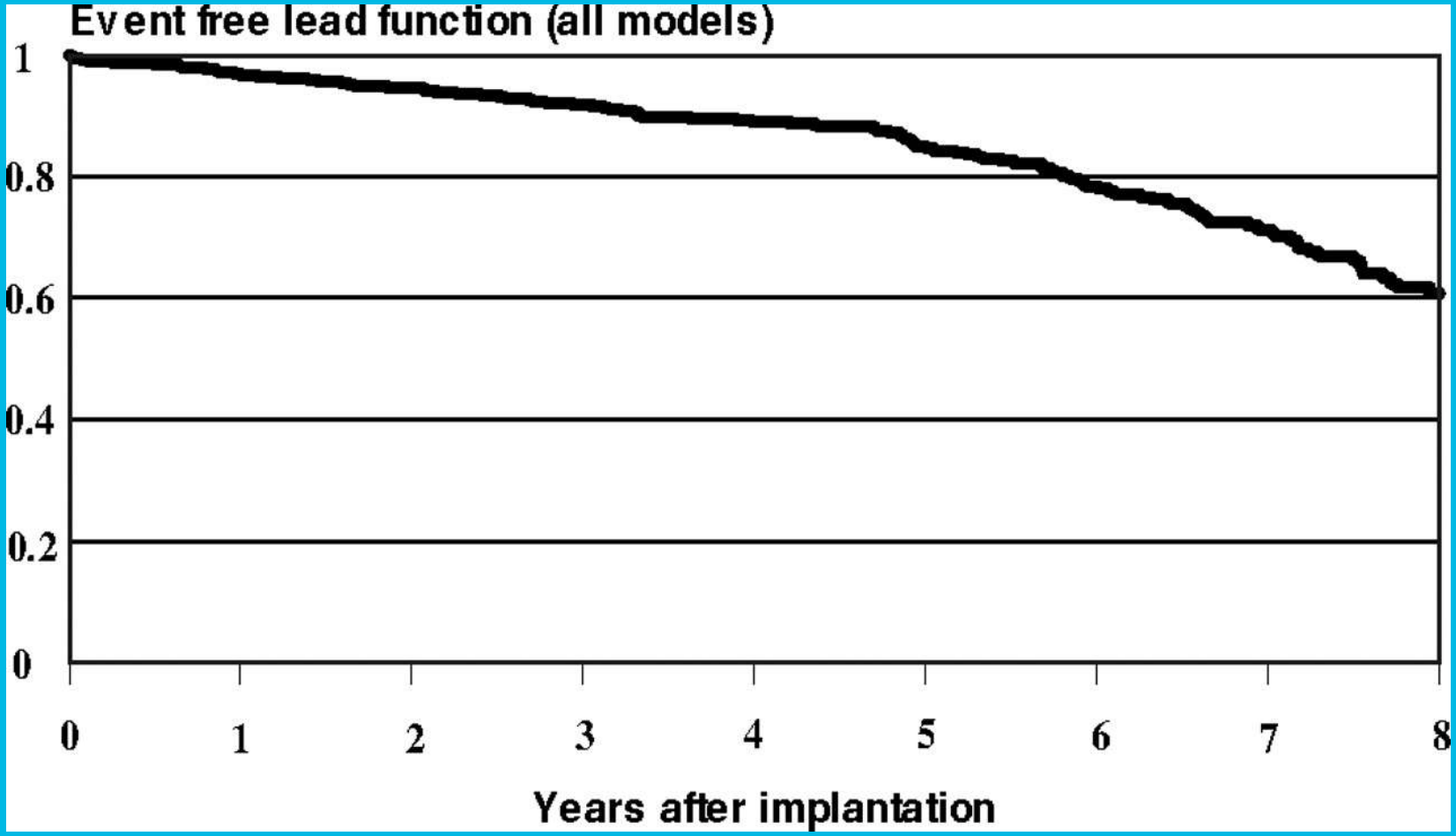
- Cumulative lead malfunction incidence is 4.6% at 10 years across manufacturers
- Lead malfunction resulted in inappropriate shocks in 76% of the cases[1]



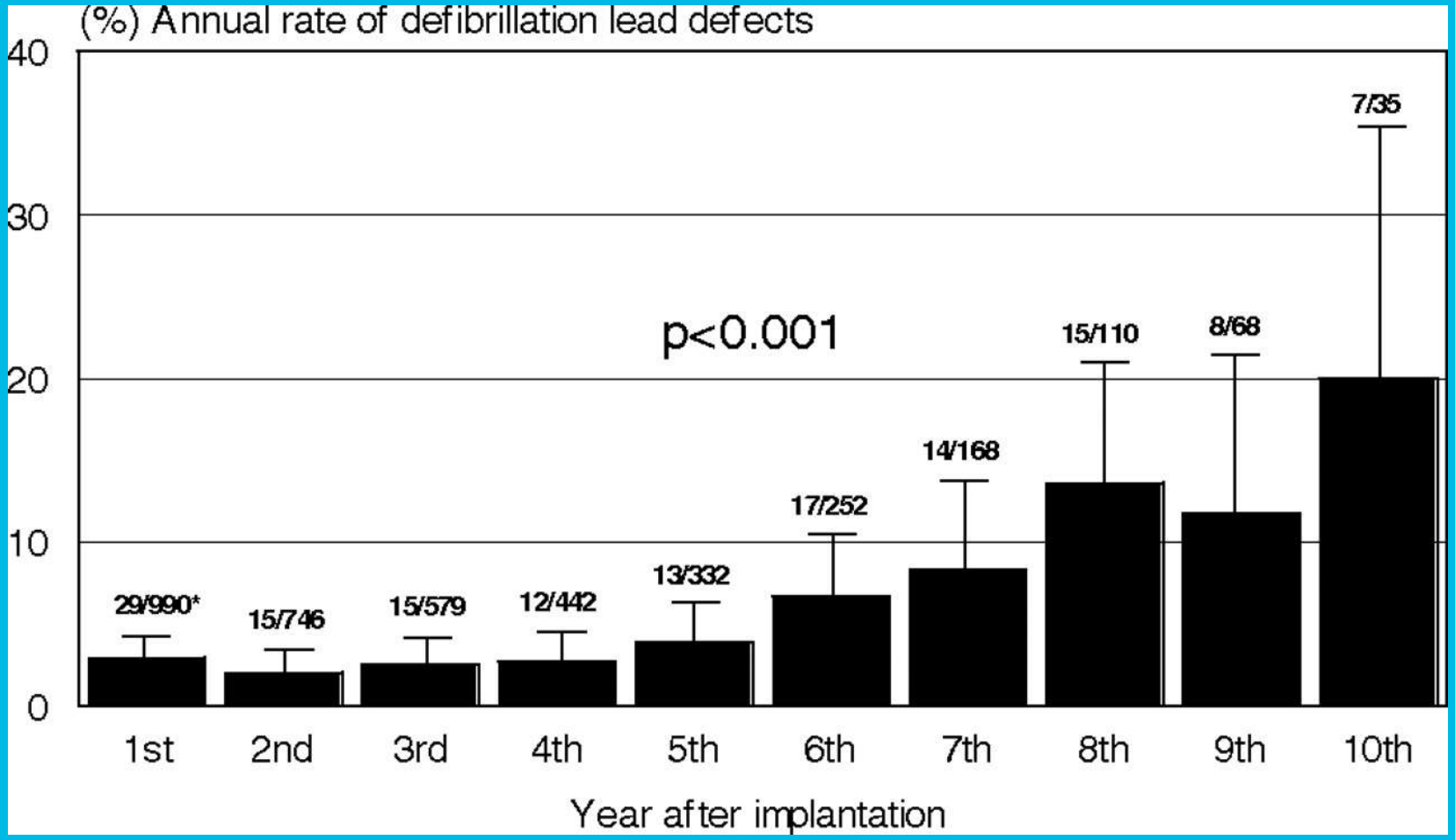
1. Eckstein J, et al. *Circulation*. 2008;117:2727-2733.
2. Gunderson BD, et al. *Heart Rhythm*. 2004;1:S244.

