DESIGN OF PM AND ICD LEADS:
Miami Lead Management Symposium
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<table>
<thead>
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<th><strong>Conflicts of Interest</strong></th>
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<td><strong>Grant/Research support:</strong></td>
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<td>Honoraria: Biosense Webster, Boston Scientific Corp., Medtronic, St. Jude Medical, Biotronik, St Jude Medical</td>
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Learning From Our Mistakes: The Dark Side

Removal of a broken Accufix “J” shaped retention wire

80A and biodegradation of inner insulation

Source: Medtronic Arrhythmia Management brochure UC9502314EN. 1995
Basic Concepts: PM/ICD Leads

• Electrode
• Conductor
• Insulation
• Connector Pin
• ICD Coils
Lead Body: Extractability considerations

Isodiametric
Single vs. Dual Coil
Lead and Coil coatings
Isodiametric lead body . . . improved maneuvering in tortuous anatomy and improved and easier extraction because diameter is the same along the lead body: from suture sleeve to tip, mostly isodiametric as well

- Smooth transitions
  - Reduced diameter enables smaller introducer without compromising insulation thickness
  - Less likely to catch on introducer
  - Easier extraction!
Pacemaker Lead Body Design

Co-axial

- Outer insulation
- Anode coil
- Inner insulation
- Cathode coil

Benefits:
- Allows extension & retraction
- Easier to manufacture

Co-Radial

- Outer insulation
- Anode coil with integral insulation
- Cathode coil with integral insulation

Benefits:
- Allows smaller diameter
- Redundant insulation
Electrode

SweetTip
Active Helix and Porous Mesh

Selute
Porous Mesh

Platinum, platinum-iridium, Elgiloy (alloy of cobalt, iron, chromium, molybdenum, nickel and manganese), carbon coating of a titanium or graphite core and irdium oxide coating.

Microscopic corrosion has been noted with platinum-iridium and Elgiloy. Without consistent clinical side effects.
Lead Tip: Extractability considerations

**Passive vs. Active Lead Extraction**

Tensile force on endocardial pacing leads three months after implantation in 10 mongrel dogs receiving 5 tined and 5 active fixation leads

- Passive Fixation: 1174 +/- 369g
- Active Fixation: 291 +/- 174 g

Lead Conductors

• Alloys for conductors used in pacing leads include: MP35N (cobalt, nickel, chromium and molybdenum), Elgiloy, and nickel silver

• Conductor coils may be unifilar, multifilar and cable design

• Single strands of conductor wire may be coated with ethylene tetrafluoroethylene (ETFE) insulation
Defibrillation Conductors and Electrodes

- To deliver current efficiently, conductors with low resistance metals used to minimize voltage losses
- Composite wire of drawn brazed strand or drawn filled tube
- Wires contain silver with stainless steel, MP35N (alloy of nickel, cobalt, chromium and molybdenum), titanium or another high strength metal
- Outer layer of platinum or platinum or iridium added
- Wires are formed into coils or twisted into cables
- Choice for materials somewhat standard
- High conducting, low corrosion, biocompatible and biostable
Fatigue Fracture

This lead had reported symptoms of inappropriate shocks, noise and oversensing. Upper right surface of SEM photo at right is smooth, indicating early repeated surface-to-surface translation, and striated surface area indicates later crack propagation via cyclic loading.
Lead Insulation

• Extend from tip of lead to lead connector

• Polyurethane and silicone. Current polyurethane is Pellethane 55D A because earlier polyurethane was subject to MIO, environmental stress cracking. Composed of a hard and soft segment, the ratio determines the durometer-which is a measure of hardness.

