

Riata® Lead Evaluation Study *Phase I Results (North America)*

July 10, 2012



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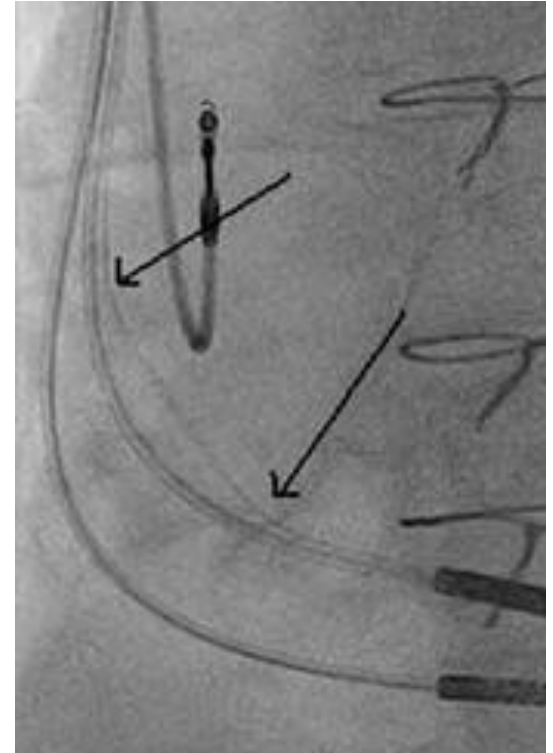
What Are Externalized Conductors (EC)?

Definition:

- The appearance on x-ray or fluoroscopy of conductors outside of the lead body due to an abrasion-related breach of the outer insulation

Clinical Presentation: Visual vs. Electrical

- Externalized conductors (EC) have been observed in SJM Riata® silicone leads
- 91% of all externalized conductors are between the SVC and RV shock coils (or the analogous region in single coil leads)¹
- More than 85% of the externalized conductors continue to function normally without electrical anomalies



The Prevalence of Externalized Conductors

- Rates of EC reported in the medical literature have ranged from 12% to 33% (when screening by x-ray or fluoroscopy)^{1,2,3,4}
- Criteria for classifying externalized conductors have not been uniform among published reports and studies

