Mechanism of Lead Failure

Results from the Pacemaker and Implantable Defibrillator Leads Survival Study ("PAIDLESS")

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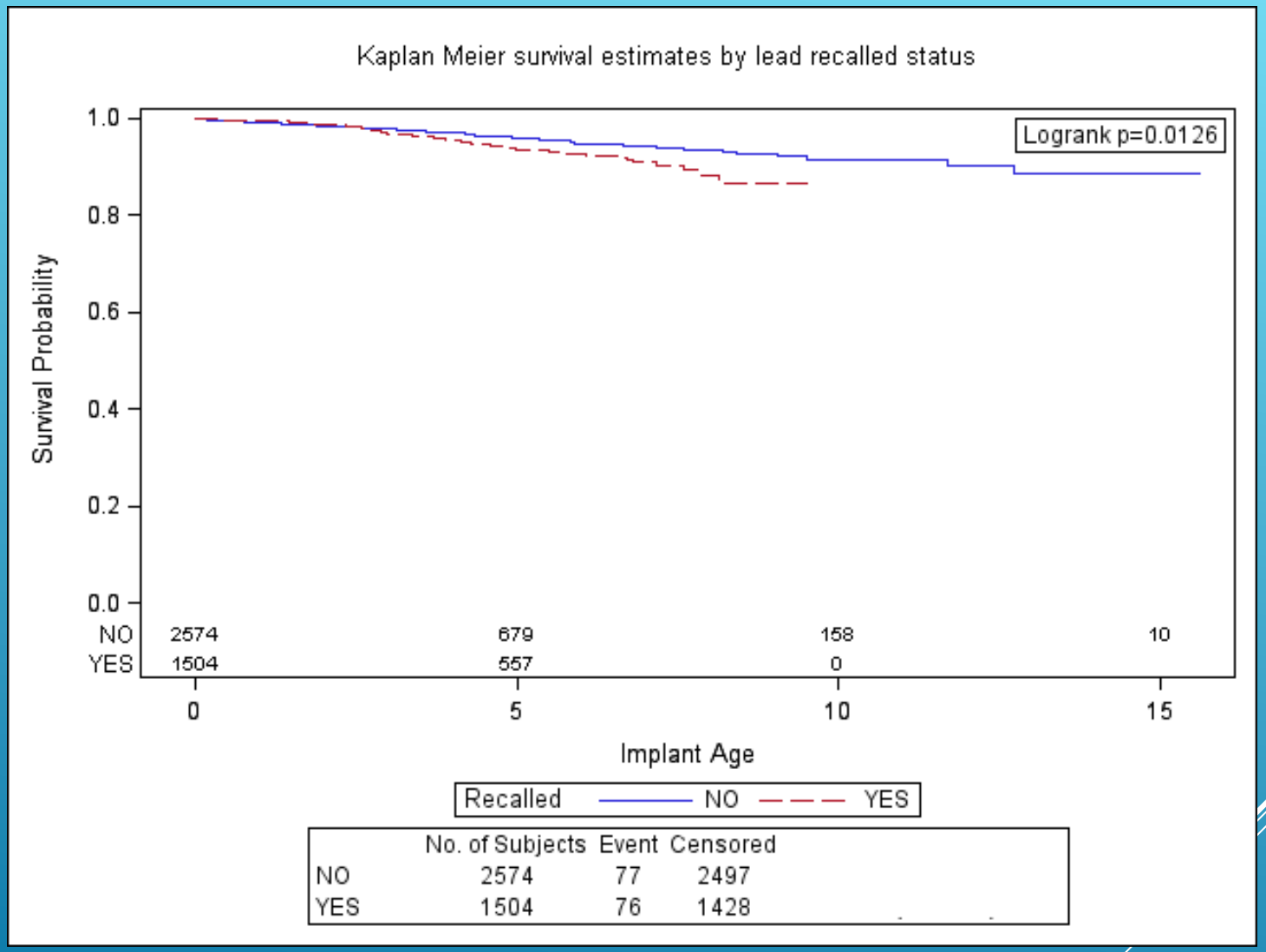
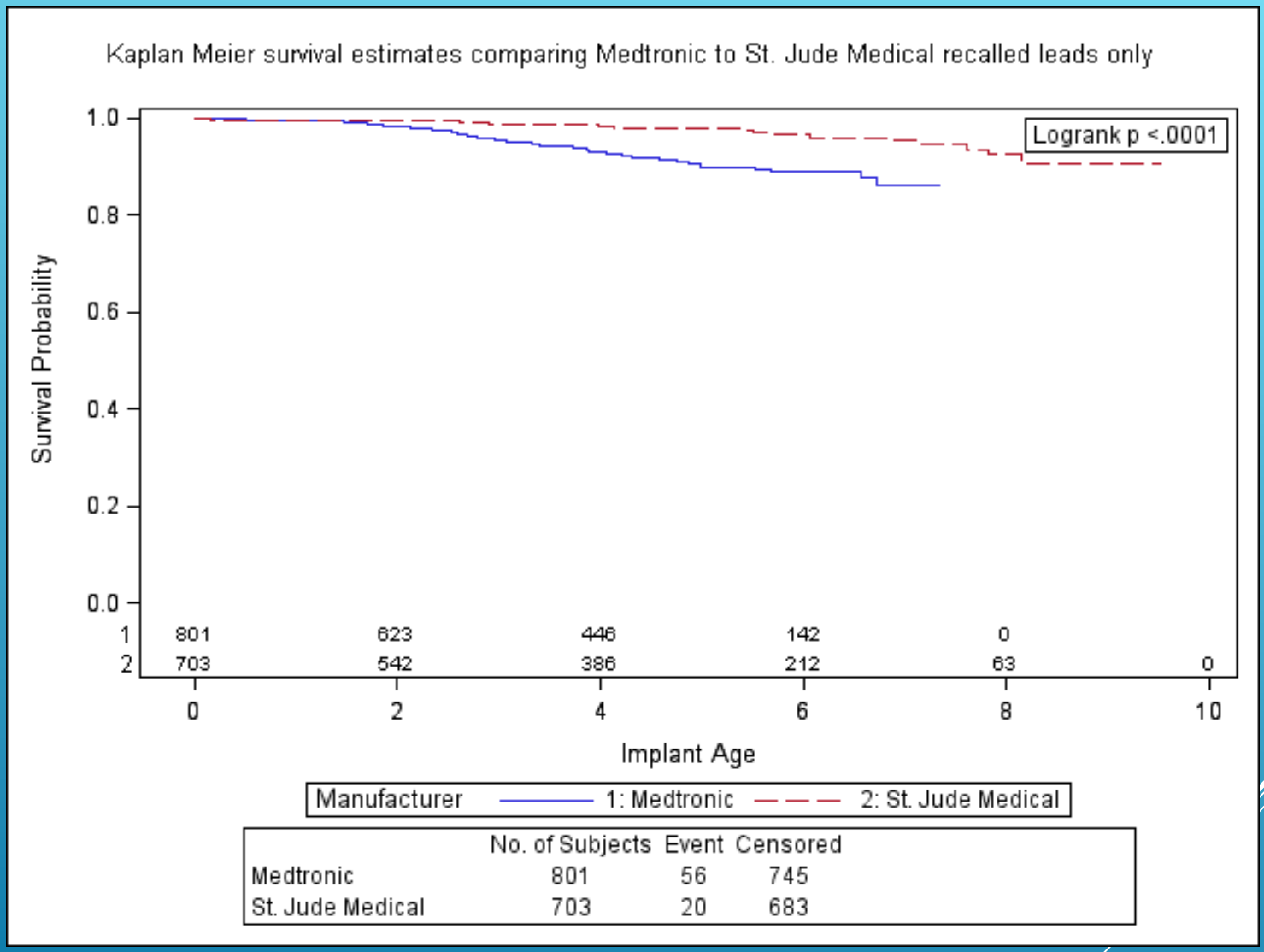
Purpose

