

Role of Lead Extractions In Clinical Practice

*Suneet Mittal, MD
Director, Electrophysiology Laboratory
Director, Electrophysiology Fellowship
The St. Luke's-Roosevelt Hospital Center
Columbia University College of Physicians & Surgeons*

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A number of large, randomized, clinical trials have demonstrated that patients with left ventricular dysfunction (ejection fraction $\leq 35\%$) due to either ischemic or non-ischemic cardiomyopathy benefit from ICD implantation.

Implantable Defibrillators

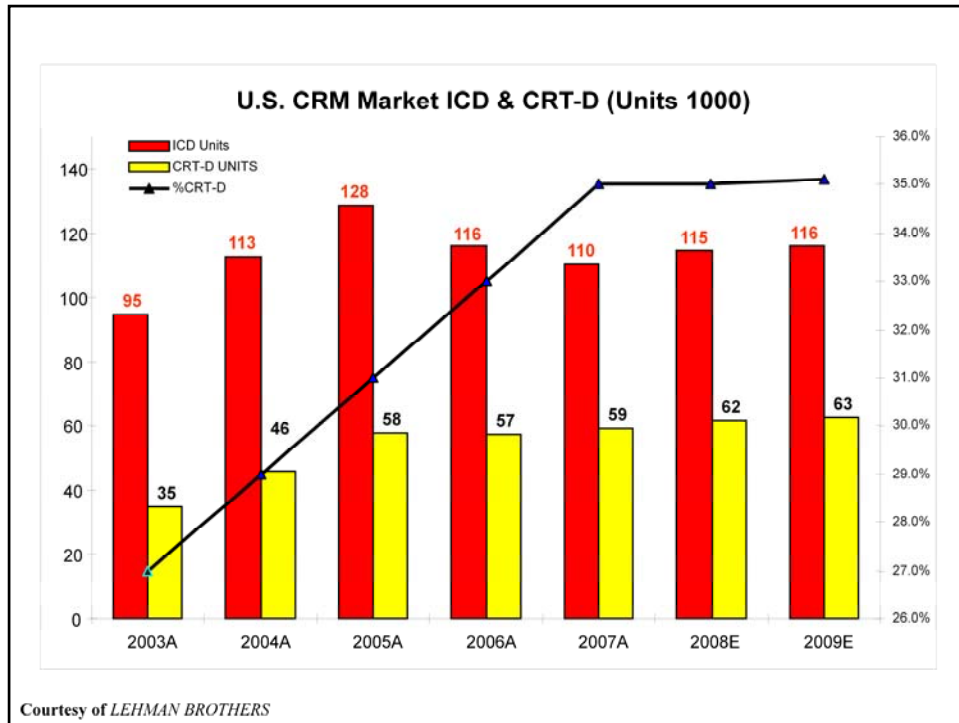


Courtesy of Medtronic

In conjunction with data from randomized clinical trials, dramatic improvements in ICD technology have facilitated an explosive growth in the number of implanted devices being implanted worldwide. One of the major improvements in technology has been the impressive reduction in the size of the ICD generator. This has allowed the routine implantation of devices in the subcutaneous (pre-pectoral) infraclavicular space.



We have also learned that some patients with left ventricular dysfunction benefit from cardiac resynchronization therapy (CRT). Today, these are patients with advanced congestive heart failure (NYHA Class II or IV) and evidence of mechanical dyssynchrony. The latter is currently defined by a QRS duration ≥ 120 msec. However, in the vast majority of these patients, a successful CRT system requires implantation of 3 leads, as opposed to the usual 1-2 leads.



This slides illustrates the maturation of the ICD industry (both with and without CRT capability) over the past 7 years. Nearly 200,000 units are being implanted annually each year in the United States alone. These numbers do not address at all the hundred of thousands of patients undergoing implantation of a permanent pacemaker.



However, when it comes to leads, a central caveat remains...

Class I Indications for Lead Extractions

- Sepsis (including endocarditis) as a result of documented infection of any intravascular part of the pacing system or pocket infection when the intravascular portion of the system cannot be aseptically separated from the pocket
- Life-threatening arrhythmia secondary to a retained lead fragment
- Retained lead or fragment that poses an immediate physical threat
- Clinically significant thromboembolic events caused by a retained lead or fragment
- Obliteration or occlusion of all useable veins with the need to implant a new pacing system
- Lead that interferes with the operation of another implanted device

Love CJ et al. *PACE* 2000; 23: 544-51

The Heart Rhythm Society has previously identified indications for lead extractions. This document is currently in the process of being updated. Nonetheless, current Class I indications for lead extractions include...

Class II Indications for Lead Extractions

- Localized pocket infection, erosion, or draining sinus that does not involve the transvenous part of the lead system, when the lead can be cut through a clean incision that is completely separate from the infected area
- Occult infection for which no source can be found and for which the pacing system is suspected
- Chronic pocket or lead insertion site pain that causes significant discomfort and is not manageable by medical or surgical techniques short of removal
- Lead that poses a potential, but not immediate, threat to the patient because of lead design or failure
- Lead that interferes with treatment of a malignancy
- Leads preventing access to the venous circulation for newly required implantable devices
- Non-functional leads in a young patient

Love CJ et al. *PACE* 2000; 23: 544-51

Class II indications for lead extractions include...

Indications for Lead Extractions

- Infections

Let's explore some of these in a bit more detail. Lead infections remain an **absolute** indication for extraction of the **entire** device system (generator *and* leads).

Cardiac Device Infections

- *Between 1990-1999*
 - 42% increase in the implantation rate of cardiac devices
 - 124% increase in the rate of cardiac device infection (CDI)

- *Presentations*
 - Pulse-generator pocket infection (local signs of inflammation at the generator pocket, including erythema, warmth, fluctuance, wound dehiscence, erosion, tenderness, or purulent drainage)
 - Blood-stream infection
 - With or without device-related endocarditis

Sohail MR et al. *JACC* 2007; 49: 1851-9

This recent study from the Mayo Clinic highlighted the growing rate of cardiac device implantations, which is (unfortunately) associated with an even faster rate of associated device related infections. These can present as either localized pocket infections or systemic infections.

