The evolution of transvenous ICD leads from the Mirowski/Mower prototype to today

Seah Nisam and Shantanu Reddy

Conflict of Interest

Seah Nisam – ex employee (Director Medical Science) Boston Scientific Corporation (BSC)

Shantanu Reddy – current employee, BSC

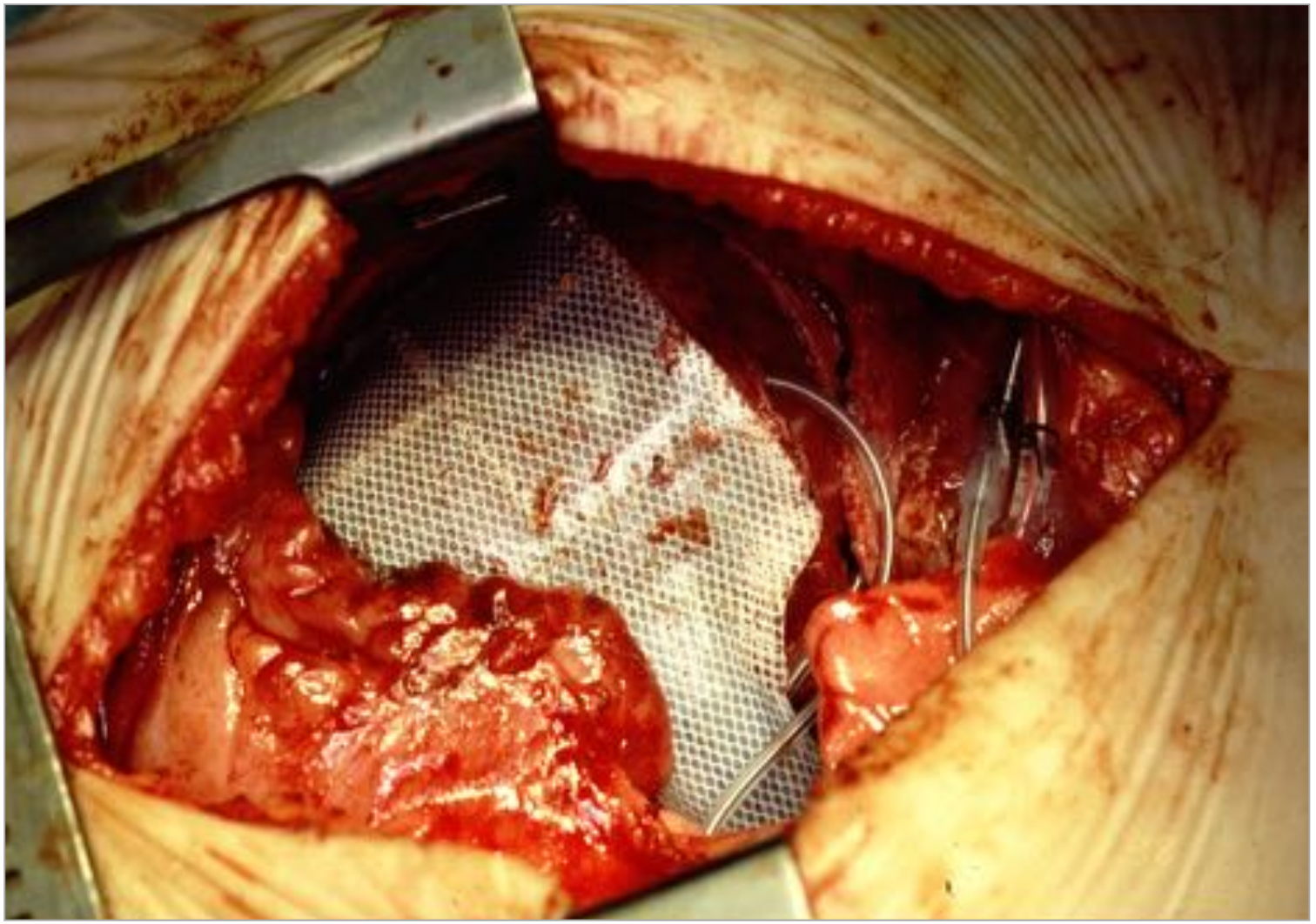
History of *one* family (ENDOTAK) ICD leads

- No claims of superiority or criticisms of other ICD leads.