• Silicone has high biocompatibility and biostability, but low tear strength and high coefficient of friction. Polyurethane has high tensile and tear strengths.
Surface looks crazed/discolored
   Not a problem unless the cracks propagate
Newer polyurethanes can display this after years of implant or under high stress conditions but cracks do not propagate
Use higher durometer and annealing process to decrease risk
ETFE: ethylenetetrafluoroethylene
• Can be applied in a thin layer that still has sufficient dielectric strength and is very resilient
• Has not proven to be a good “sheath” type of insulator
  – Difficult to manufacture

PTFE: polytetrafluroethylene
• Has to be applied in a thicker layer when used to coat wire/cable
• Has proven to be a good “sheath” insulator
• Ease of use in manufacturing, can be heat shrunk, etc.

Both are durable & biocompatible & strong & abrasion resistant & increasingly used fluoropolymers
Insulation Abrasion

Lead body insulation erosion

• Increase thickness of existing material
• Make existing material more abrasion-resistant
• Change to alternate, more abrasion-resistant material

Lead body insulation degradation

• Polyurethane failure mode
• 80A durometer polyurethane susceptible
• Metal Ion Oxidization (MIO)
• Environmental Stress Cracking (ESC)
Insulation Abrasion Types

**Lead-on-Lead:** Most often located within the pocket, this abrasion type has a morphology which mirrors the shape of the lead-lead interaction surfaces – typically elongated ovals – and typically has a smooth and shiny abrasion surface.

**Lead-on-Can:** This abrasion type has a morphology which is dependent on lead dress and the particular can surface shape; the abrasion surface can be smooth but is usually rough, and is not shiny; the exposed surface is usually irregularly shaped or jagged.

**Lead-on-Tissue:** This abrasion type has a morphology which is dependent on the location and type of tissue it interacts with; it may be with the valve, calcification in the heart or the vasculature, or other structure.
Insulation Abrasion Example

This lead had symptoms of oversensing and noise.
Insulation Abrasion Example

This lead (same as previous photo) had reported symptoms of oversensing and noise.
Lead Abrasion

RA lead

RV lead
EXPLANTED SILICONE RUBBER LEADS

*Abrasion:* Implanted 4 years in human

Silicone rubber is well known to be susceptible to *abrasion wear* and *cold flow* due to *cyclic compression*.

*Wear* comes from lead-to-lead, can-to-lead & yoke-to-lead mechanical contact.

Cold Flow & Abrasion; Implanted 1 year in human

ICD Lead Abrasion

Abrasion; Implanted 11 Months
Lead Body Insulation

Abrasion resistance – comparing two different silicone rubber tubing materials

![Silicone Rubber Abrasion Testing](image)
Pacing Lead Body Designs: Select Secure™

Lumenless Coaxial lead Body Design

- Polyurethane 55D
- Silicone Rubber
- Cable
- Multi-filar Coil
- ETFE Insulation Coating
- Silicone Rubber
Lumenless Leads

• Lumenless leads utilize a cable to the tip assembly for tensile properties.
• If laser is required a Cook’s BULLDOG™ Lead Extender can be used to lock into the cable conductor.
Fixation mechanism of the 4195 StarFix lead with retractable tines.

Source: H. Nägele, M. Aziz, S. Hashagen, M.A. Castel and S. Behrens
Twelve patients underwent transvenous lead extraction (TLE) of Medtronic StarFix™ lead. The cohort was 83% male with mean age 71 ± 14 years. Average implant duration was 14.2 ± 5.7 months (2.3–23.6 months). All leads but one were removed for infectious indications (67% systemic infection). At the time of explant, the fixation lobes were completely retracted in only 1 of 12 cases & ES assistance was required for lead removal in all cases (58% laser, 25% cutting, 25% mechanical, and 25% femoral). The majority of cases required advancement of the sheath into the CS (75.0%) and often into a branch vessel (41.7%). One lead could not be removed transvenously and required surgical extraction. There were no major complications. Examination of the leads after extraction frequently revealed significant tissue growth into the fixation lobes.