Surprisingly High Failure Rate in Some Series

Kleemann T et al. Circulation 2007;115:2474-2480
Single Centre Study (n=990)

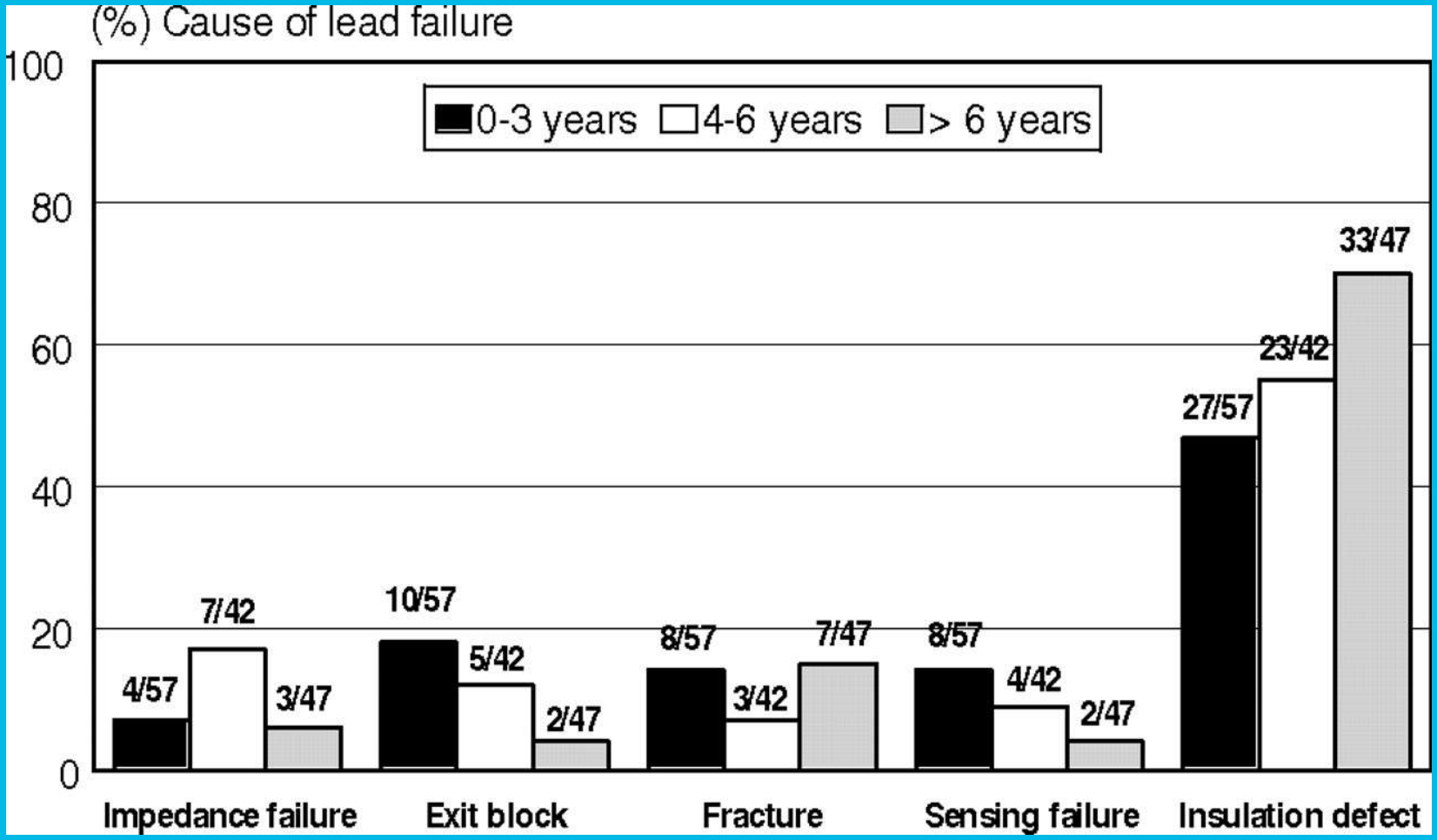


Failure Rate Increases With Time (unsurprisingly)



Kleemann T et al. Circulation 2007;115:2474-2480

Majority of Failures Compromise ICD Function



Kleemann T et al. Circulation 2007;115:2474-2480

Causes of ICD Lead Failure

Subclavian crush

Exit block

Insulation attrition

Twiddler’s syndrome

Excessively tight coiling of lead in pocket

Intrinsic lead design flaw

Sprint Fidelis 6949 Lead

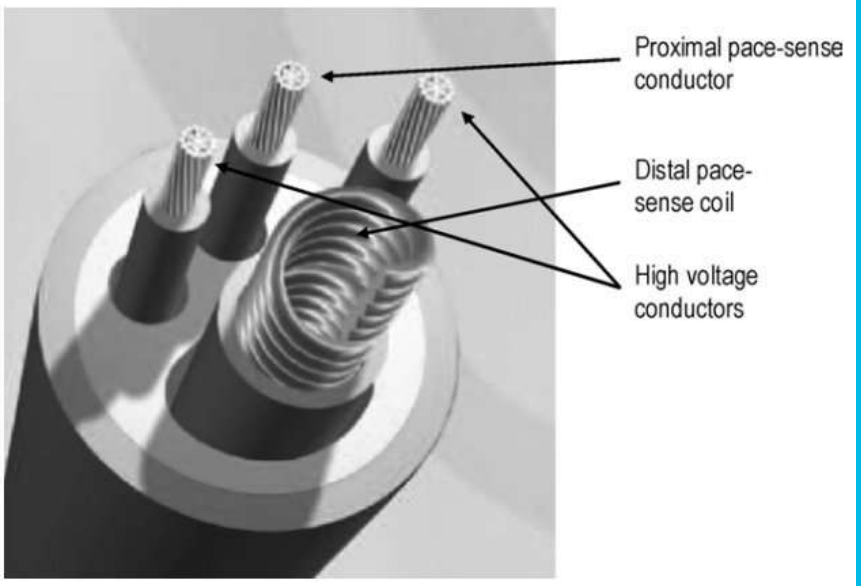


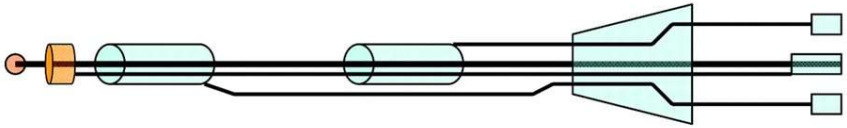
Figure 1 Cross-section of Sprint Fidelis model 6949 lead.

6.6F bipolar lead

2 areas prone to fracture:

1) the ring electrode
2) near the anchor sleeve

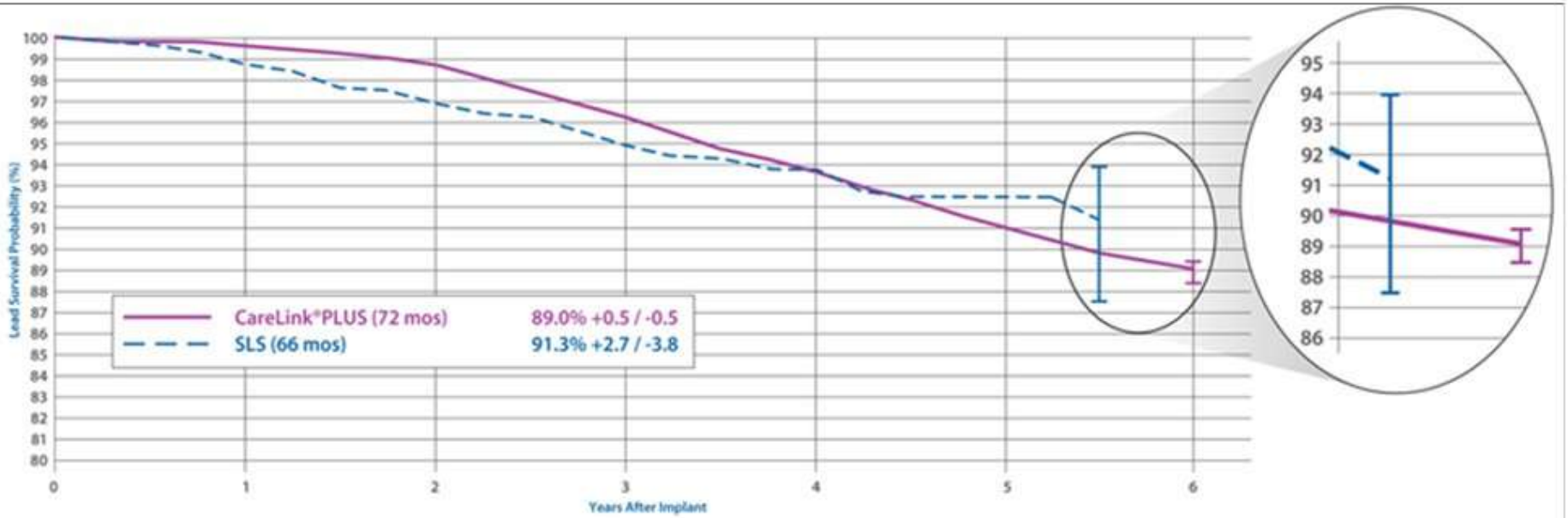
predominantly affecting the cathode (helix tip electrode)