- We cover the multiple problems encountered by one manufacturer*, and the technological improvements to overcome them.

* CPI/Guidant/Boston Scientific

First decade: thoracotomy implantation with one or two “patch” leads



Feasibility and Effectiveness of Low-Energy Catheter Defibrillation in Man

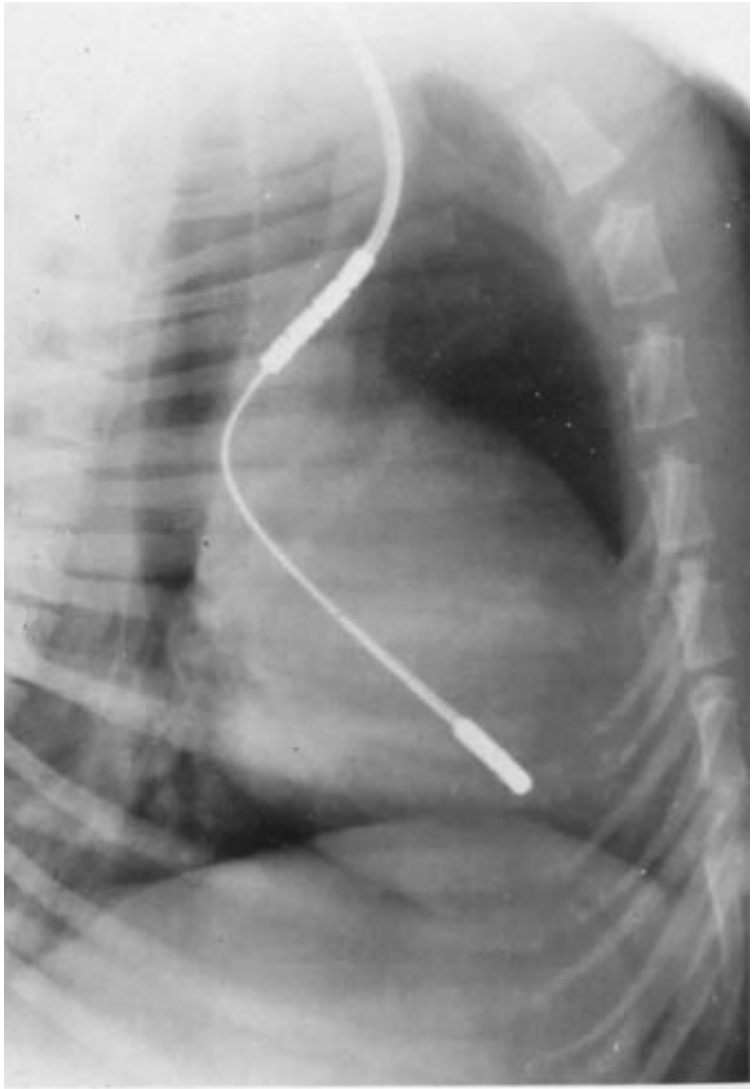
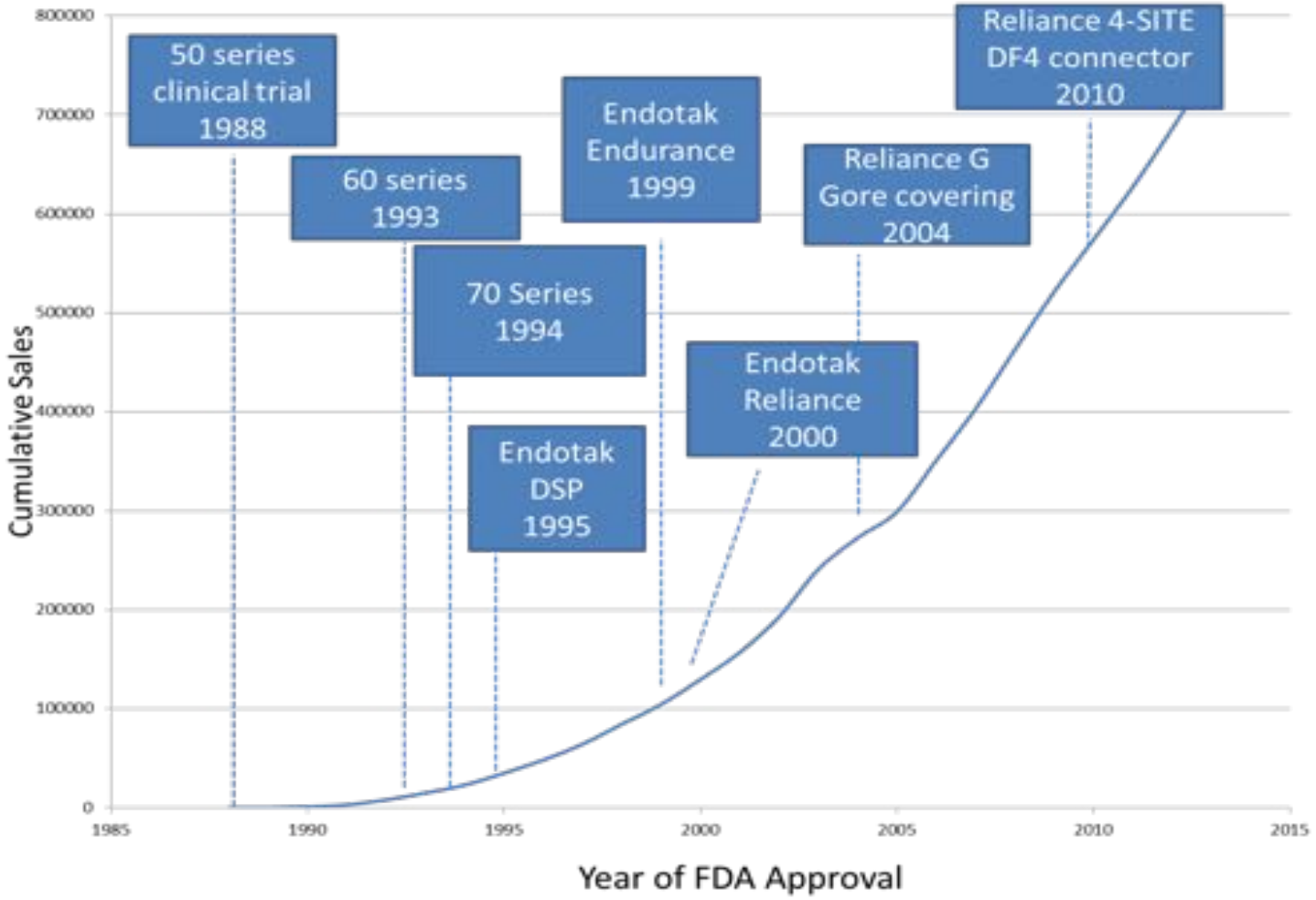