Cardiac Device Infections: Pocket Infection



Courtesy of Boston Scientific

Shown is an example of an infected right infraclavicular ICD. There is marked erythema and swelling at the ICD site.

Cardiac Device Infections: Pocket Erosion



Courtesy of Boston Scientific

A catastrophic and feared presentation of a device infection in which the device has eroded through the skin surface. This type of situation can be treated only with extraction of the entire system (device and leads).

Cardiac Device Infections

- *Mayo Clinic retrospective review (189 patients with a CDI)*
 - Median time from device implantation to infection
 - ICDs: 125 days
 - PPMs: 415 days
 - Presentation
 - Pocket infection without blood-stream infection: 52%
 - Pocket infection with blood-stream infection: 17%
 - Device-related endocarditis: 23%
 - Bacteremia without localizing signs at pocket: 11%
 - Erosion of lead or device generator, without accompanying inflammatory signs at the generator site: 5%

Cardiac Device Infections

- *Mayo Clinic retrospective review (189 patients with a CDI)*
 - Microbiology
 - Coagulase-negative Staphylococci: 42%
 - *Staphylococcus aureus*: 29%
 - Gram-negative bacilli: 9%
 - Rare: polymicrobial, fungal

Sohail MR et al. *JACC* 2007; 49: 1851-9

Staphylococcus species (increasingly of the methicillin resistant variety) remain the most important organism in device related infections.

Cardiac Device Infections

- The Prospective Evaluation of Pacemaker Lead Endocarditis (PEOPLE)
 - *Prospective* study involving 6319 patients undergoing transvenous device implantation in 2000
 - *De novo* implants in 71% and pacemaker implants in 93% of cases
 - Infectious complications
 - 42 patients developed an infection over the first 12 months: 0.68 per 100 patients
 - *De novo* implants: 0.56 per 100 patients
 - Non *de novo* procedures: 0.99 per 100 patients
 - Risk factors for infections (adjusted odds ratio)
 - Fever within 24 hours of pacemaker implantation (5.83)
 - Temporary pacing before pacemaker implantation (2.46)
 - Early re-intervention for hematoma or lead replacement (15.04)
 - *De novo* procedures (0.46)
 - Failure to use antibiotic prophylaxis (0.40)

Klug D et al. *Circulation* 2007; 116: online

This French study provides a **prospective** look into the issue of device related infections. It should be kept in mind that this study was skewed towards *de novo* pacemaker implants. As such, patients undergoing ICD implants, especially CRT-D devices, were grossly underrepresented. This is important because CRT devices may be associated with a higher infection rate due to the increased length of these procedures.

De novo procedures were associated with nearly ½ the risk of infection. Other important variables that predicted infection were (1) failure to use intravenous antibiotic prophylaxis, (2) use of a temporary pacemaker prior to permanent pacemaker implantation, (3) fever within 24 hours of pacemaker implantation, and (4) early re-intervention for any reason. As a result, in our practice, we are vigilant to administer 1 gm of cefazolin (or vancomycin in patients with a penicillin allergy) with an hour of the skin incision. In addition, whenever possible, we try to avoid insertion of a temporary pacemaker, going directly to permanent pacemaker implantation instead.

Indications for Lead Extractions

- Infections
- Lead malfunctions

Another important cause for lead extractions is lead malfunction.

Lead Malfunctions: Telectronics Accufix Leads

- Recalled on 11/3/94 after 2 deaths and 2 non-fatal injuries reported
- Electrically inactive J wire
- Mechanism of injury
 - Fracture of the J retention wire
 - Protrusion from the polyurethane insulation
 - Laceration of the right atrium
 - Embolization of the wire into the pulmonary circulation

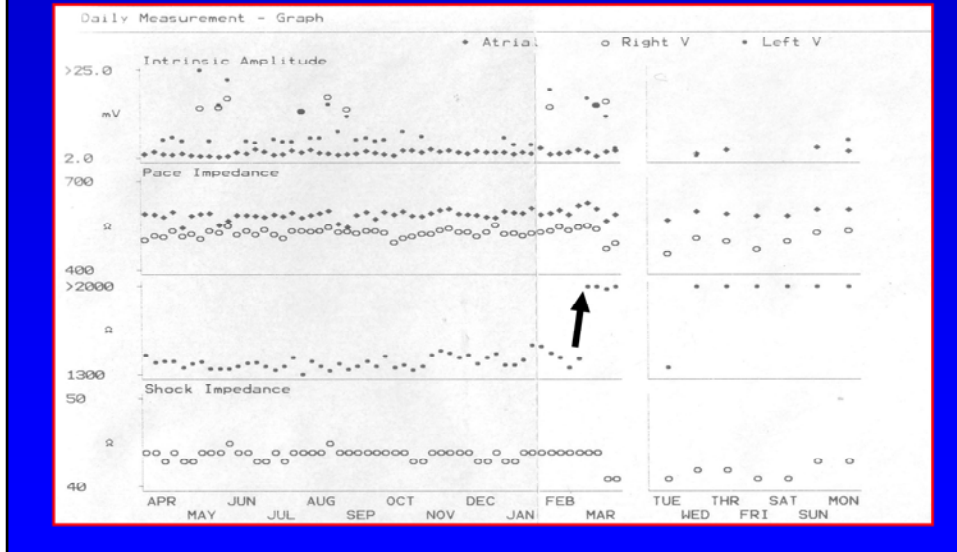
Kay GN et al. *Circulation* 1999; 100: 2344-52

Daoud EG et al. *Am heart J* 1996; 131: 266-9

Leads often malfunction due to intrinsic problems with their design. This was learned with the experience with the Telectronics Accufix leads, in which fracture of the J retention wire could result in significant morbidity and mortality.