<10% of fractures affect the HV conductor

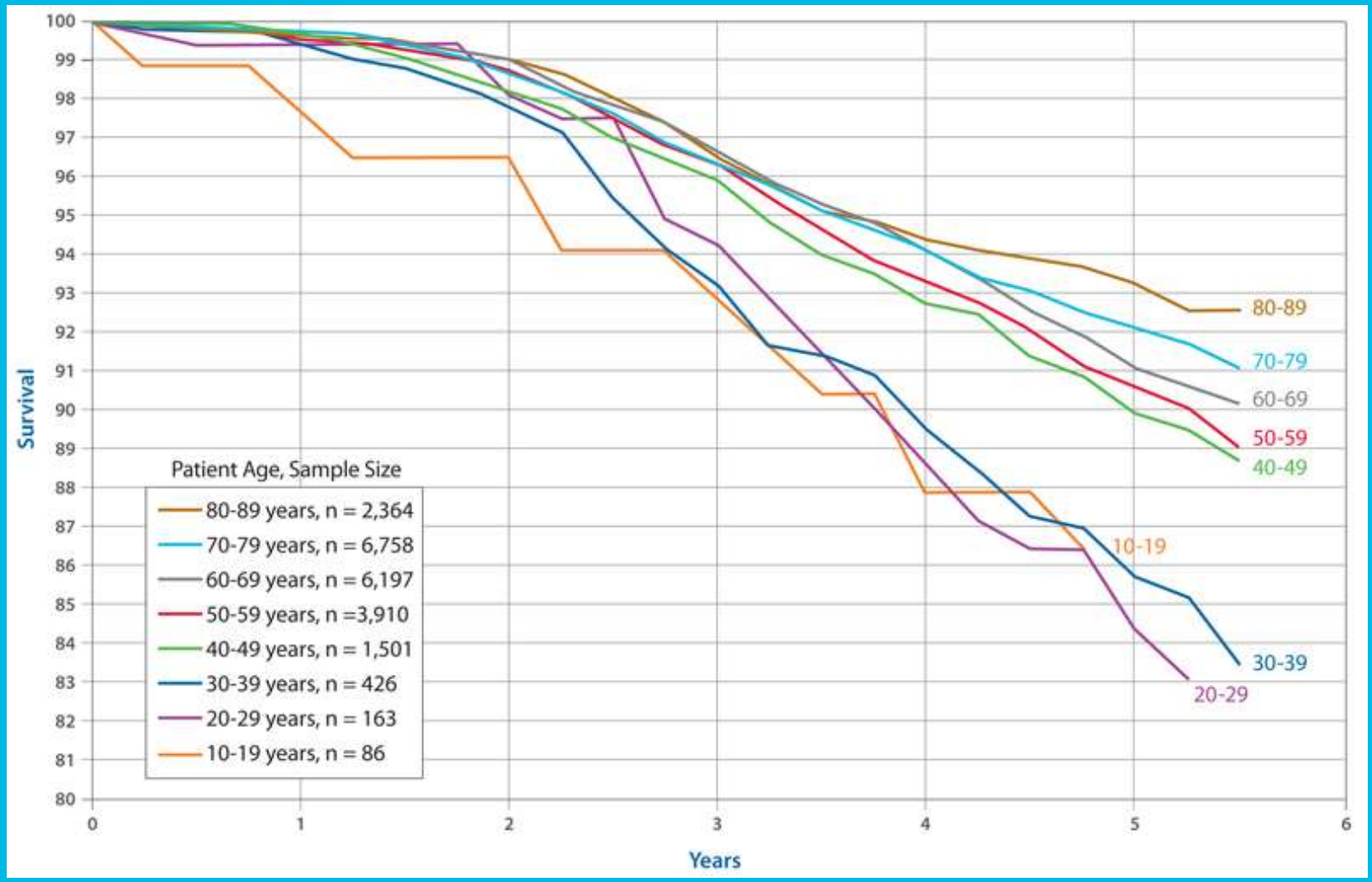
Hauser et al Heart Rhythm 2007;4:892-6

Sprint Fidelis 6949 Lead Performance

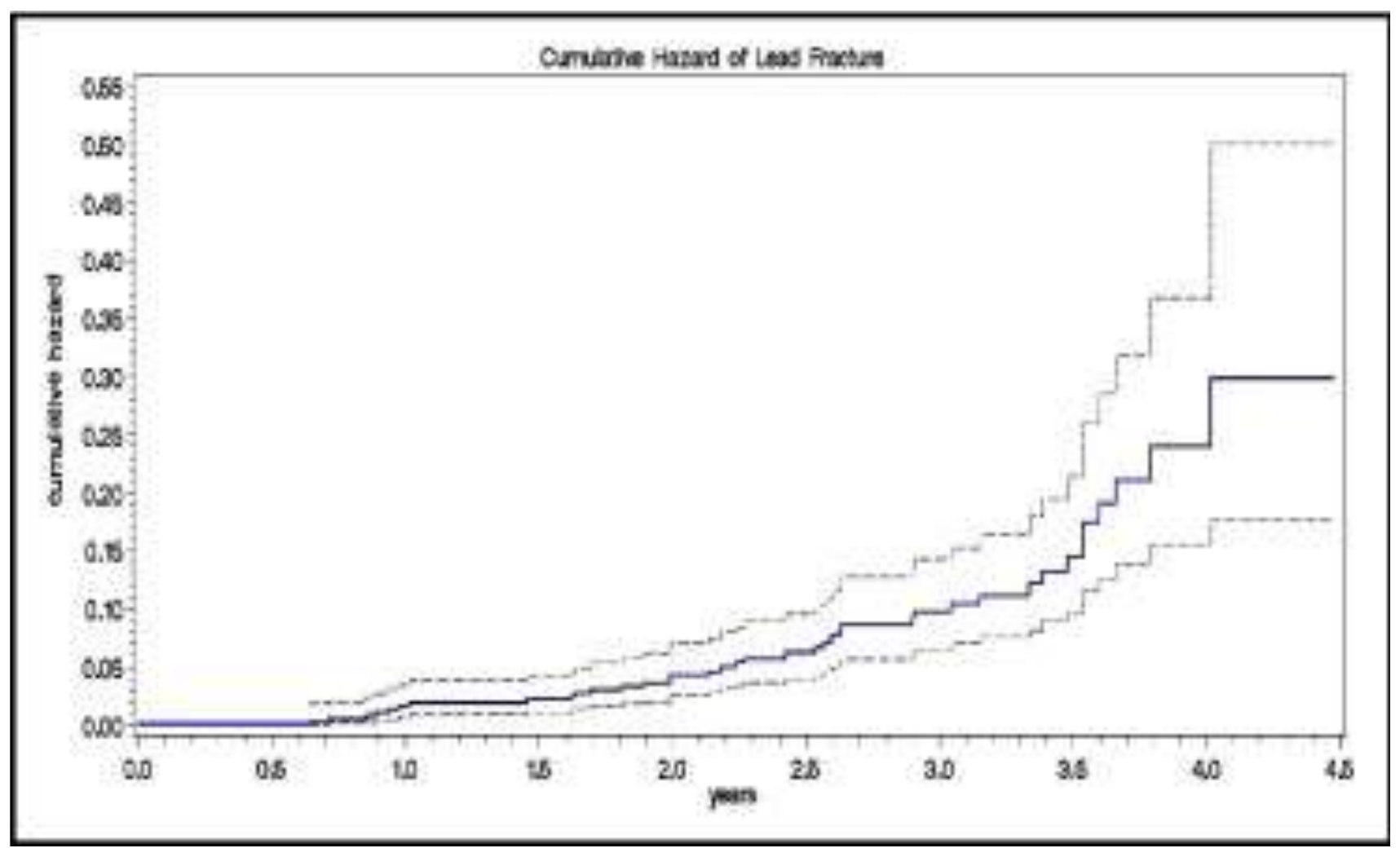


Model 6949	0 yr	1 yr	2 yr	3 yr	4 yr	5 yr	Last Point
CareLink PLUS	21,500	21,218 99.7% [+0.1/-0.1]	20,059 98.7% [+0.1/-0.2]	17,796 96.2% [+0.3/-0.3]	15,542 93.6% [+0.3/-0.4]	12,709 91.0% [+0.4/-0.4]	at 6 yrs: 2,663 89.0% [+0.5/-0.5]