Bottom Line: BEWARE !!!
Multilumen lead design

- Bear Paw design maximizes insulation thickness
- Designed to be durable and crush resistant by placing conductors in oversized lumens
- Large-diameter lumens allow displacement without stress on drawn brazed strand (DBS) and pace/sense conductors
Lead Construction

Multilumen lead designed for durability and crush resistance

- Redundant silicone layers and PTFE insulate/protect conductors
- Silicone sleeve applied over multilumen silicone tubing

![Diagram of lead construction with labels for redundant silicone layer, multilumen tubing, and PTFE coated conductors.](image)
Cross Sectional ICD Lead Design

BSX 0181

SJM Riata, Durata

Figure from Ellis, CR “Complications of small caliber ICD leads” HRS 2010.
Conductor Coil Design Key Parameters

- **Coil Wire Diameter**

- **Coil Filarity**: The number of separate wires in the coil

- **Pitch**: A dimension which is a function of the individual coil wire diameter x the number of filars in the filar set + the space between filar sets

- **Coil Outer / Inner Diameter**: The dimension of the coils diameters
Coil Design

- Multiple filars (wires) are used to keep resistance low and to tailor stiffness of the coil
- The tighter the wire is wound (coil diameter), the more stressed the wire
- The more wires there are, the higher the pitch
Complicating factors

- Fibrosis almost certainly explains the difficulty that can be encountered when transvenous ICD leads are explanted.
- Tissue ingrowth into the lead & coils is one of the complicating factors in lead extraction.
- Thrombus formation on the lead is the initial response to intravascular foreign body. Thrombus eventually organizes with fibrosis especially at all contact points.
- Fibrosis propagates along the lead and becomes denser over time.
Tip. Fibrous capsule. Outer zone with inflammatory cells. Occasional cells inside the pores. Bar 50 m (Patient 1Va).
Background: Shocking Electrode Coil Design

Ribbon wire vs. Round wire
Silastic backfill designed for limiting tissue ingrowth
All use round wire for coils
Bonded coils: MDT-SJM, ePTFE-BSc
Bare coil vs. MA vs. ePTFE

1) No Coating

2) Medical Adhesive Back Filled (MABF)

3) ePTFE coated
ePTFE Covered Shocking Coil Study

• Goal – Compare extraction of GORE® coated shocking coils to standard shocking coils
  • CS tachy leads built with:
    – GORE® coated coils
    – Bonded coils
    – Non-bonded coils
  • Sheep implanted for 6 and 14 months (4 / study arm)
  • Extraction attempted with simple traction or Electro-Dissection Sheath
  • Histology of implanted lead/tissue

1. Wilkoff, Bellott, Love et al. Improved Extraction of ePTFE and Medical Adhesive Modified Defibrillation Leads from the Coronary Sinus and Great Cardiac Vein. PACE, Vol. 28, March 2005
Extracted coronary sinus defibrillation lead comparisons:
A) “Extracted control lead. Note that the shocking coil is covered with connective tissue and has been stretched during the extraction process.
B) Extracted ePTFE lead with connective tissue attachment at the tip.
C) Extracted ePTFE lead. Note that the lead is intact and no connective tissue is present.”

1. Wilkoff, Bellott, Love et al. Improved Extraction of ePTFE and Medical Adhesive Modified Defibrillation Leads from the Coronary Sinus and Great Cardiac Vein. PACE, Vol. 28, March 2005
Pore size dictates performance of ePTFE

• Pores smaller than cells (< 5 µ) prevent tissue in-growth
  – Ex: RELIANCE G ePTFE covering

• Pores larger than cells (> 20 µ) promote tissue in-growth
  – Ex: GORE-TEX™ vessel graft

1. Wilkoff, Bellott, Love et al. Improved Extraction of ePTFE and Medical Adhesive Modified Defibrillation Leads from the Coronary Sinus and Great Cardiac Vein. PACE, Vol. 28, March 2005
Principles of ePTFE