However, this early experience all taught us that the risk of extracting a malfunctioning lead must be weighed carefully against the potential benefit to a patient. For example, it has been argued that many more patients were harmed by attempts at lead extraction by inexperienced operators than were actually injured by the defective lead itself.

Lead Malfunctions



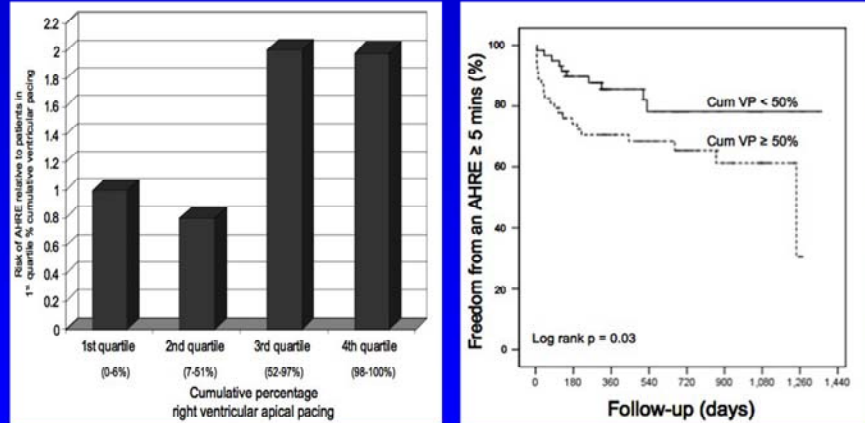
This slide illustrates an abrupt increase (as shown by the black arrow) in left ventricular lead impedance. This is consistent with a lead fracture in a patient with an implanted CRT device. In these patients, it is generally necessary to extract the existing left ventricular lead in order to successfully place a new functional lead.

Indications for Lead Extractions

- Infections
- Lead malfunctions
- Device upgrades
 - Pacemakers to CRT devices
 - Pacemakers to ICDs
 - ICDs to CRT-devices

An increasingly important part of electrophysiology practice is that of “device upgrades”. Many of these procedures require lead extractions to overcome problems with lack of vascular access (e.g. occluded veins) and to prevent abandonment of unwanted leads.

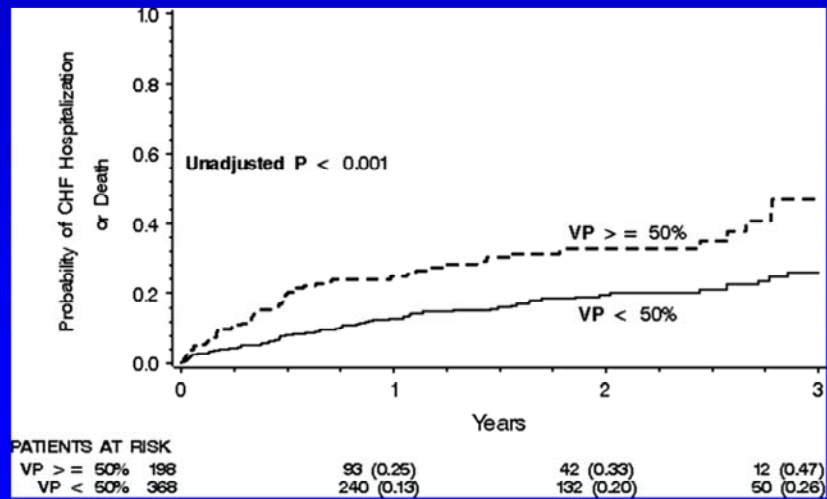
Adverse Consequences of Excessive Right Ventricular Apical Pacing



Cheung JW et al. *JCE* 2006; 17: 1323-28

For example, we have learned the adverse consequences of excessive right ventricular pacing. In this study, $\geq 50\%$ right ventricular pacing was associated with a significantly greater risk of developing at least one atrial high rate episode lasting more than 5 minutes.

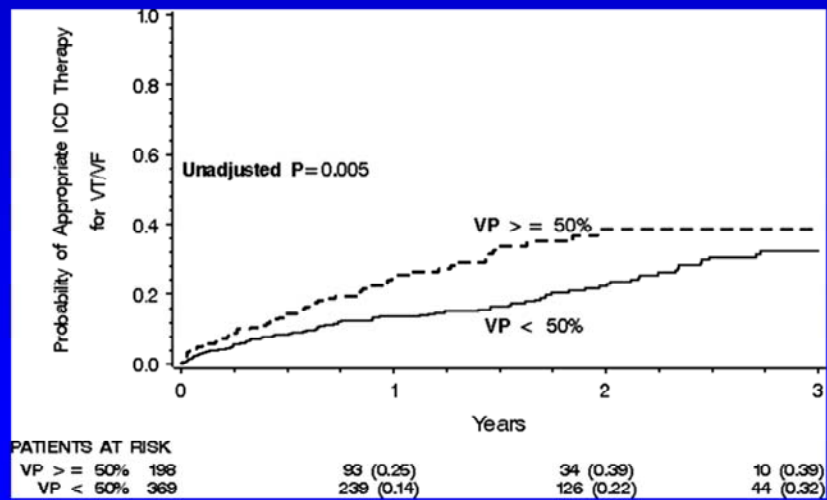
Impact of Right Ventricular Pacing in the MADIT II Trial



Steinberg et al. *JCE* 2005; 16: 359-365

Similarly, in an ICD population, it has been shown that $\geq 50\%$ right ventricular pacing doubled the composite risk heart failure hospitalization or death.