SLS	795	716 98.8% [+0.6/-1.1]	625 96.9% [+1.1/-1.5]	513 94.9% [+1.4/-2.0]	321 93.8% [+1.7/-2.2]	130 92.5% [+2.0/-2.7]	at 66 mos: 50 91.3% [+2.7/-3.8]

Sprint Fidelis 6949 Lead Performance

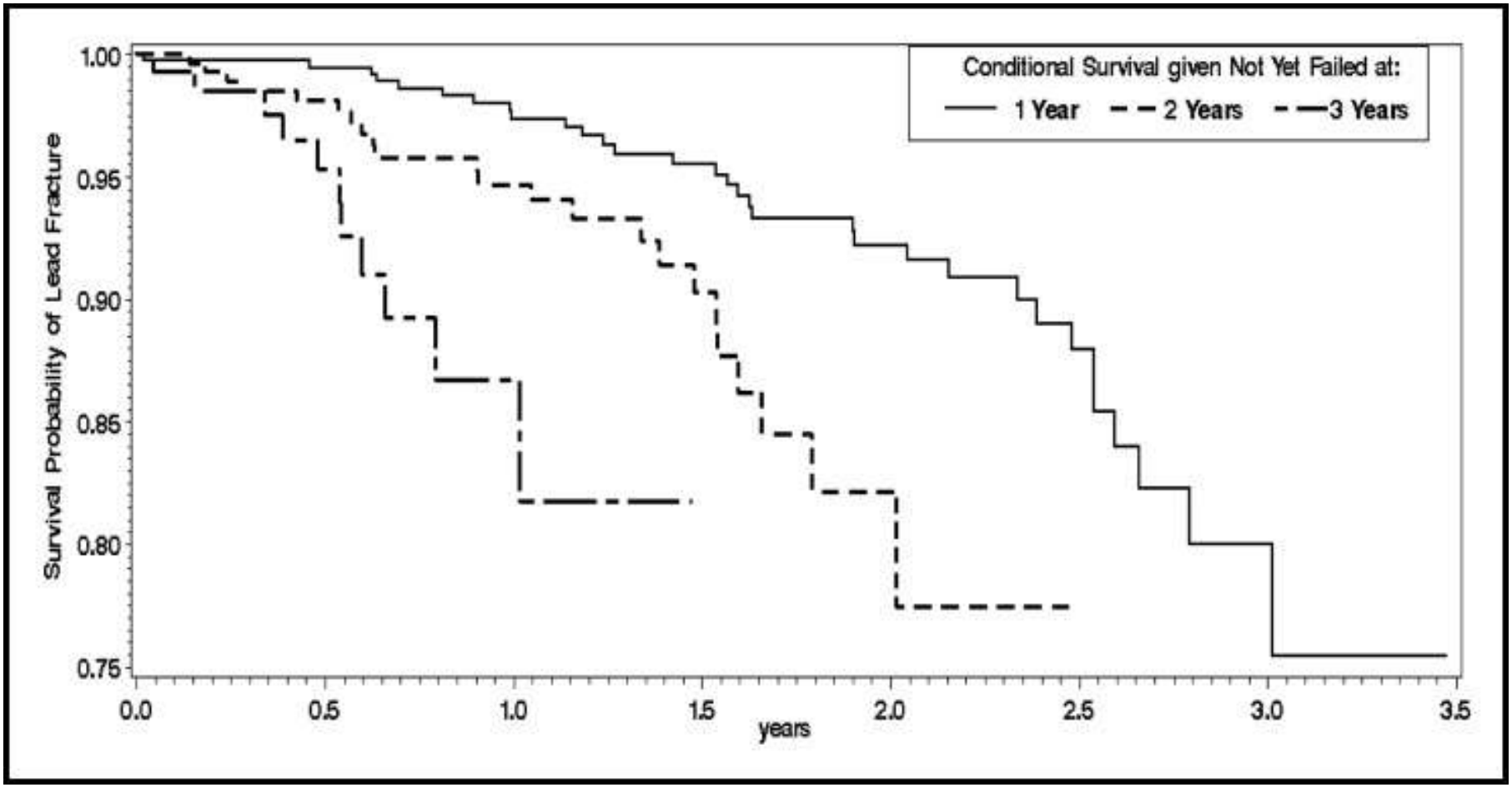


Sprint Fidelis 6949 Lead Performance



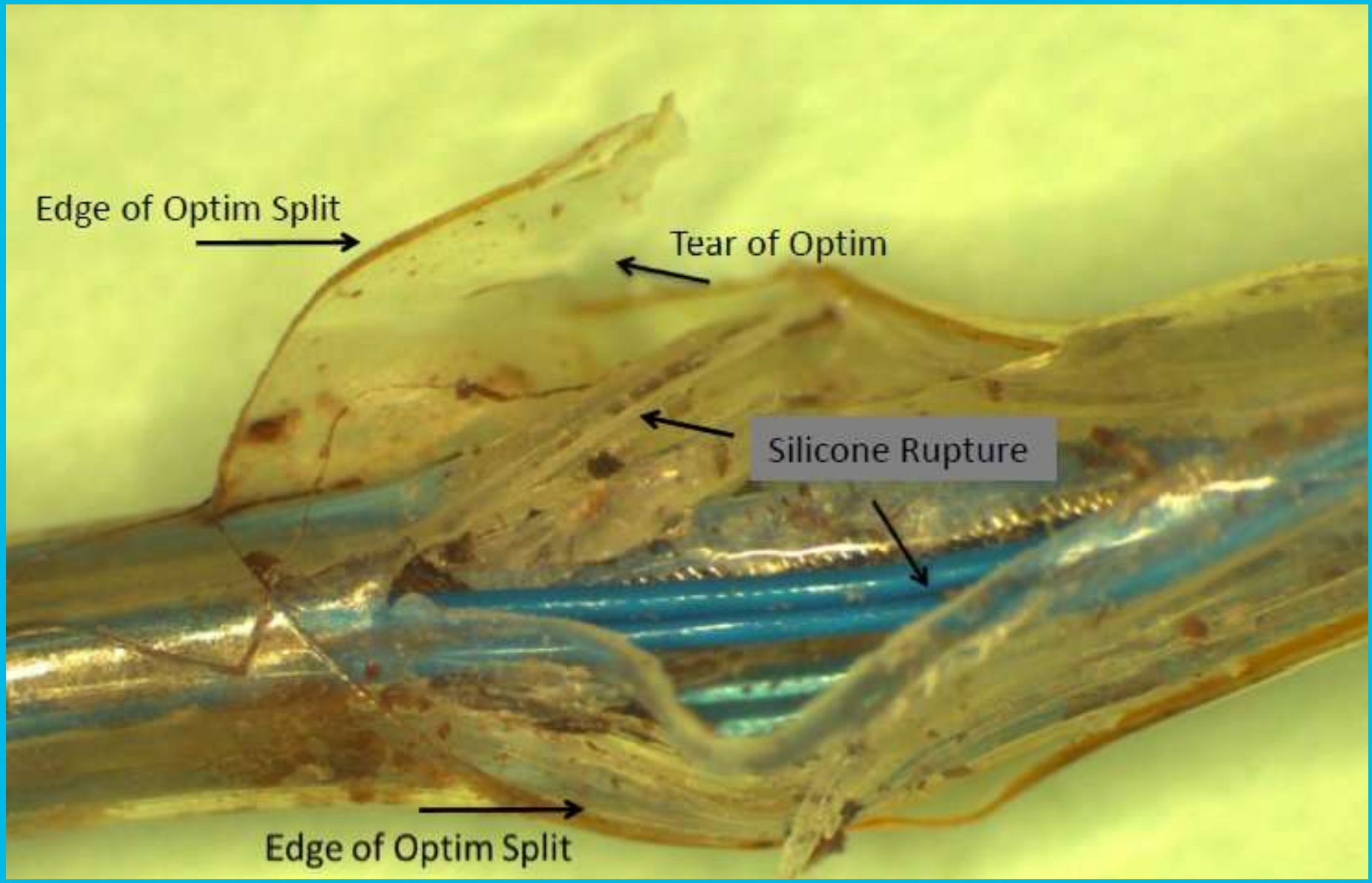
Faulknier B et al. Am J Cardiol 2010;105:95-99