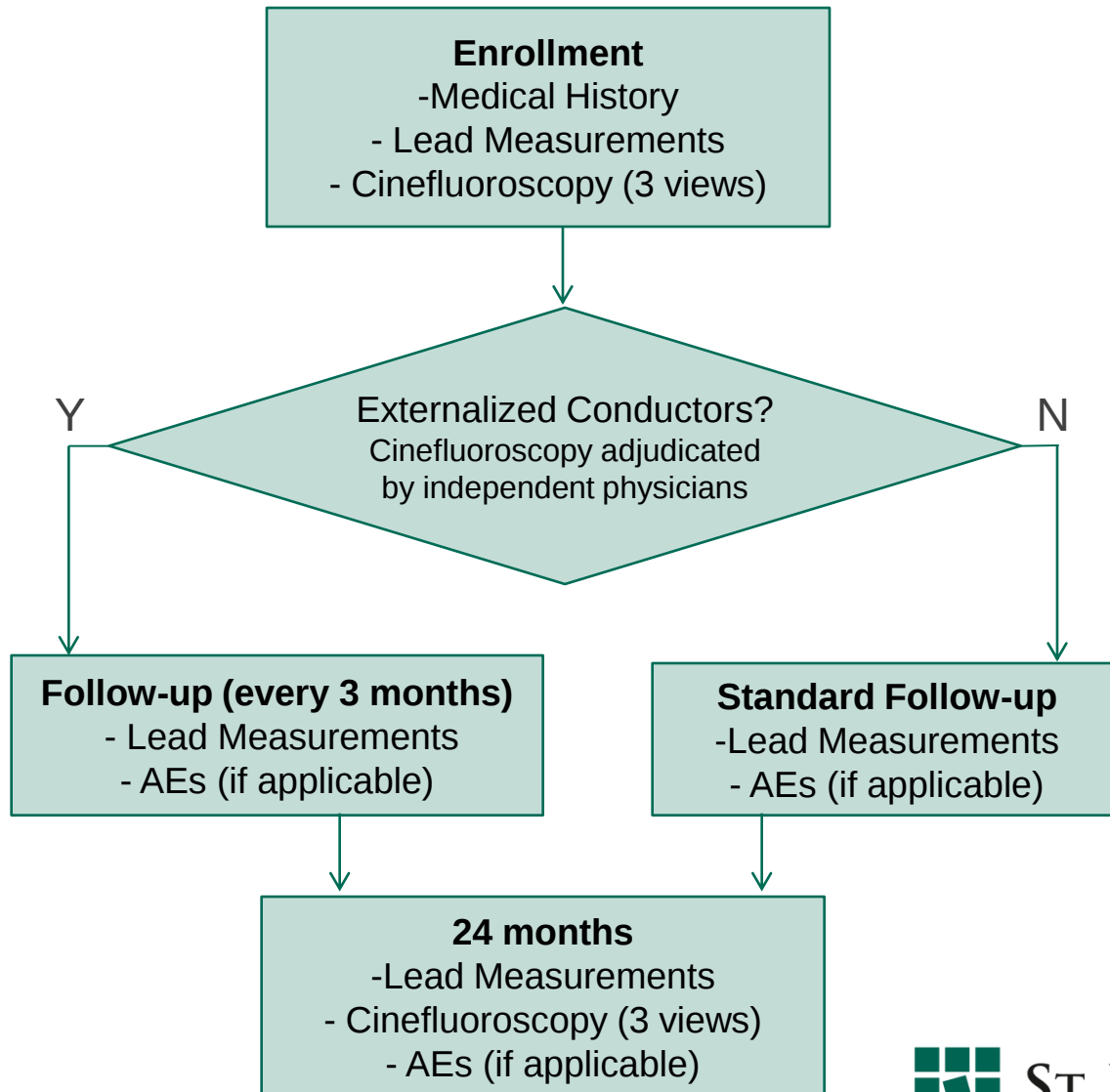
1. Kodoth V et al. European Heart Journal (2011) 32(Abstract Supplement), 310.
2. Hodkinson E et al. JACC (2012) vol. 59(13s1):E585.
3. Schmutz M et al. International Journal of Cardiology, 2012 Jan 9 (Epub).
4. Parvathaneni SV et al. Heart Rhythm 2012 Mar 23 (Epub).

Riata® Lead Evaluation Study Objectives

- Phase I: To determine the prevalence of EC in patients implanted with Riata and Riata ST Silicone leads
- Phase II: To determine the incidence of electrical malfunction in leads with and without ECs



Study Design



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Patient Enrollment Criteria

Inclusion Criteria

- Patient has a market released St. Jude Medical ICD or CRT-D
- Patient has a market released Riata/ Riata ST right ventricular defibrillation lead
- Patient has the ability to provide informed consent for study participation and be willing to comply with the prescribed evaluations as detailed in this study plan.
- Be 18 years of age or older

Exclusion Criteria

- Patient is pregnant
- Patient is participating in another study with an active treatment arm



Externalized Conductor Adjudication

- An experienced physician panel using predefined criteria adjudicated analyzable fluoroscopic images
- Leads were classified as having EC if either of the following was present on fluoroscopy
 - The appearance of a conductor cable outside the body of the lead as defined by the shock electrode shadow
 - A change in the radius of curvature of the suspected externalized conductor as compared to the remainder of the lead body