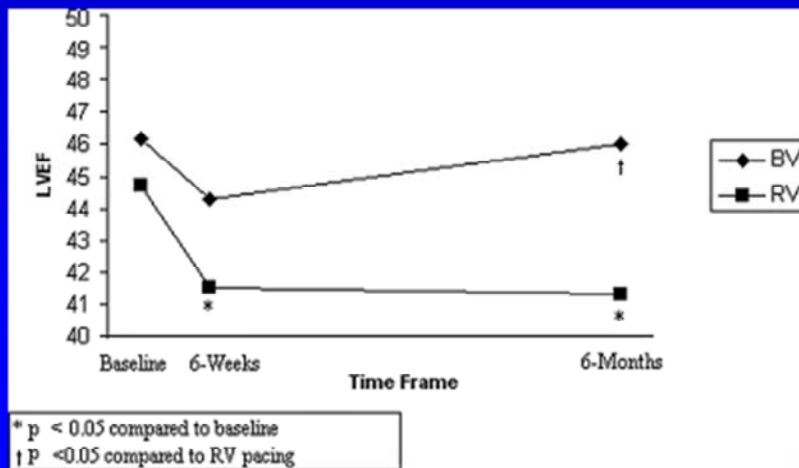
Impact of Right Ventricular Pacing in the MADIT II Trial



Steinberg et al. *JCE* 2005; 16: 359-365

Similarly, excessive right ventricular pacing resulted in a markedly increased risk of receiving an appropriate ICD therapy for management of ventricular tachycardia or fibrillation.

The Post AV Nodal Ablation Evaluation (PAVE) Study

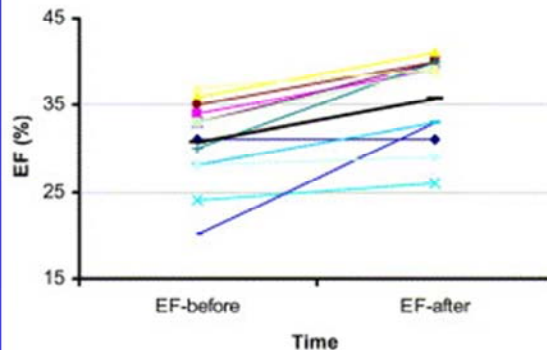


Doshi RN et al. *JCE* 2005; 16: 1160-65

We have learned that biventricular pacing, as opposed to right ventricular pacing alone, is more likely to preserve left ventricular function in patients obligated to long-term pacing (e.g. post AV node ablation).

Device Upgrades

Left-ventricular Ejection Fraction Before and After Upgrade to Cardiac Resynchronization Therapy



Upgrade to a CRT device associated with

- Reduction in QRS d
- Reduction in LV end-systolic and diastolic volumes
- Improvement in NYHA class
- Indices of ventricular dyssynchrony

Eldadah ZA et al. *Heart Rhythm* 2006; 3: 435-42

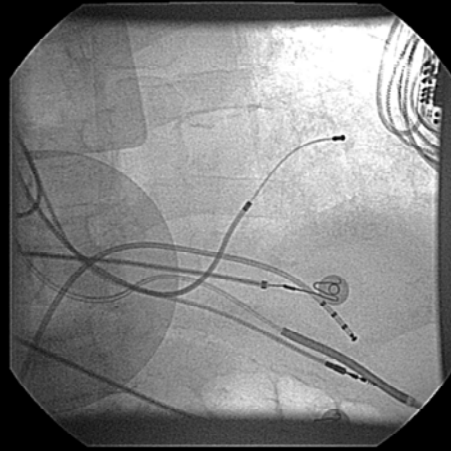
Furthermore, in patient's demonstrating a decrease in left ventricular function in response to obligate right ventricular pacing, upgrade to a biventricular device results in an improvement in clinical symptoms and echocardiographic indices of reverse remodeling.

Indications for Lead Extractions

- Infections
- Lead malfunctions
- Device upgrades
 - Pacemakers to CRT devices
 - Pacemakers to ICDs
 - ICDs to CRT-devices
- LV lead revision

A final reason to consider lead extraction is when a left ventricular lead needs to be revised.

LV Lead Dislodgement



An important reason for why left ventricular leads need to be revised is the problem of lead dislodgement. In this RAO image, one can see that the left ventricular pacing lead has “pulled back” into the most basal aspect of a lateral vein. The lead was removed and a new lead placed into a more favorable location.

Risk Factors for Increased Difficulty

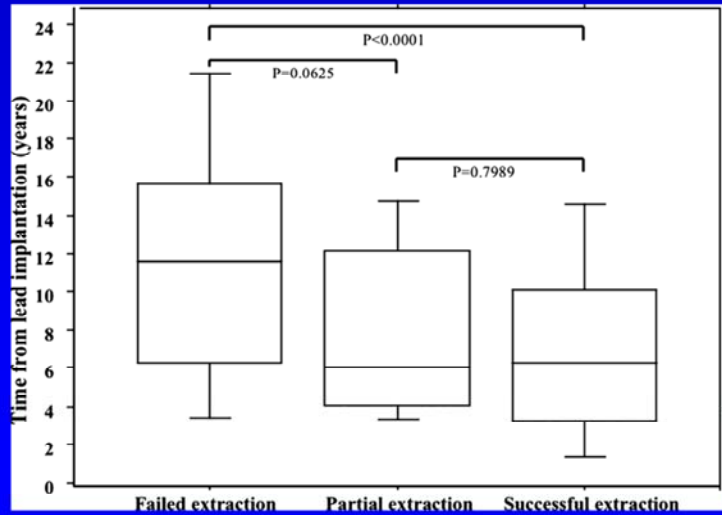
- Patient specific
 - Duration of implant
 - Younger patient
 - Female gender

- Lead specific
 - Calcifications along lead
 - Multiple leads (lead to lead binding)
 - ICD leads, especially ones incorporating a SVC coil
 - Tined leads

Field ME et al. *Heart Rhythm* 2007; 4: 978-85

A number of patient as well as lead specific variables influence the ease with which chronic leads can be extracted.