Sprint Fidelis 6949 Lead Performance



Faulknier B et al. Am J Cardiol 2010;105:95-99

It’s Not Only the Fidelis….



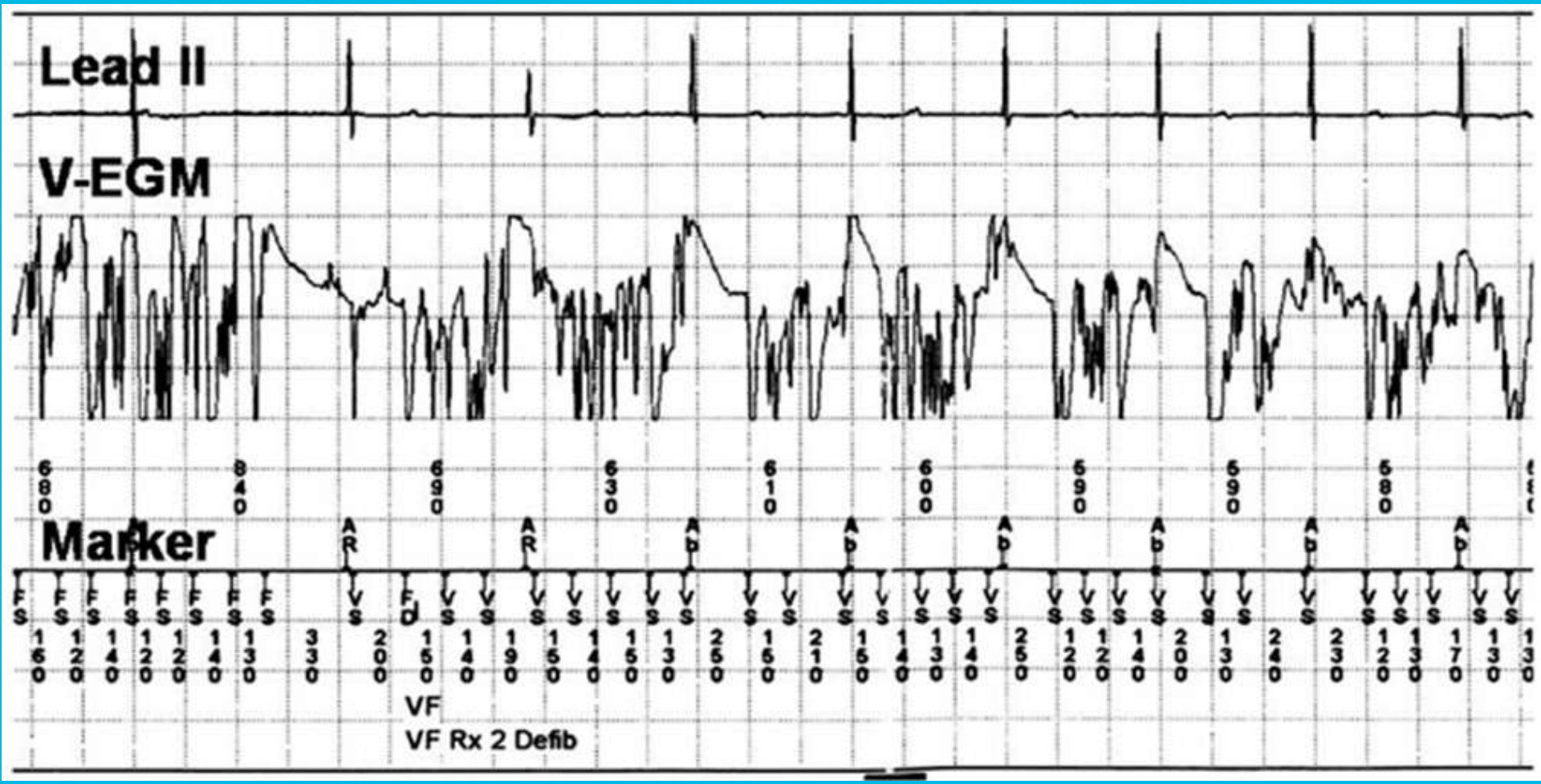
Effects of ICD Lead Failure

Inappropriate shocks

High pacing/shock impedance leading to failure to pace or failure to shock

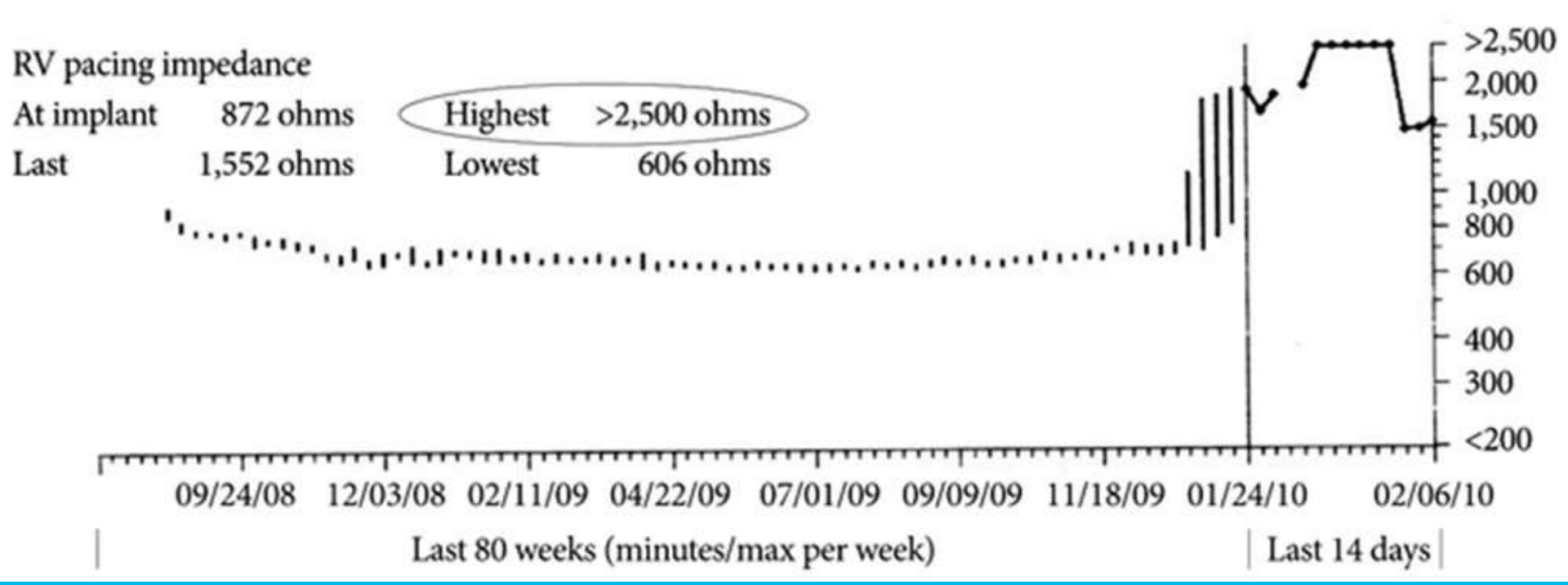
Noise/short V-V intervals

Effects of ICD Lead Failure - Noise



Park JS et al. Korean Circ J 2011; 41: 164-6

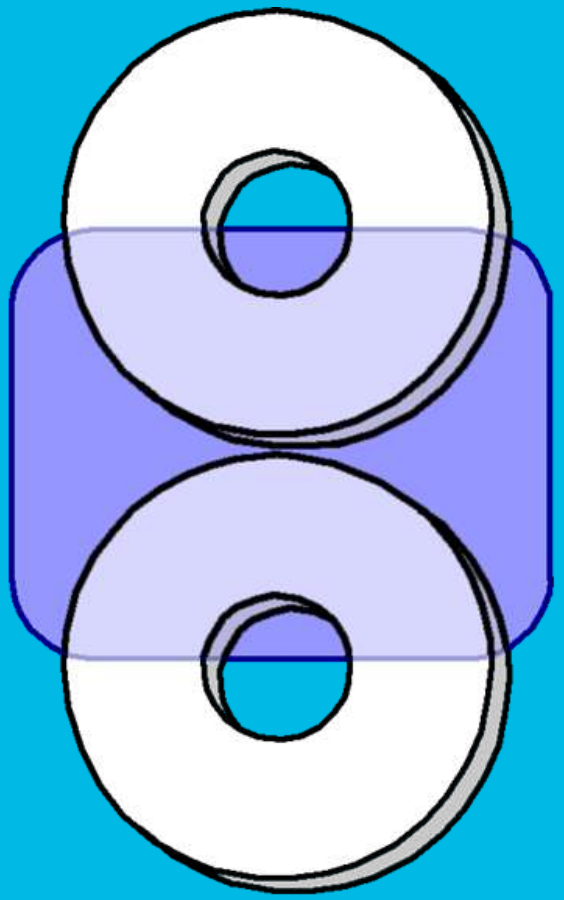
Effects of ICD Lead Failure – Sudden Rise in Impedance



Park JS et al. Korean Circ J 2011; 41: 164-6

Horse Hospitals

Short-term Management of Failing ICD Lead



Admit to monitored bed

Suspend tachycardia therapy using ring magnet

Urgent device interrogation

Long-term Management of Failing ICD lead

Options

Reprogramming of device

New P/S lead

New HV coil

New lead with abandonment of defective lead

Extraction of failed lead with implantation of new lead

Long-term Management of Failing ICD Lead

Device-Related Factors

Mechanism of lead failure

Type of lead

Lead advisory/recall guidelines

Age of lead

Number of chronic leads

Long-term Management of Failing ICD lead

Patient-Related Factors

Age of patient

Co-morbidities

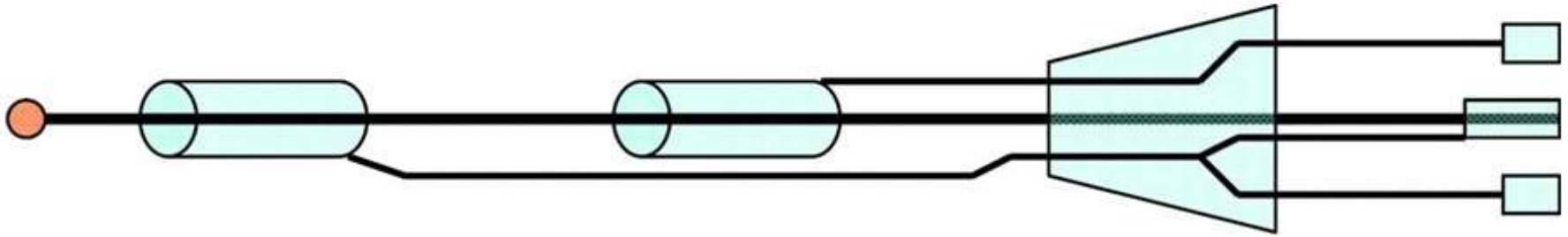
Ease of implant of additional hardware

Initial indication for ICD

Patient choice

Integrated Bipolar Lead