Histology shows function of ePTFE

With ePTFE: Connective tissue does not show in-growth

Without ePTFE or MA: Connective tissue in-growth behind coils, next to lead body
Results of the study showed that ePTFE covering:

- Prevented tissue ingrowth into coils
- Fibrotic capsule was smaller than control and MA backfilled leads

1. Wilkoff, Bellott, Love et al. *Improved Extraction of ePTFE and Medical Adhesive Modified Defibrillation Leads from the Coronary Sinus and Great Cardiac Vein*. PACE, Vol. 28, March 2005
ePTFE (Gore) Lead Histology

1. Wilkoff, Bellott, Love et al.  
   Improved Extraction of ePTFE and Medical Adhesive Modified 
   Defibrillation Leads from the Coronary Sinus and Great Cardiac Vein.  
   PACE, Vol. 28, March 2005
Coil Design

• As coils are made smaller, coil stress increases and fatigue life can be reduced

• With the market drive to downsize, coil stress has increased and insulation thickness has decreased with coaxial designs

• Fewer filars, large coil diameter means reduced coil stress and therefore very resilient to fatigue fracture
An Engineering Theory For Coil Fracture

The coil bends sharply near binding forces (i.e. tight suture sleeve ties), the result can be high induced shear stress in the coil, which can exceed the coil wire's design limit, creating high risk for coil fracture.
Clavicle-First Rib Ductile Fracture

This lead had reported symptoms of inappropriate pacing and oversensing. Necking of the filar(s) is seen in both the photo and SEM image, as well as reduction in overall coil diameter indicating crush.
Conductor Coil Design & Stress Levels
(Based Upon Engineering Computer Modeling -- Flexing @ 0.5” Bend Radius; +/- 90º )

<table>
<thead>
<tr>
<th>Lead / Parameter</th>
<th>Filarity</th>
<th>Wire Diameter</th>
<th>Coil Outer Diameter</th>
<th>Spacing Between Filar Groups</th>
<th>Shear Stress Induced @ 0.5” Bend Radius</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cenelec Standard Coil</strong>: Considered worst case; used by industry for design limits for coils (From obsolete MDT 4016 lead)</td>
<td>2</td>
<td>0.009”</td>
<td>0.036”</td>
<td>0.0024”</td>
<td>45,500 psi</td>
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<tr>
<td>ICD Brand Lead 1</td>
<td>4</td>
<td>0.006”</td>
<td>0.0285”</td>
<td>0.002”</td>
<td>43,000 psi</td>
</tr>
<tr>
<td>ICD Brand Lead 2</td>
<td>8</td>
<td>0.004”</td>
<td>0.025”</td>
<td>0.004”</td>
<td>39,000 psi</td>
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</tbody>
</table>

Note: The **shear stress** is the stress induced in the coil wire when the coil is flexed in a specific bend radius. **The higher the shear stress, the greater the risk for flex fatigue fracture at or near the flex site.**

**Coils used in any lead should have shear stress < “Cenelec Coil”**
Tensile Strength ?’s

1) Lead strength - what force will leads tolerate? Is a defibrillation lead tolerance different than a pacing lead?

• Axial load durability: pacing and defibrillation leads must meet axial strength requirements as defined by the international standard

• Terminal connector insertion/withdrawal force: terminal connectors must be able to be inserted into/withdrawn from an appropriate IS-1 header port (or appropriate test block) with a force not to exceed 14 N.

• Composite pull strength: leads are subjected to a tensile force to destruction - a minimum 1.1 lb extraction force from terminal pin to the distal tip fixation. There is a more stringent test requirement of 2.2 lb for welded connections, as they are presumed to be the "weakest link".
2) Conductor strength - is there a difference with pace/sense conductor strength vs. HV coil strength?