Relationship Between Time from Implantation and Procedural Outcome



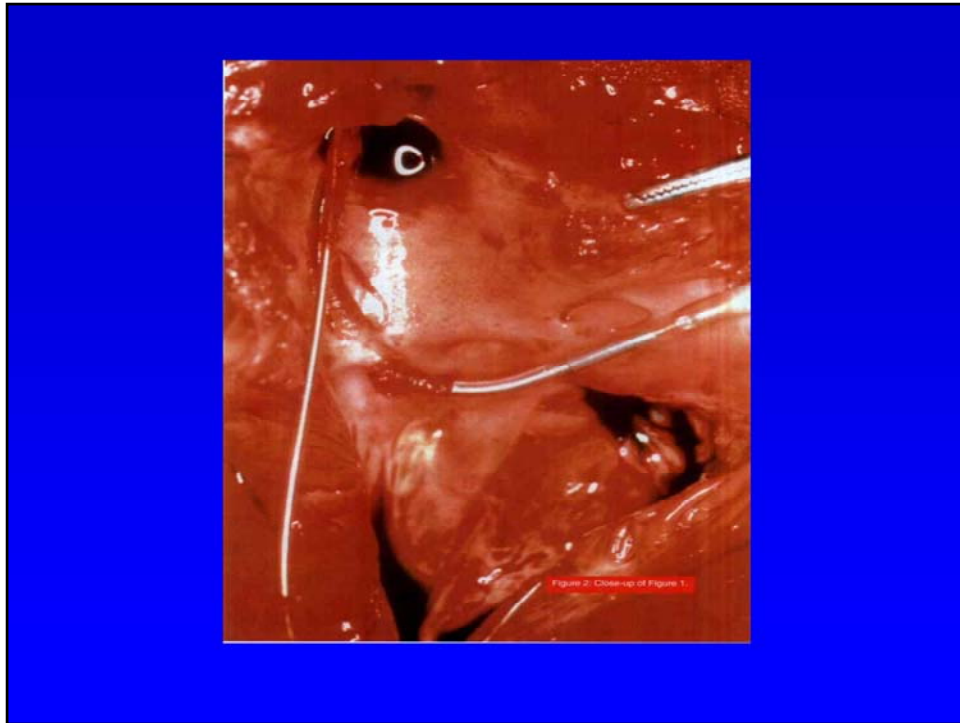
Roux JF et al. *PACE* 2007; 30: 214-20

Clearly, one of the most important variables is the time from implantation to extraction.

Why Do Implanted Leads Not Come Out With Gentle Pulling?

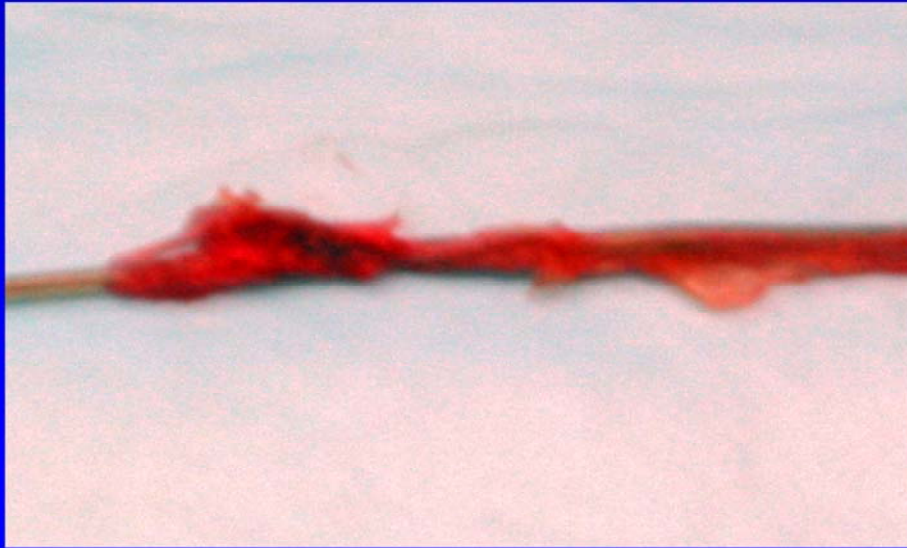
- Mechanism for binding
 - Thrombus form over a new lead
 - Form points of fibrous attachment to intravascular and cardiac structures

- Common binding sites
 - Site of entry of the lead into the vein
 - Passage of the lead under the clavicle
 - The superior vena cava-right atrial junction
 - The distal electrode-myocardium interface



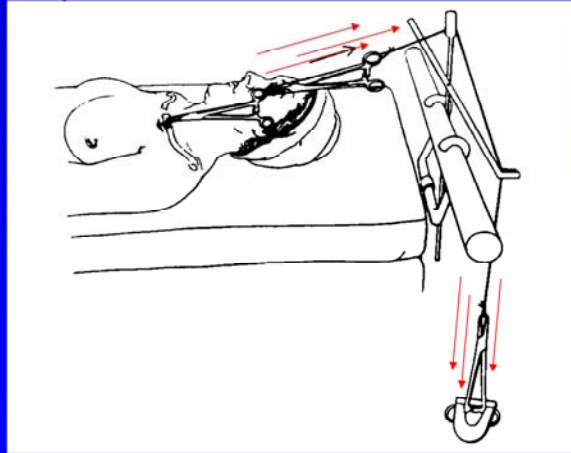
This illustrates the challenge associated with lead extraction. As can be seen, a portion of the lead has been “endothelialized”, thus making it difficult to extract the lead without causing significant damage to the cardiac structures.

***Pacemaker Lead Extraction:
18 Years Duration***



In this extracted lead, one can appreciate the dense amount of fibrosis present along a long segment of the lead.