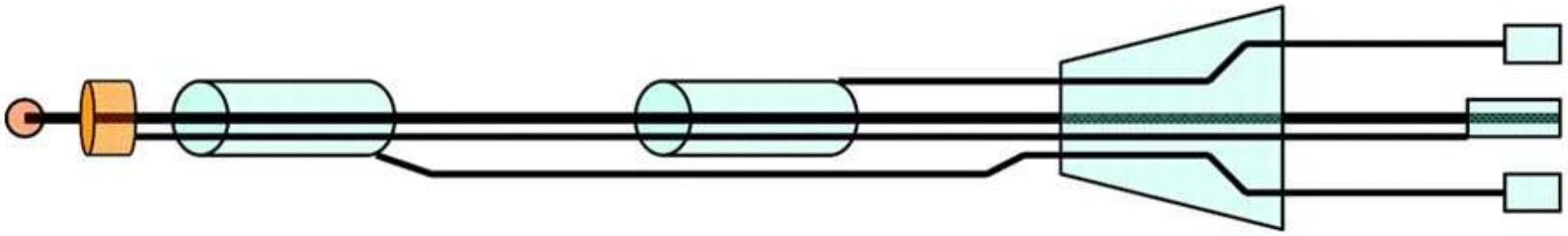
The distal defibrillation coil also serves as the ring electrode - failure of the conductor to the RV coil will necessitate replacement of the entire lead



Kalahasty G , Ellenbogen K A Circulation 2011;123:1352-1354

True Bipolar Lead

The ring electrode and defibrillation coil have independent conductors



Kalahasty G , Ellenbogen K A Circulation 2011;123:1352-1354

Long-term Management of Failing ICD lead

Reprogramming of Device

Reduce HV impedance alarm from 200 to 100 ohms

(1 week extra notice for 26% of patients)

Set RV pacing impedance alert at 1000 ohms

(47% of patients would have 4 or more extra days notice)

Long-term Management of Failing ICD lead

Sensing Integrity Counter

Battery and Lead Measurements Report

Device: **D1AT930** Serial Number: **DAT012SIMR** Date of Visit: **04-Apr-2003 08:00:02**

Patient: ID: Physician: --- ---

Last Interrogation: 04-Apr-2003 08:00:02

Battery Voltage

(ERI=2.61 V)

09-Jan-1997 03:07:42

Voltage 3.38 V

Last Capacitor Formation

08-Jan-1997 20:23:33

Charge Time 13.0 sec

Energy 1.9 - 30 J

Last Charge

09-Jan-1997 09:40:16

Charge Time 9.4 sec

Energy 0.0 - 20 J

Sensing Integrity Counter

(if >300 counts, check for sensing issues)

Since 13-Jan-1994 22:41:21

Short V-V Intervals 17

Atrial Lead Position Check

No measurement since reset.