Figure 1

Mirowski, Mower, Gott, Brawley.
Circulation 1973;57:79-85.



Time line & accumulative implants for ENDOTAK and subsequent iterations

Europace (2015) **17**, 677-688

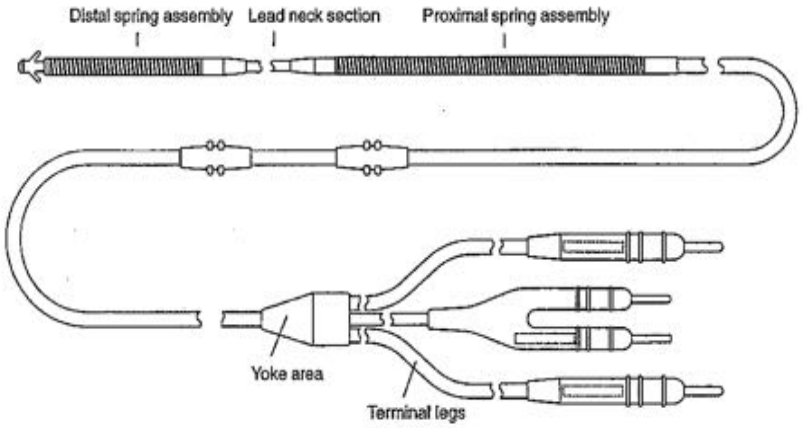
REVIEW

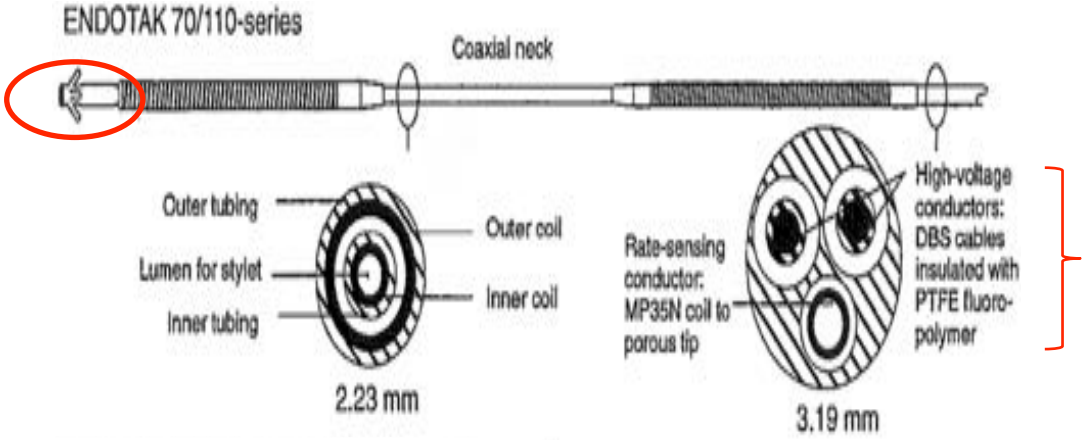
The story of . . . a lead

Seah Nisam[1]* and Shantanu Reddy[2]

Few examples of technological solutions to real-world clinical challenges

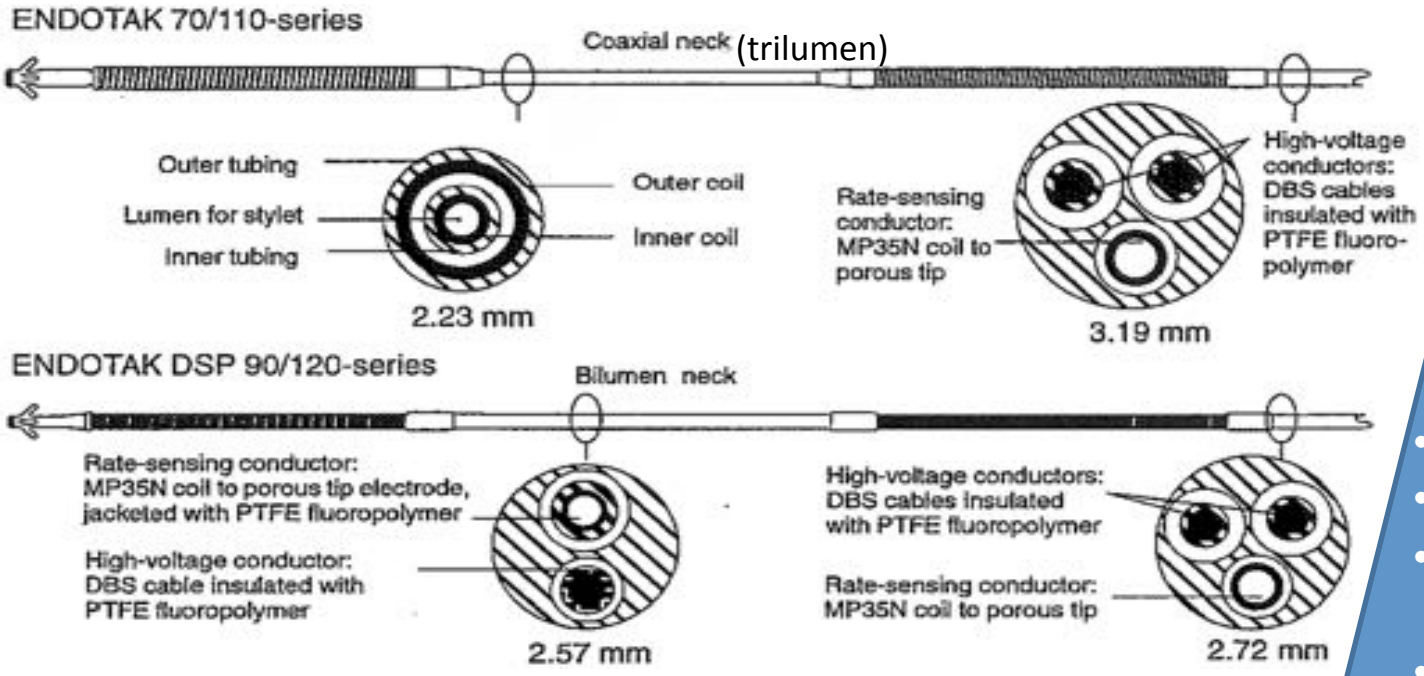
ENDOTAK C (50, 60 and 70 series)