Pace/sense conductors are generally coiled wires and this geometry will endure higher axial elongation than HV conductor cables, which are braided wires and are closer to straight wires than the coils. The conductor strength depends on the conductor material and treatment prior to lead construction.
Lessons from Larry Epstein

• J Card EP
Volume 14, Issue 4,
344–349, April 2003
SVC Defibrillator Coils Make Transvenous Lead Extraction More Challenging and Riskier

- Retrospective analysis from 9 high volume centers
- Outcomes based on HRS consensus document
- From 1/2000 to 2/2011
- 2201 pts underwent TLE of 2274 ICD leads
- 82% with single coil, and complete procedural success in 98.8%
- 18 major complications, all involving dual coil ICD leads (p=0.03). Ten cases of tamponade, 4 cases of tamponade required urgent/emergent thoracotomy/sternotomy and all tears/avulsions in RA/SVC junction.
There was no fibrosis where ePTFE covered the shocking coils. Alternatively, 23 of 99 (23%) noncoated leads demonstrated fibrosis adherent to the shock coil. There were no procedure-related complications in either group.

Conclusions: Compared to noncoated leads, ePTFE-coated leads are associated with shorter extraction times and are less likely to require extraction tools for removal. The difference is likely related to the absence of fibrosis over the ePTFE-coated high-energy coils. (PACE 2013; 00:1–7)

Single center experience from Kutalek et al. recorded prospectively in a database August 2004-December 2009
Lead Insulation

Medtronic Sprint Quattro®

Guidant ENDOTAK RELIANCE®

St. Jude Riatta®

Insulated cable
Silicone tubing
PTFE tubing
Inner coil
Riata & Fidelis Lead Body Design Differences

ALL SJM RIATA LEADS

- Oversized Lumen Provide Crush Force Absorption
- Symmetrical Design With Protected Central Coil in the lead body’s neutral stress central axis
- 3 Pair of Dual, Redundant, Protective ETFE Insulated Cables (Always Present, Even If Not Needed)
- Protective Optim™ Insulation Overlay

MEDTRONIC FIDELIS LEADS

- Single Offset Cables (Middle Cable is Pace-Sense Anode Cable)
- Non-Symmetrical Design With Unprotected Offset Coil
- Multi-Lumen Silicone Rubber Insulated Cables
- Polyurethane (80A) Overlay
Multilumen ICD Lead Designs

Medtronic Quattro Secure

St. Jude Medical Riata
Cable Movement, Creep, Disruption
Role of ETFE

- ETFE protects cables from silica.
- ETFE has not been used as the primary insulation for an ICD or pacing lead.
- ETFE coating is 1.5 mils thick.
- MAUDE data (SJM) suggests ETFE has been abraded in some returned leads.
- **MAY BE LARGE CLOTS ON EXTRUDED RIATA LEADS**
Small Caliber ICD Lead Failures