Lead Impedance

05-Jan-1997 08:34:50

A. Pacing	257 ohms
RV Pacing	256 ohms
RV Defib	128 ohms
SVC Defib	129 ohms

Sensing

01-Jan-1994 00:00:01

P-Wave Amplitude	5.3 mV
R-Wave Amplitude	9.4 mV

Last High Voltage Therapy

10-Jan-1997 02:09:54

Measured Impedance	<20 ohms
Delivered Energy	28 J
Waveform	Biphasic
Pathway	AX>B

Lead Integrity Suite

Combines two algorithms that detect, alert,
and withhold inappropriate therapy for lead failure:

Lead Integrity Alert

Provides advance warning for lead fracture and extends the VF detection time

Lead Noise Discriminator + Alert

Identifies oversensing due to noise artifacts and provides ability to withhold therapy delivery

No compromise of VT/VF detection sensitivity

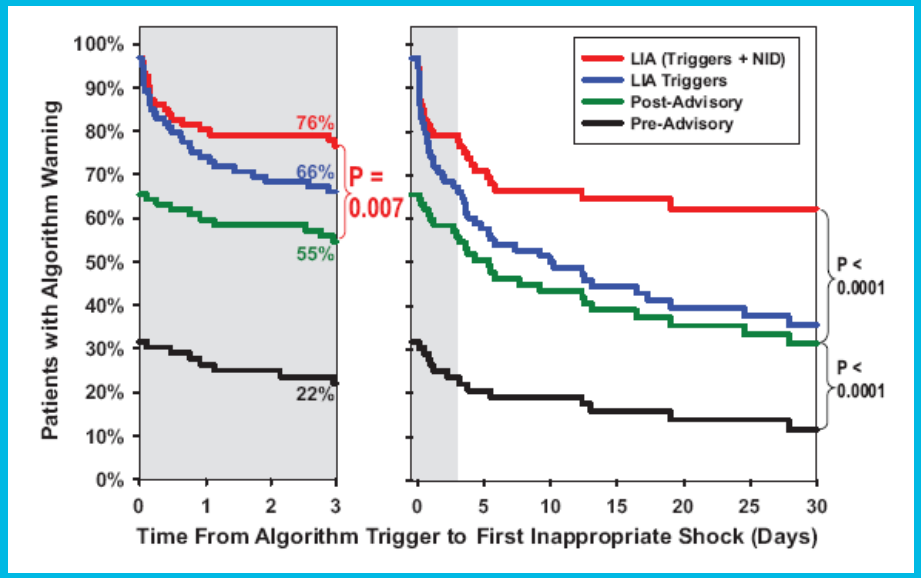
Notifies clinician of potential lead noise

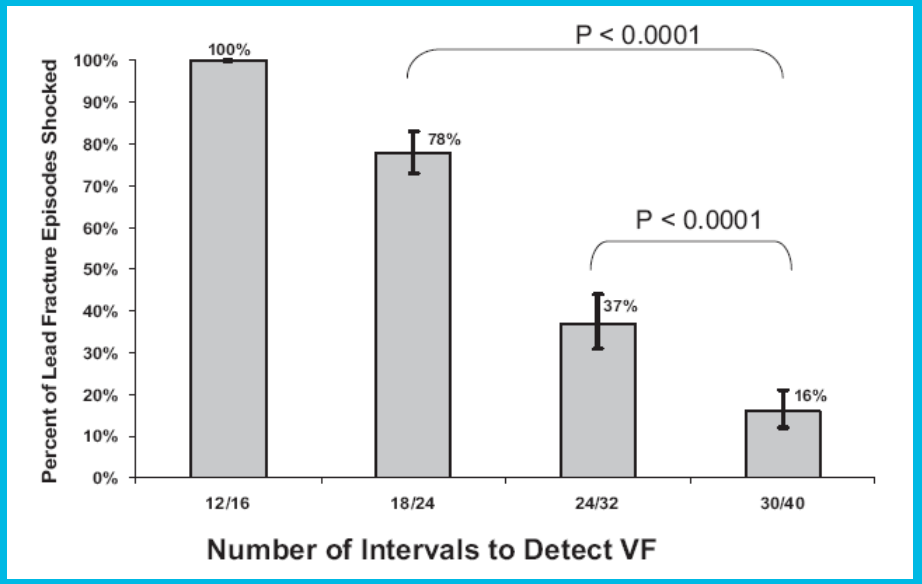
Shock Avoidance in Lead Failure

LIA is based on lead impedance and an oversensing trigger

When triggered it extends the NID to 30 out of 40

LIA provided at least 3-day warning of inappropriate shocks in 76% of patients





Swerdlow CD. *Circulation.* 2008; 118: 2122-2129

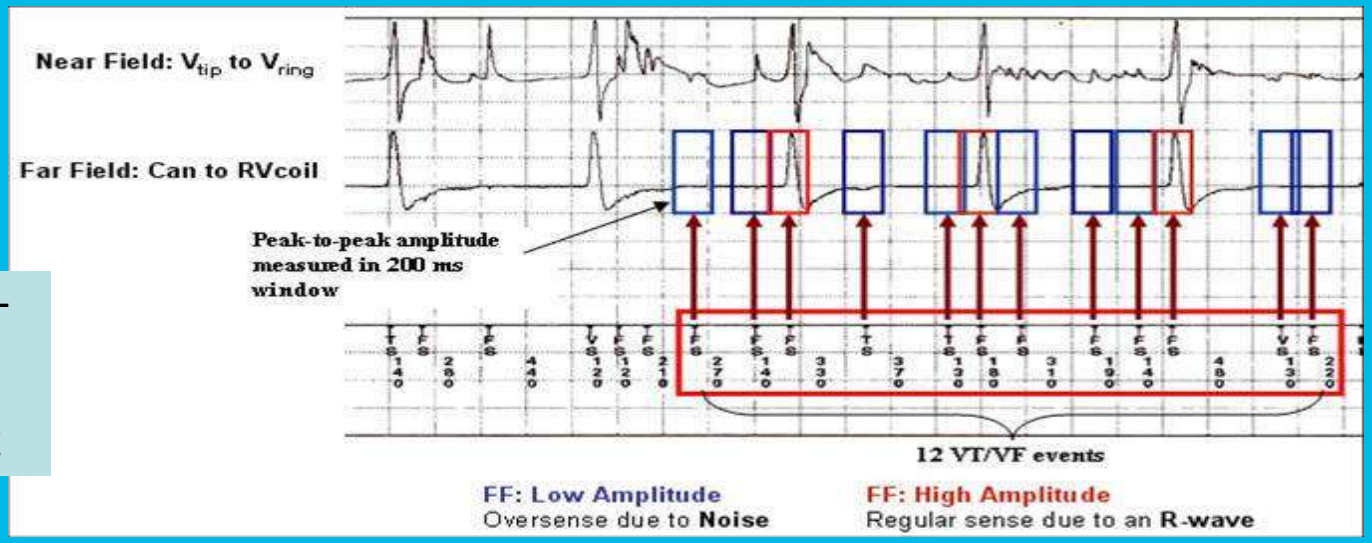
RV Lead Noise Discrimination

Noise oversensing is typically isolated to the near field sensing signal

Compare near-field sensing signal:

- Far field EGM used to confirm senses

Compares far-field cardiac activity to sensed event

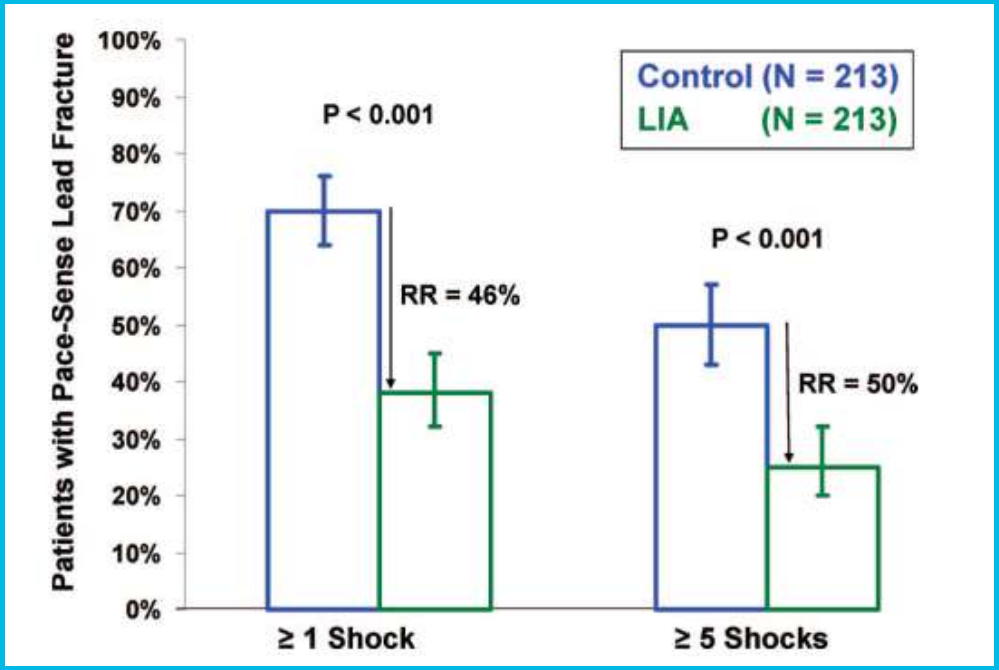


Medtronic Protecta™ and Protecta™ XT system reference guides.