Improved fatigue resistance – overcame 50-series fracture problem

ENDOTAK 70 vs ENDOTAK DSP



- Less stiff
- Thinner
- Better extraction
- Nusil (better abrasion resistance)

70 series: ribbon wire shock coil

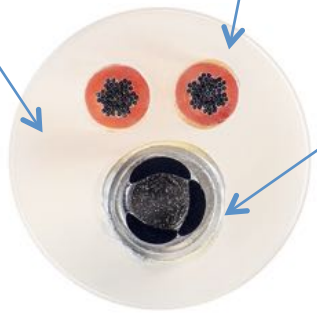
90 series: round wire shock coil

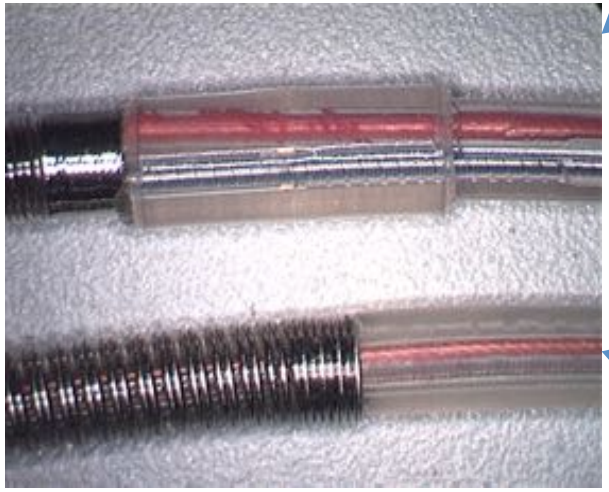
ENDURANCE → RELIANCE

Silicone rubber core structure

PTFE coated 7X7 316L stainless steel silver DBS cable

Outer layer of silicone rubber





ENDURANCE (1997)

- High impedance electrode (reduced battery drain → longer p.g. life)
- Transition components conductor… affects passage and complicates extraction

RELIANCE (2000)

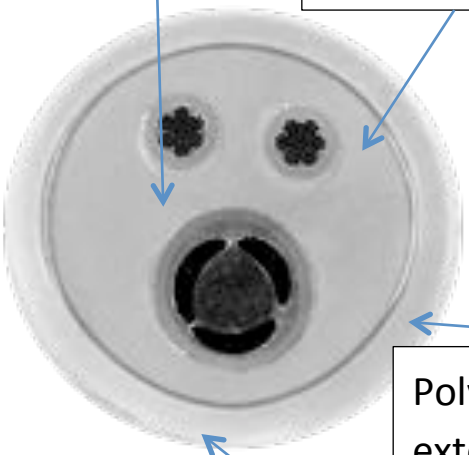
- Transition step eliminated (↑ Extraction & Reliability)
- Silicone insulation 2X (Reliability)

Gore ePTFE shock electrode covering to prevent tissue ingrowth onto the shock electrode

RELIANCE G (2004)

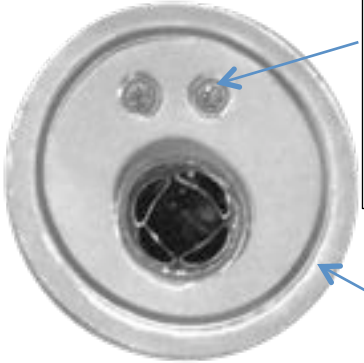
Gore covering reduces extraction time and complexity (many studies)

RELIANCE 4-SITE (2010)



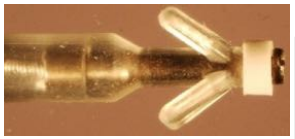
RELIANCE 4-FRONT (2012)