- To examine the mechanisms of lead failure among three manufacturers:
  - Boston Scientific (BSC)
  - Medtronic (MDT)
  - St. Jude Medical (SJM)



A Comparative Study of Defibrillator Leads at a Large-Volume Implanting Hospital: Results from the Pacemaker and Implantable Defibrillator Lead Survival Study ("PAIDLESS")

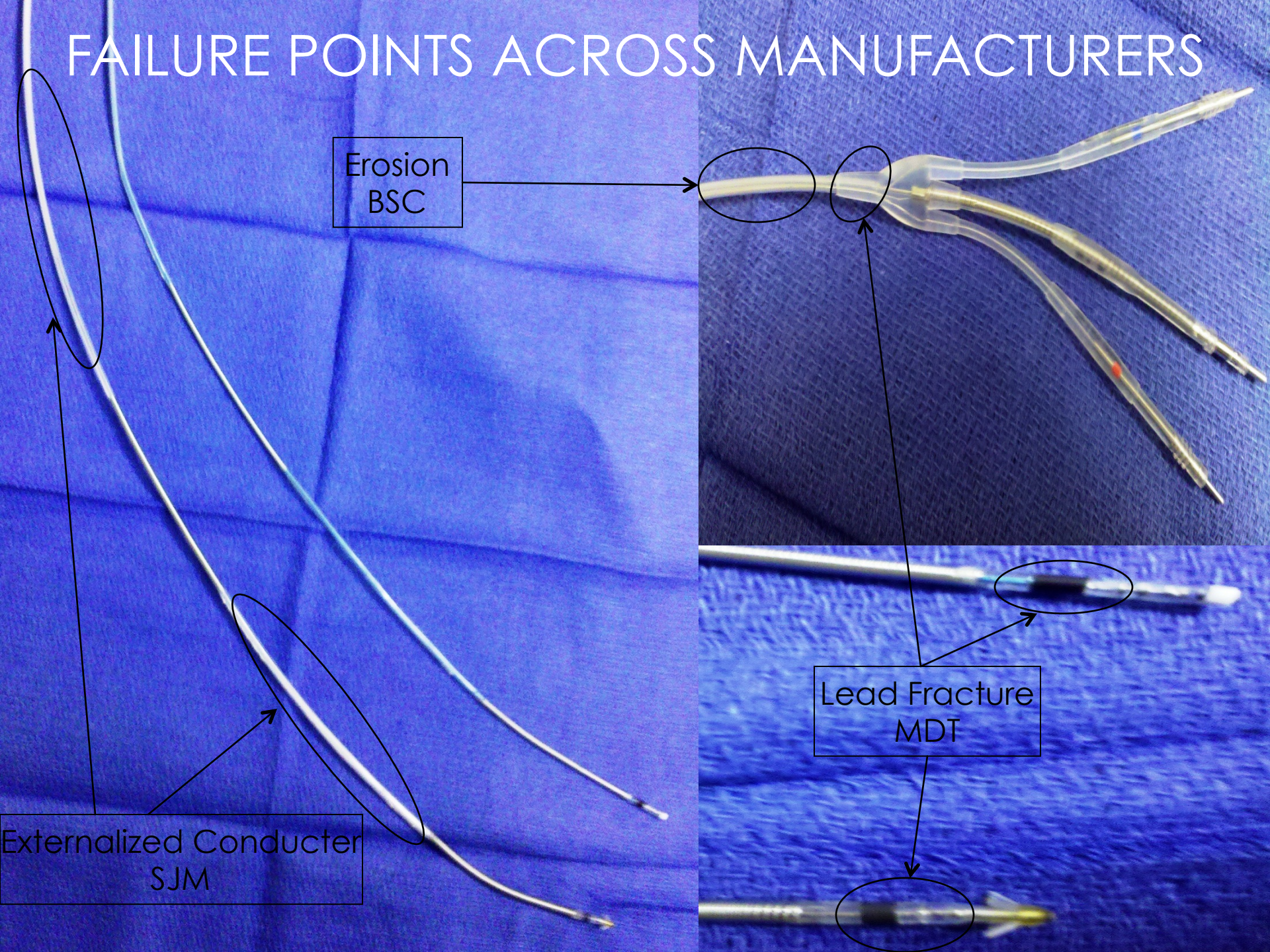


A Comparative Study of Defibrillator Leads at a Large-Volume Implanting Hospital: Results from the Pacemaker and Implantable Defibrillator Lead Survival Study ("PAIDLESS")

Methods

- This study analyzed all leads implanted at Winthrop University Hospital between February 1, 1996 and December 31, 2011
- Lead failure was defined by Medtronic Systems Longevity criteria: failure to capture, failure to sense, abnormal pacing impedance, abnormal defibrillation impedance, insulation defect, lead fracture, extracardiac stimulation, cardiac perforation, tricuspid valve entrapment, lead tip fracture, and/or lead dislodgement
- Statistical analyses included Chi-Square and Fisher's Exact Tests

FAILURE POINTS ACROSS MANUFACTURERS



Results

- Total failures = 153

- Significant differences between manufacturers:

Lead type	Number of failures (N=153)	Causes of lead failure		
		High impedance	Insulation defects	Dislodgements
Boston Scientific	18 (12%)	2	1	2
Medtronic	99 (65%)	**36**	**6**	1
St. Jude Medical	36 (23%)	7	0	**6**
	p-value	0.03	0.007	0.0016

Results

- Failure in non-recalled leads: 77 (3% of non-recalled leads)
- Failures in recalled leads: 76 (5% of all recalled leads)
  - Medtronic's Sprint Fidelis: 56
  - St. Jude Medical's Riata and Riata ST: 20