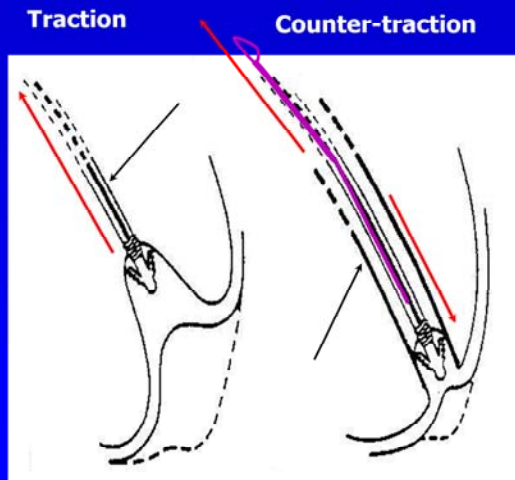
Lead Extraction Techniques: Early Approaches



Courtesy of Spectranetics

Techniques for lead extraction have gradually evolved over time. The initial approach involved traction on an exposed portion of the lead. One waited for the “thud” of the weight fall to the ground. At that point, the lead was usually out; one had to hope that essential cardiac structures did not come out as well!

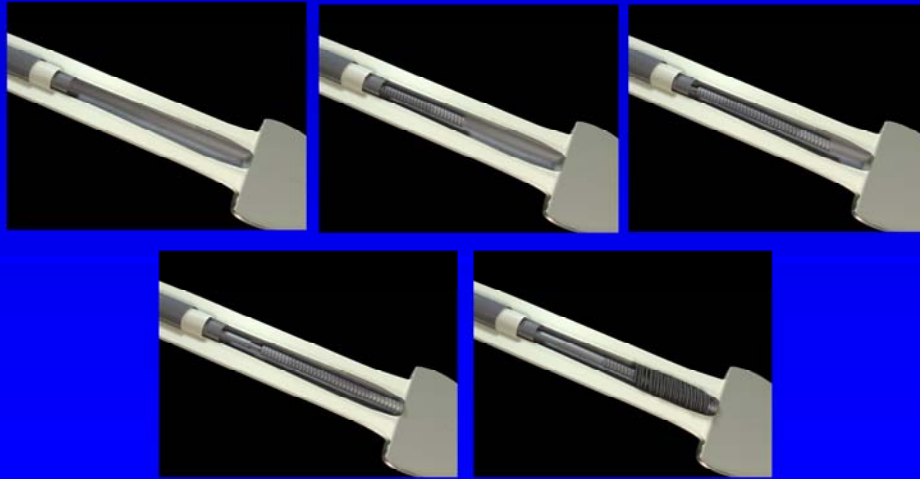
Lead Extraction Techniques: Traction and Counter-Traction



Courtesy of Spectranetics

Today, a technique using traction **and** counter-traction is generally used in the lead extraction process.

Lead Extraction Techniques: The Locking Stylet



Courtesy of Cook Medical

An important advance has been the development of locking stylets. These are inserted via the inner lumen of the lead and can provide support along the entire length of the lead, thus making the “traction” portion of the procedure much safer.

Spectranetics
CVX-300[®] Excimer Laser

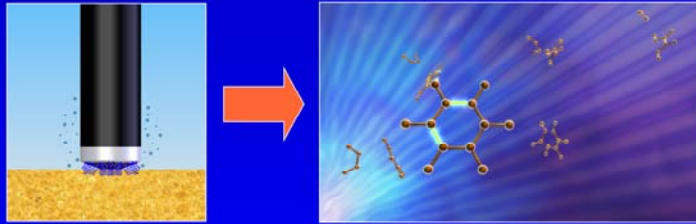


- Generates light at 308 nm wavelength in the ultraviolet spectrum
- Excimer laser enables photoablation of lipids and proteins
- Medium = XeCl gas

Courtesy of Spectranetics

Another major advance in lead extractions has been the availability of a laser lead extraction system.

Mechanism of Action: Dissolving Molecular Bonds



- Light pulse targets tissue for 125 billionths of a second
 - Pulsing aids in keeping the target cool – energy dissipates between pulses
- 50 microns penetration depth
 - Contact laser sheath allows for focused ablation
- Micron sized particles generated
 - Sub-cellular sized material is easily absorbed by the bloodstream

Courtesy of Spectranetics

Time scale : 0 -125 nanosecond (ns) – billionth of a second

- Ultraviolet light hits the tissue for 125 billionths of a second. (Light speed travels 2.4 meters in this time) (This is 2.4 million times faster than the blink of an eye)
- UV light is highly absorbed into the tissue and only penetrates 50 microns in depth.
- The UV photon energy is greater than the molecular bonds of the tissue. Billions of bonds fracture per pulse. This is unique to excimer lasers.

Mechanism of Action: Producing Photothermal Energy



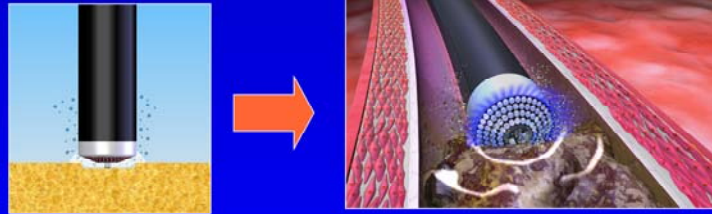
- Absorption creates molecular vibration in molecules through heating of intracellular water - water vaporizes, rupturing cells
 - Fibrotic tissue is dissolved
- Gaseous byproducts produce a vapor bubble
- Occurs in 100 millionths of a second

Courtesy of Spectranetics

Time scale: 100 millionths of a second

- Ultraviolet light is absorbed and produces fast vibration of molecular bonds in the tissue
- Vibration heats the intracellular water
- The intracellular water vaporizes exploding the cell from the inside out.
- Macroscopically the vaporization forms a steam bubble.
- Process time is less than the thermal relaxation time of tissue- heat does not diffuse into the tissue.