Gore ePTFE covering anchor



Low Titanium MP35N-Ag core (DFT) 19 strand cable conductor coated with ETFE

Same wall thicknesses as Reliance and Reliance 4-SITE

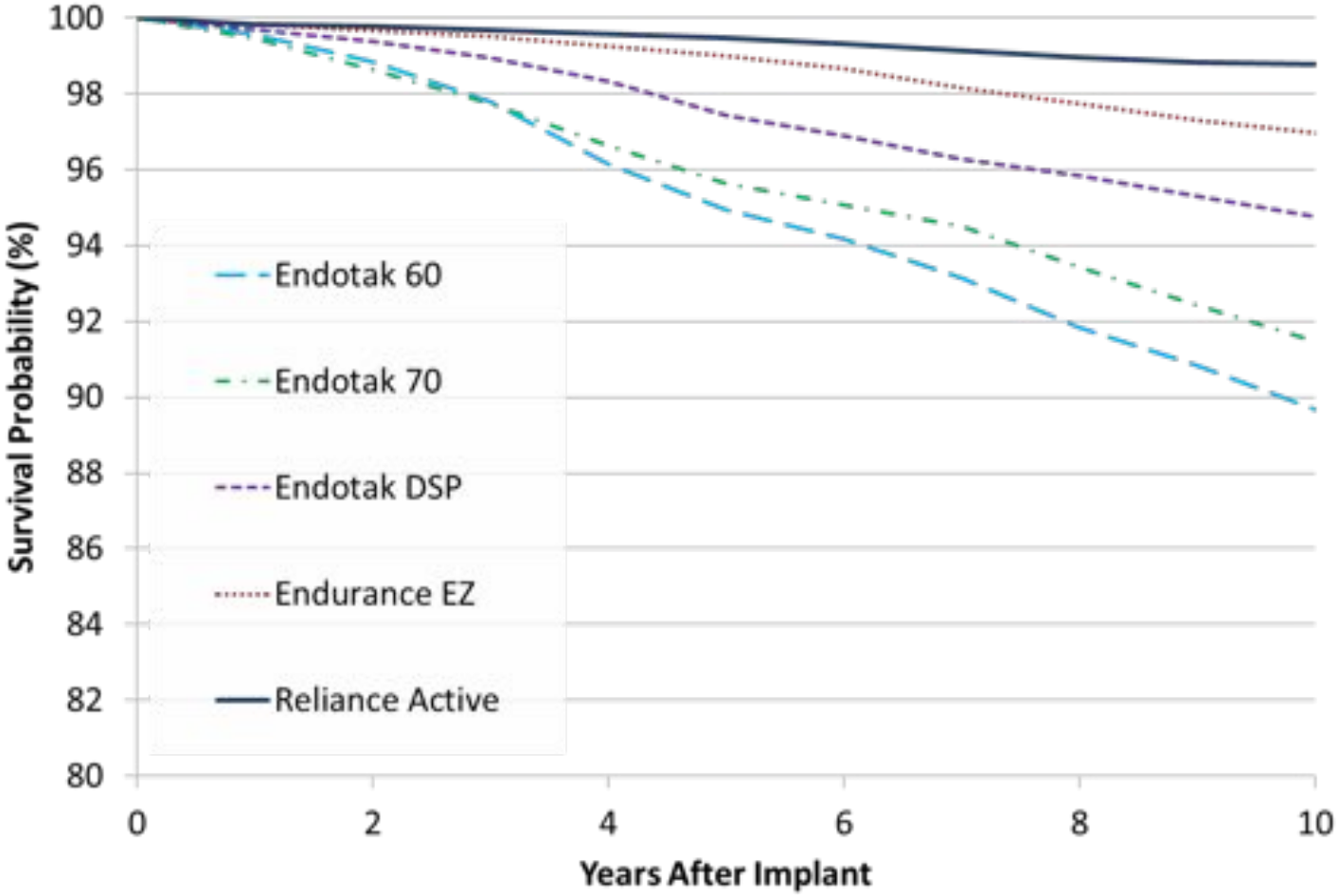


IROX active and passive fixation electrodes

RELIANCE 4-FRONT

Thinner without compromising insulation thickness

Reliability of successive generations of ENDOTAK (and iterations) ICD leads



Conclusions

- ~ 50 y from initial Mirowski prototype to today
- ~ 0.9 M patients implanted with “ENDOTAK family”
- Many of the original principles still adhered to today
- In the case of BSC, focus on *incremental* development
- The reliability improvement generation to generation is the key takeaway point. Should be R&D focus
- Need for continued close collaboration between physicians and industry, focused on reliability & longevity of the leads as critical components of ICDs

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Thank you!

I welcome your questions…