- Significant differences based on recall status:

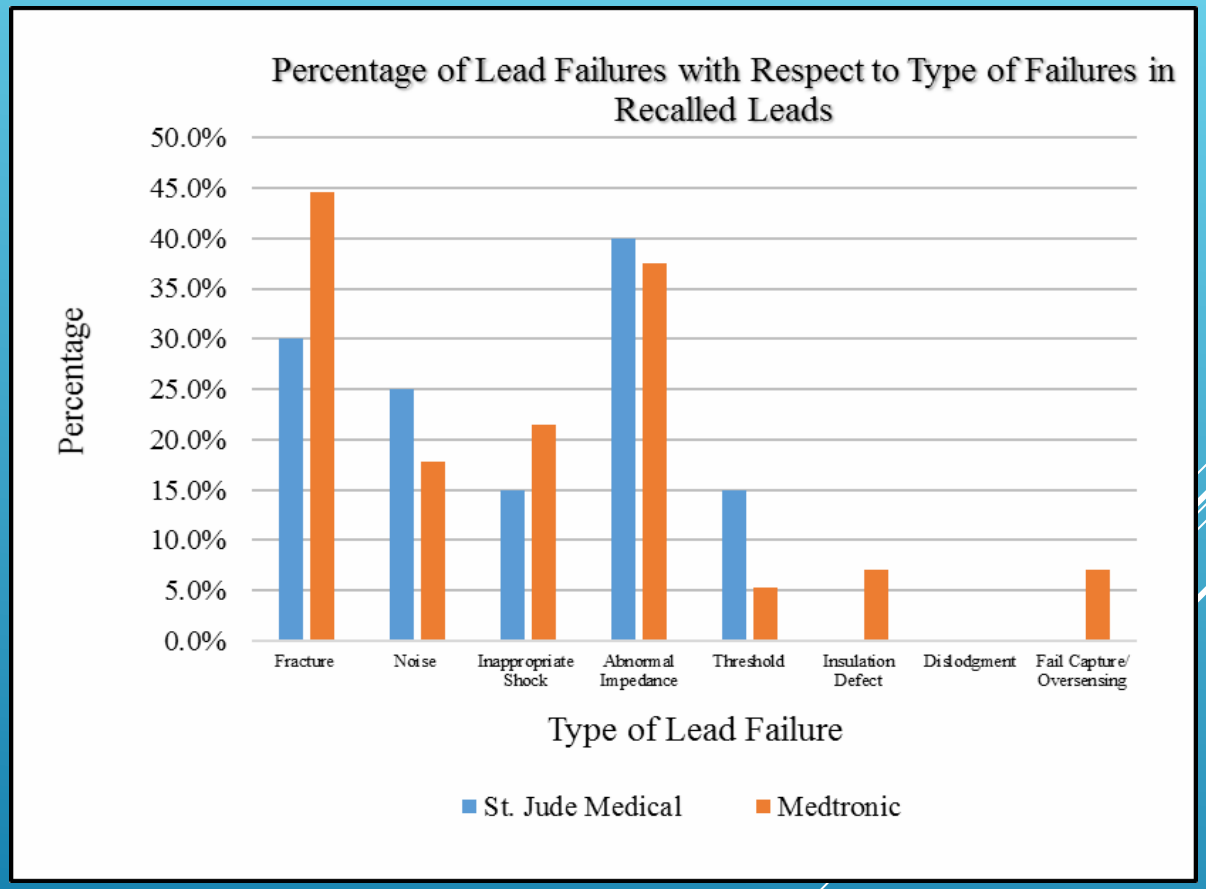
Recall status	Causes of lead failure			
	Sensing	Fractures	Dislodgements	Abnormal thresholds
Recalled	**14 (18%)**	**31 (41%)**	0 (0%)	6 (8%)
Non-recalled	4 (5%)	13 (17%)	**9 (12%)**	**15 (19%)**
p-value	0.001	<0.001	0.002	0.04

Results

- Recalled leads: Medtronic vs. St. Jude Medical

- Abnormal impedance – low only:
  - Recalled Medtronic: 0 (0%)
  - Recalled St. Jude Medical: 3 (15%)

    (p=0.003)



Conclusions

- Lead failure mechanisms differ amongst manufacturers as well as between recalled and non-recalled leads
- Lead failure mechanisms also differ by manufacturer within the recalled group
- Limitation: Recall of the St. Jude Medical Riata and Riata ST leads occurred in 2011, the same year the PAIDLESS study ended
- Future research in this field would help determine the importance of understanding the mechanism behind lead failures