LIA Reduces Inappropriate Shocks

213 patients with lead fracture and LIA vs 213 patients with lead fracture but without LIA

LIA group had 46% reduction in inappropriate shocks



Swerdlow CD. *Circulation.* 2010; 122: 1449-1455

Lead Integrity Suite and Remote Monitoring

CareLink website sends a CL Notification (text message, or email)

Clinic chooses whether this alert should be red, yellow, or website only up to a patient level

Lead/Device Integrity Alerts	Red Alert	Yellow Alert	Website-only Alert
RV Lead Integrity Two of the three criteria are met within the last 60 days: two or more fast non-sustained episodes, Sensing Integrity Counter >= 30 in three days and/or a right ventricular impedance variation. This could be triggered by a dislodged lead, an improperly connected lead, or a lead failure.	◉	○	○

Extract or Abandon

Wollmann et al JCE 2007;18:1172-7
Single Centre Study
Abandoned leads largely due to failed extraction or venous thrombosis

Table 5. Adverse Events in Follow-Up after Implantation of Additional and Replaced HV-P/S Lead

	Additional HVPS (n = 33)		Replaced HVPS (n = 53)		p
	n	%	n	%	
Follow-up					
Oversensing with inappropriate shocks	2	6.3	2	3.6	
Oversensing only	1	3.1	2	3.6	
Other P/S problems (e.g., exit block)	1	3.1	5	9.4	
Combined defect (HV + P/S)			1	1.9	
System infection	1	3.1			
ICD recall	2	6.3	5	3.6	
Death	6	18.2	7	13.2	
Total	13	39.4	22	41.5	ns

Extract or Abandon

Scott et al Europace 2010;12:522–6
Single centre observational study
45 patients with isolated P/S problem
Treated with additional P/S lead

	Not under advisory ($n = 35$)	Under advisory ($n = 10$)	*P*-value
Complications (%)			
Device infection	5.7 (2)	0 (0)	1.0
Rising shocking coil impendence	0 (0)	10.0 (1)	0.499
Death (%)	14.3 (5)	0 (0)	0.47

87% cumulative survival from further lead defects 3 years

HV Survival After P/S Fracture

Months after a Pace-Sense Conductor Fracture	0	6	12	18	21
N (leads)	182	120	88	63	54
High Voltage Conductor Survival	100%	98.7%	89.0%	80.3%	77.7%

If a Fidelis lead fracture of any type has occurred a new HV lead with or without extraction of the Fidelis lead is recommended

Implantation of a P/S lead while maintaining use of the Fidelis high voltage conductors after a Fidelis P/S fracture has occurred is no longer recommended

Long-term Management of Failing ICD lead

Advantages of Extraction + Reimplant

Preservation of venous access

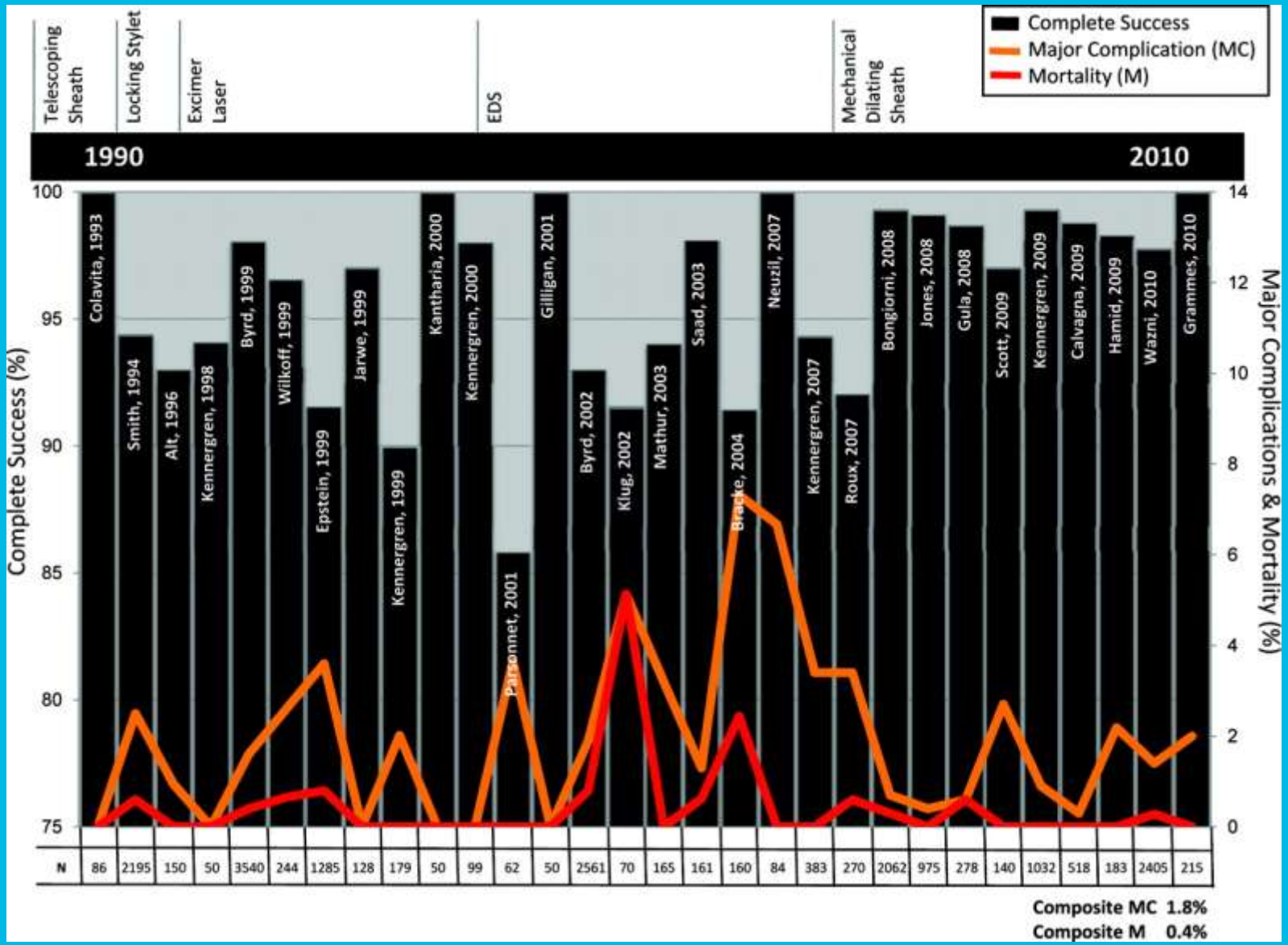
Reduced infection risk

Avoids lead-lead interaction

Reduced lead burden

Reduced risk of future extraction

Risks of Extraction



Maytin et al. Circ Arrhythm Electrophysiol 2010;3:413-424

Real World Practice

Xu et al. *PACE* 2009;32:1130 –1141.

Data from 376 ICD-implanting physicians in 28 countries (USA 83.2%)

Implant experience: >10 years 61.1%

3-10 years 29.1%

<3 years for 10.4%

RV coil failure: 52% abandoned, 48% explanted

P/S failure: 53.1% implanted a new P/S lead or switch sensing electrodes, using the intact lead components