Enrollment Details

- Patient Enrollment
 - 724 patients enrolled at 20 sites in North America (19 sites in USA and 1 in Canada)
 - 51 patients enrolled at 3 sites in Japan (Note: Data from these patients are awaiting adjudication and are not included in the presented study results)
- Of the 724 patients enrolled in North America:
 - Images were not retrievable in 4 patients
 - Images were classified in 2 patients as indeterminate*
- Of the remaining 718 patients:
 - 8F Leads (1500 Series) = 459
 - 7F Leads (7000 Series) = 259

***Indeterminate represents images for which the fidelity was not adequate to determine whether an externalized conductor was present or absent**

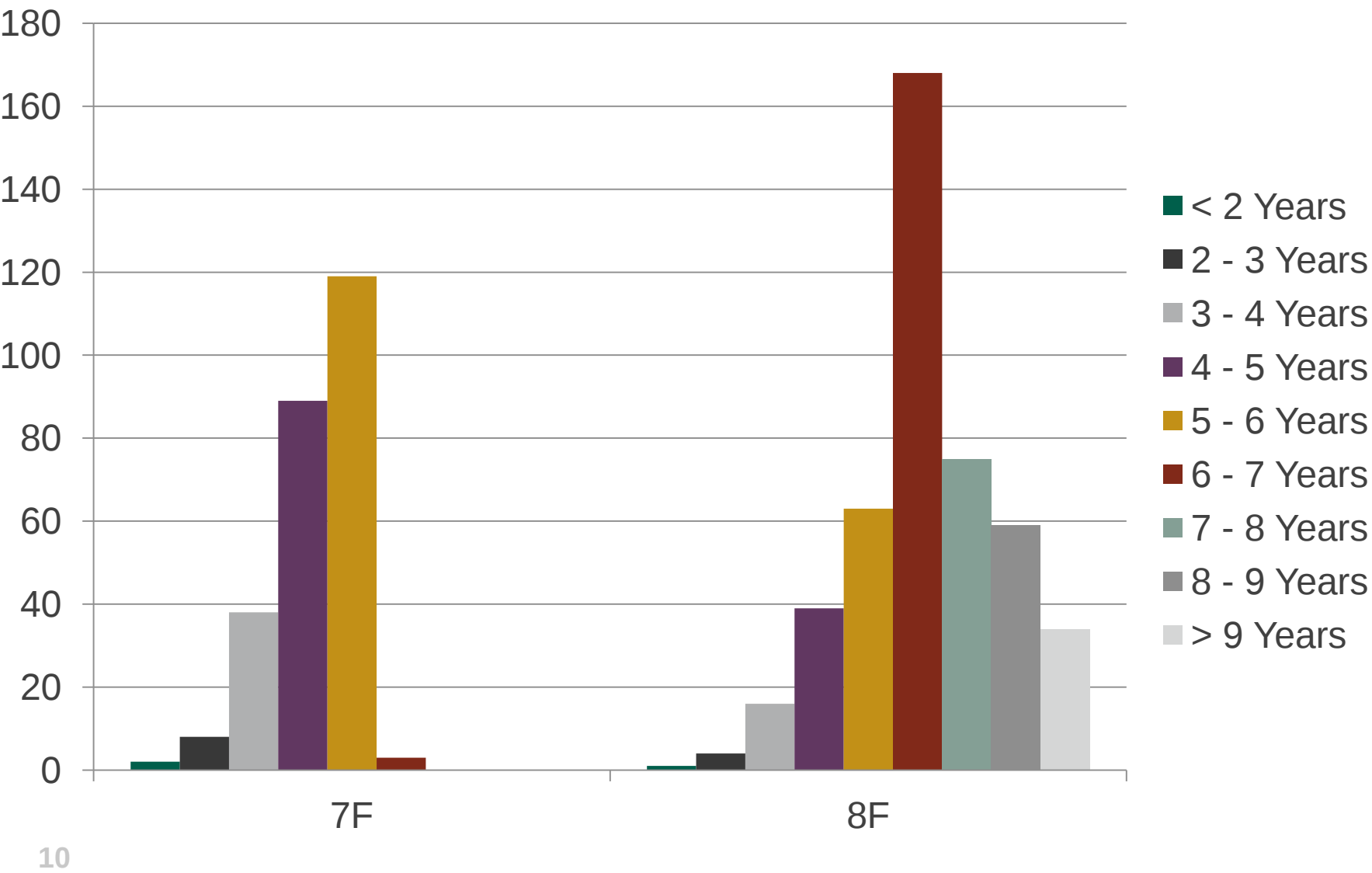
Patient Demographics

	7F Leads (7000 Series) (N = 259)	8F Leads (1500 Series) (N = 459)	Overall (N = 718)
Age (years)	66.2 ± 12.6	67.6 ± 11.4	67.1 ± 11.8
Gender	73.4% male	74.7% male	74.2% male
LVEF (%)	36.3 ± 15.8	35.4 ± 14.4	35.7 ± 14.9
BMI (lbs/in ²)	30.5 ± 7.5	29.9 ± 6.5	30.1 ± 6.9
Ischemic CM (%)	55.6	59.7	58.2
Hypertrophic CM (%)	4.6	6.8	6.0