Table 2: Complications listed by patient

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age</th>
<th>Lead model</th>
<th>Implant date</th>
<th>Duration, days</th>
<th>Pacing system</th>
<th>Complication</th>
<th>Additional notes</th>
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<tr>
<td>1</td>
<td>58</td>
<td>1580</td>
<td>1/29/2007</td>
<td>71</td>
<td>WFI</td>
<td>Thresh</td>
<td>Screw failure at reposition</td>
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<tr>
<td>2</td>
<td>64</td>
<td>1580</td>
<td>2/5/2007</td>
<td>11</td>
<td>WFI</td>
<td>Thresh</td>
<td>Cardiac tamponade</td>
</tr>
<tr>
<td>3</td>
<td>77</td>
<td>1580</td>
<td>4/3/2007</td>
<td>111</td>
<td>WFI</td>
<td>Perfusion</td>
<td>Pleuritic pain</td>
</tr>
<tr>
<td>4</td>
<td>61</td>
<td>7000</td>
<td>7/20/2007</td>
<td>3</td>
<td>WFI</td>
<td>Perfusion/Thresh</td>
<td>Abrupt rise in impedance during implant</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>7000</td>
<td>8/8/2007</td>
<td>9</td>
<td>BIV</td>
<td>Fracture</td>
<td>Dislodgement at revision</td>
</tr>
<tr>
<td>6</td>
<td>67</td>
<td>6949</td>
<td>1/23/2007</td>
<td>120</td>
<td>BIV</td>
<td>Fracture</td>
<td>No effusion, diaphragm stimulation</td>
</tr>
<tr>
<td>7</td>
<td>80</td>
<td>6949</td>
<td>3/7/2007</td>
<td>0</td>
<td>WFI</td>
<td>Thresh</td>
<td>Present at 2 months, persisted</td>
</tr>
<tr>
<td>8</td>
<td>45</td>
<td>6947</td>
<td>3/16/2007</td>
<td>28</td>
<td>WFI</td>
<td>Thresh</td>
<td>&gt;50% Decrease in R wave, T-wave oversensing</td>
</tr>
<tr>
<td>9</td>
<td>69</td>
<td>1580</td>
<td>3/26/2007</td>
<td>1</td>
<td>BIV</td>
<td>Thresh</td>
<td>Pleuritic pain</td>
</tr>
<tr>
<td>10</td>
<td>60</td>
<td>7000</td>
<td>5/9/2007</td>
<td>111</td>
<td>DDD</td>
<td>Thresh</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>73</td>
<td>7000</td>
<td>7/17/2007</td>
<td>41</td>
<td>WFI</td>
<td>Sensing</td>
<td></td>
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<tr>
<td>12</td>
<td>40</td>
<td>7000</td>
<td>8/15/2007</td>
<td>16</td>
<td>DDD</td>
<td>Perfusion</td>
<td></td>
</tr>
</tbody>
</table>

Small caliber failure 11/138  8%
Large caliber failure 1/167  <1%
Physical ICD Lead Characteristics

- BSX 0185/0184 lead testing by Medtronic and St. Jude Medical shows tip pressure of 1.6-1.8 psi.

- 1580 = stiffest lead, 7000= thinnest outer insulation.

C Ellis, J Rottman, *Heart Rhythm* Vol.6, No.5, 619-624 May 2009
Two areas of conductor extrusion identified. Stylets (St Jude Medical “soft”, “extra soft,” and Spectranetics clearing stylet) would not advance beyond the yellow arrow, although a #EZ locking stylet was ultimately advanced to the end of the lead.
Lower long-segment extrusions without visible changes in ETFE
Microscopic view:
irregular ETFE insulation in the near-SVC region
DF-1 Cable Fracture

This lead had reported symptoms of inappropriate shocks, oversensing and muscle stimulation. The cable experienced a high stress concentration due to a tight bending radius at the end of the terminal. This is evidenced by the uniform length of the strand breaks (almost a single plane) in the SEM image.
High Voltage Cable Fracture

HV cable fracture – two filars demonstrating possible fatigue fracture
Yoke/Connector: Potential failure modes

Yoke splice tube
DF-1 terminal
IS-1 terminal
Yoke Fracture

Fractured high voltage cable – proximal to the yoke stake block (panel B represents a closer view of the cable captured in the yoke stake block).
Yoke Fracture

Scanning electron micrograph showing the proximal side of the fractured cable (panel A); panel B represents a higher magnification micrograph, showing necking and ductile dimples consistent with overload (see blue arrows).
IS-4 Terminal Standard

The IS4/DF4 Standard Consists Of Two Connector Types

**High voltage** ICD Leads – DF4

Low  Low  High  High  

DF4-LLHH

Different Pin Designs (The IS4 pin is larger diameter. It will not fully insert into a DF4 connector cavity)

**Low voltage** LV Quadripolar Leads – IS4

Low  Low  Low  Low

IS4-LLLL

**Low** = Pacing/Sensing  // **High** = Cardioversion/Defibrillation
Conclusion

• Much to be learned about the process of lead maturation, lead inflammation, lead fibrosis, and how lead design effects lead function and lead extractability over time.