Mechanism of Action: Creating Kinetic Energy



- Expansion and collapse of vapor bubble breaks down tissue and clears byproducts away from tip
 - Laser sheath tip is continually in contact with fibrotic material
- By-products of ablation are water, gas, and small particles (90% <10 microns, ~ size of red blood cell)
 - Easily absorbed by the blood stream

Courtesy of Spectranetics

Time scale : 120 μ s - 400 μ s (120–400 millionth of a second) after laser pulse.

- The fast expansion and implosion of the steam bubble produces cavitation and pressure effects that further break down tissue and assists in sweeping ablated debris from the face of the catheter.

-Debris byproducts consist of water, hydrocarbons (gases), and small particles. Notably absent are oxidative byproducts, which implies that the molecules in the tissue do not burn. More than 91 percent of the particles are less than 10 microns in diameter, the same size as blood cells.

- Secondary cavitation bubbles can form after the implosion of the first vapor bubble further assisting in tissue ablation and removal of debris.

-The entire process (per pulse) is over in approximately 500 millionth of a second.

-Next pulse arrives 24 milliseconds (0.025 seconds) later

Clinical Efficacy: The Laser Sheath

- PLEXES Study – Laser sheath (SLS) vs. non-laser (mechanical) sheath
 - Patients: 153 SLS, 301 total; Leads: 244 SLS, 465 total
 - Complications
 - SLS: 3.3% of patients (n=5); Non-laser: 1.4% (n=2)
 - Death – 0.7% (n=1) only in SLS arm
 - Complete success – 94.3% (SLS) vs. 64.2% (mechanical)

- Total Experience in U.S. Study – 1,684 patients, 2561 leads
 - Complications
 - Major - 1.9% of patients
 - Death – 0.8%
 - Complete success – 90%

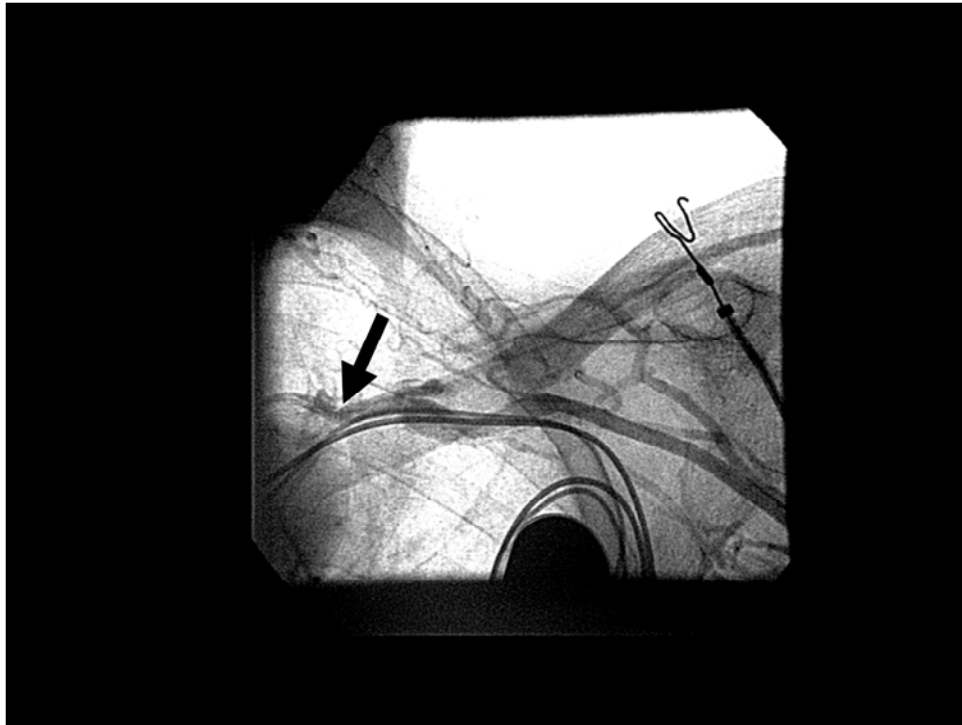
Wilkoff BL et al. *JACC* 1999; 33: 1671-6
Byrd CL et al. *PACE* 2002; 25: 804-8

The experience to date with the laser lead extraction system demonstrates a high degree of success (with respect to complete extraction of the lead) with an acceptable rate of complications. However, the risks and benefits of lead extraction must be carefully weighed in **each** patient as the procedure does carry a finite risk of mortality.

Venous Occlusions

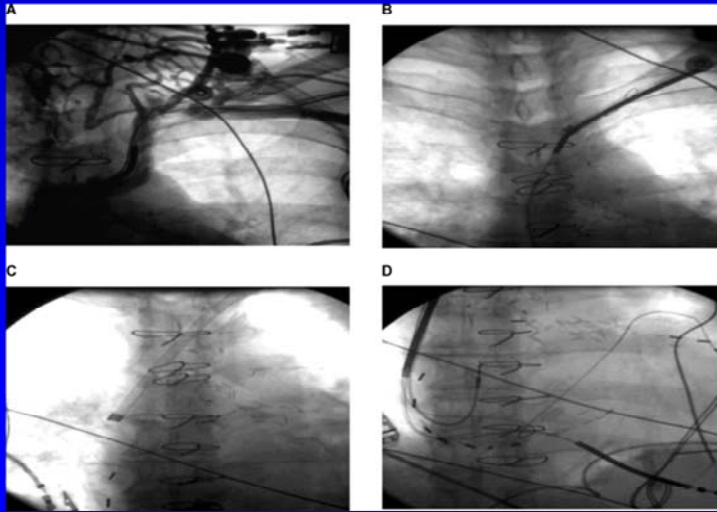
- At time of a generator replacement, 25% of patients demonstrated evidence for venous obstruction
 - Complete occlusion: 36%
 - Severe stenosis (>75%): 24%
 - Moderate stenosis (50-75%): 40%
- Use of dual coil ICD leads a very strong predictor of developing a venous occlusion
- The venous occlusion can be “crossed” using lead extraction sheaths; extraction of the existing leads can then provide “room” or a “channel” for the insertion of new leads