Distribution of 7F and 8F Leads

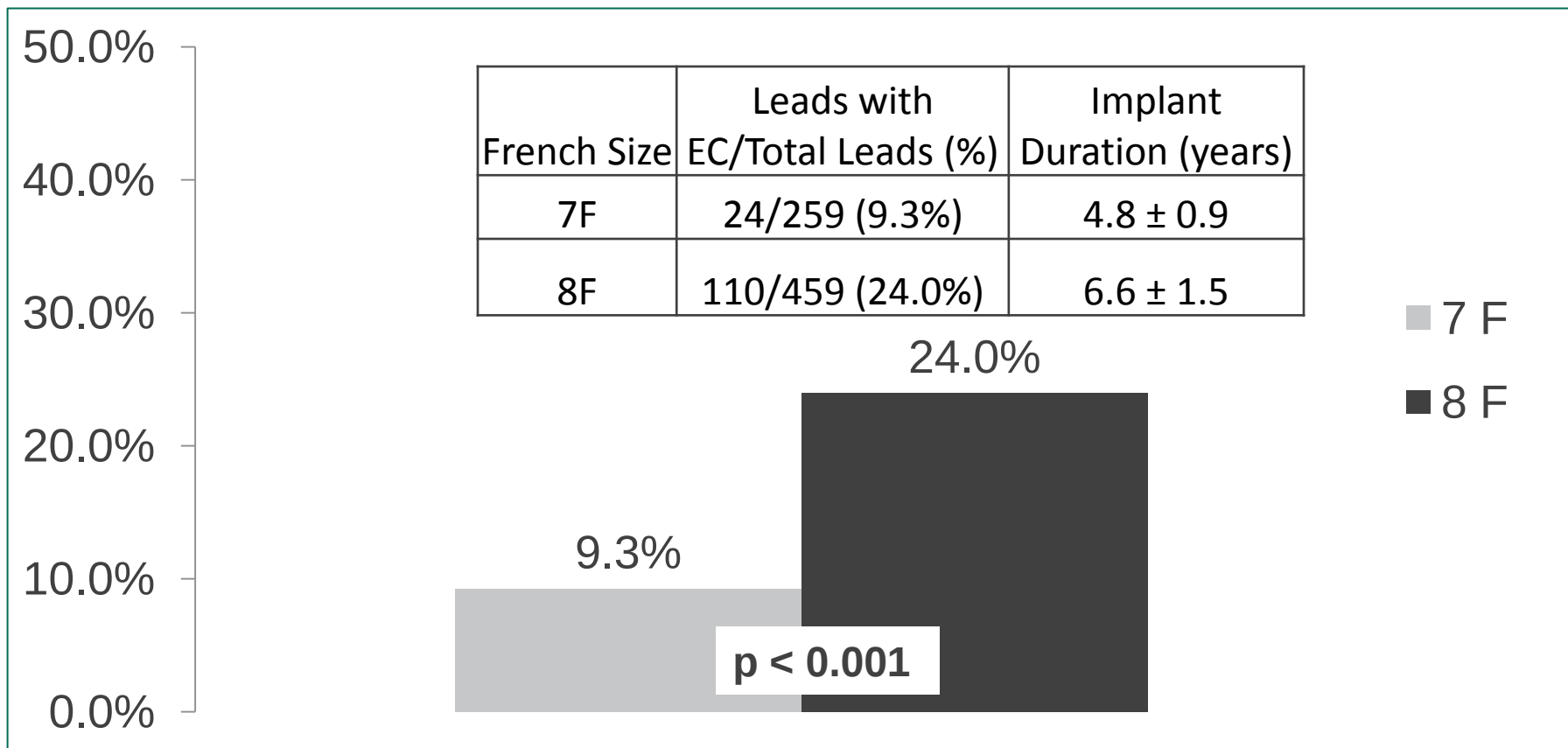
Implant Duration



Prevalence of EC in the Total Cohort

7F versus 8F Leads

Overall prevalence of EC in 7F leads is significantly lower than 8F leads ($p < 0.001$)



NUMERATOR: Total number of leads with ECs

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DENOMINATOR: Total number of leads



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Prevalence of EC

French Size and Coil Configuration

	Prevalence of EC N (%)	Implant Duration (All leads)
7F Single (N = 47)	2 (4.3 %)	4.4 ± 1.0 years
7F Dual (N = 212)	22 (10.4 %)	4.9 ± 0.8 years
8F Single (N = 52)	15 (28.9 %)	6.3 ± 1.4 years
8F Dual (N = 407)	95 (23.3 %)	6.7 ± 1.5 years

- Not enough single coil enrollments* to perform statistically powered sub-analyses of single vs. dual coil leads (99 total single coil leads or 13.8% of total)
- 8F dual coil leads have higher prevalence of EC compared to 7F dual coil leads ($p < 0.001$)
- 8F single coil leads have higher prevalence of EC compared to 7F single coil leads ($p = 0.001$)

Prevalence of EC

Leads with Implant Duration $\leq$ 6 Years

To account for differences in implant duration between the 7F and 8F lead cohorts, an analysis was performed for leads with implant durations up to 6 years (includes 256 of 259 7F leads):

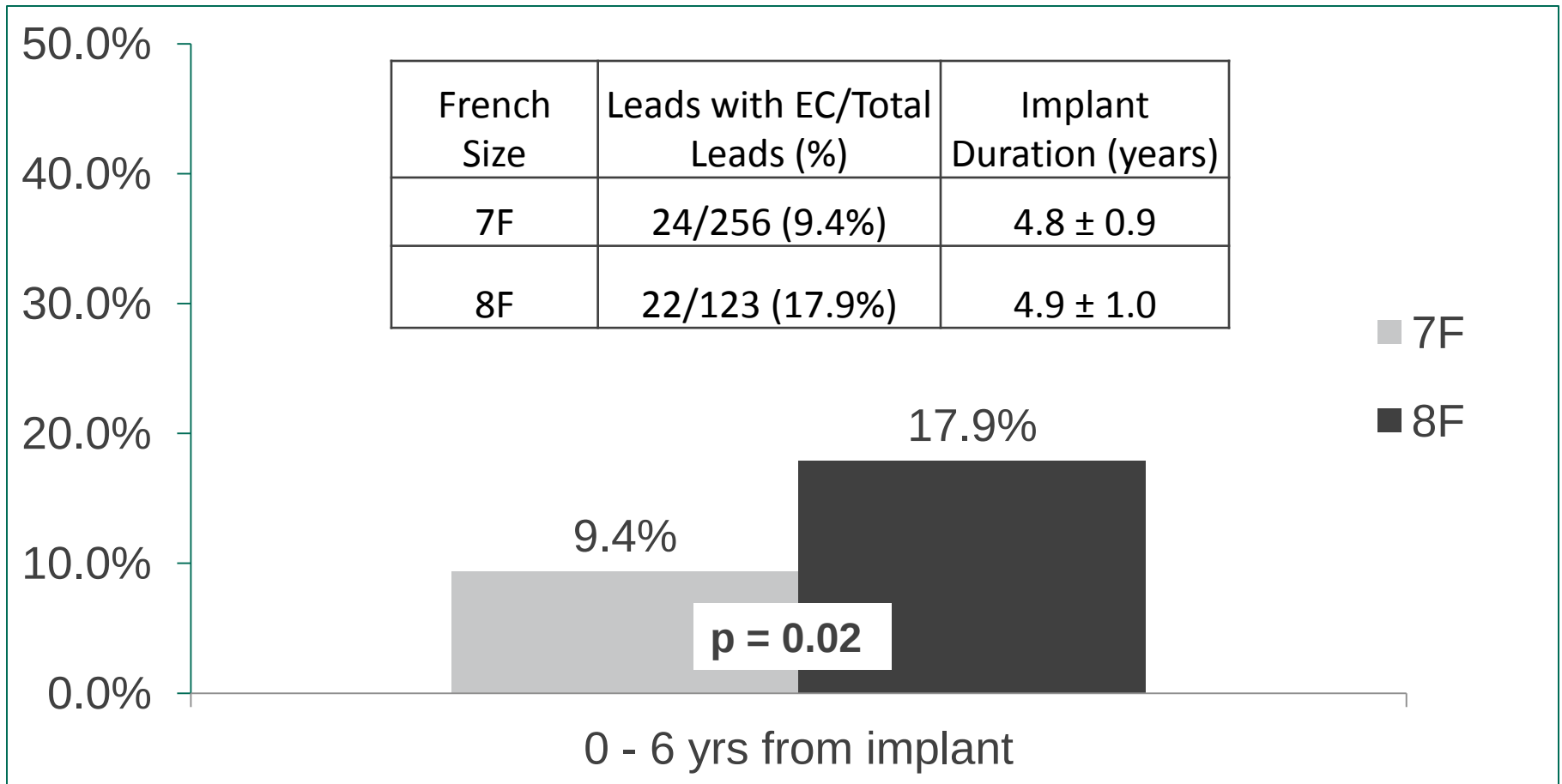
French Size	No. Leads	Implant Duration (years)*
7F	256	4.8 $\pm$ 0.9
8F	123	4.9 $\pm$ 1.0

* Difference in implant duration not significant ($p = 0.50$)



Prevalence of EC

Leads with Implant Duration ≤ 6 Years



NUMERATOR: Total number of leads with ECs aged ≤ 6 years

14 **DENOMINATOR:** Total number of leads with implant duration ≤ 6 years

Predictors of Externalized Conductors

- Lead size was a significant predictor ($p < 0.001$) of conductor externalization
- Univariate analyses of the following variables did not yield any predictor of conductor externalization
 - Age
 - Gender
 - LVEF
 - BMI
 - Vascular access.



Conclusions

- The prevalence of externalized conductors in this study is in the range of that reported in other studies.
- The prevalence of externalized conductors was lower in 7F leads as compared to 8F leads, even when accounting for implant duration.
- These differences reflect the significant design changes made from 8F (1500 series) to 7F (7000 series) leads.
- Phase II of the study will continue for a minimum of 2 years of follow-up with a focus on the incidence of electrical malfunctions in leads with externalized conductors. The prevalence of externalized conductors reflects a visual anomaly only and not electrical failures. These data will be collected as part of Phase II of the study.
- The St. Jude Medical independent Leads Medical Advisory Board has reviewed the data and recommends no changes to existing patient management recommendations.