Korley VJ et al. *JICE* 2000; 4:523-8
Lickfett L et al. *Europace* 2004; 6: 25-31



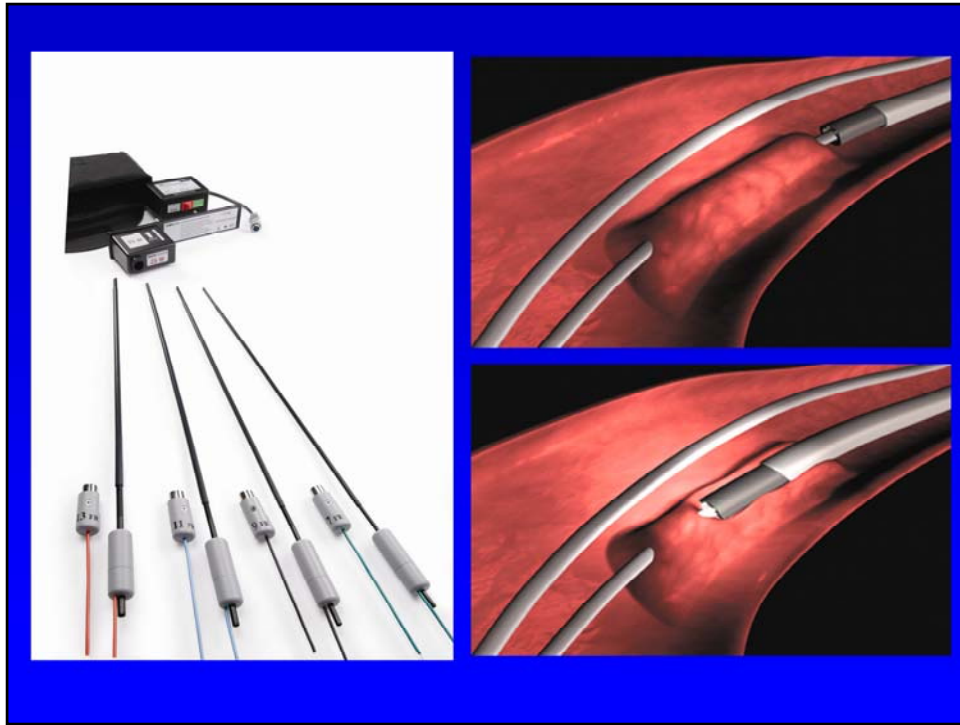
This venogram of the left subclavian vein was obtained during a procedure in which there was a need to add a left ventricular pacing lead (i.e. upgrade from a dual chamber to biventricular system). Note that the left subclavian vein was entirely occluded (black arrow) at the point where the prior leads entered the vein.

Venous Occlusions



Gula LJ et al. *PACE* 2005; 28: 661-6

In patients with venous occlusions (panel a), it is possible to “cross” the occlusion with a laser sheath (panel b), remove the existing leads (panel c), and use the channels created to implant an entirely new multi-lead system (panel d).



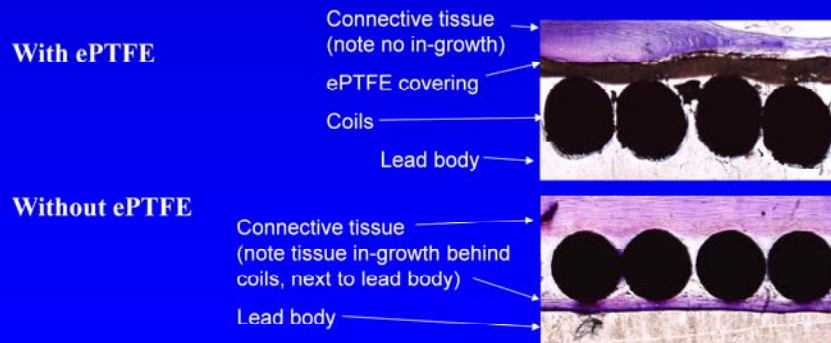
Several additional methods for lead extraction are commercially available. These include a system that uses radiofrequency energy to cross binding sites, as well as...

***Tools for Lead Extraction:
Cook Medical Evolution Device***

A hand-held (non-powered) device that acts as a mechanical cutting device and can assist with the extraction process.

Preventing Tissue In-Growth: GORE™ e-PTFE covered coils

- Pores in ePTFE covering do not allow blood and tissue cells to pass through, but do allow electrically conductive fluid to pass through.
- Histology (from a Guidant pre-clinical study, six months post-implant) shows function of ePTFE:



Courtesy of Boston Scientific

Finally, a great deal of effort has gone towards developing leads that are less likely to develop excessive fibrosis. This has significant implications for the lead extraction process. One such attempt is the market availability of a defibrillator leads in which the shocking coils are covered with GORE, which is designed to prevent u in-growth into the lead.

***Preventing Tissue In-Growth:
GORE™ e-PTFE covered coils***



Top: Non-Gore lead; Bottom: Gore covered lead-at time of extraction

Conclusions

- An aging population and expanded clinical indications have led to an explosive growth in the number of implanted cardiac devices
- A variety of reasons may necessitate the removal of these devices; in this instances, complete removal of the implanted electrodes poses a significant challenge
- Furthermore, because of changing clinical conditions, revisions to existing implantable systems may be necessary in a given patient
- Improvements in lead design as well as lead extraction technology offer an effective method for dealing with patients with implanted cardiac devices in day to day clinical practice