Role of Lead Extractions In Clinical Practice

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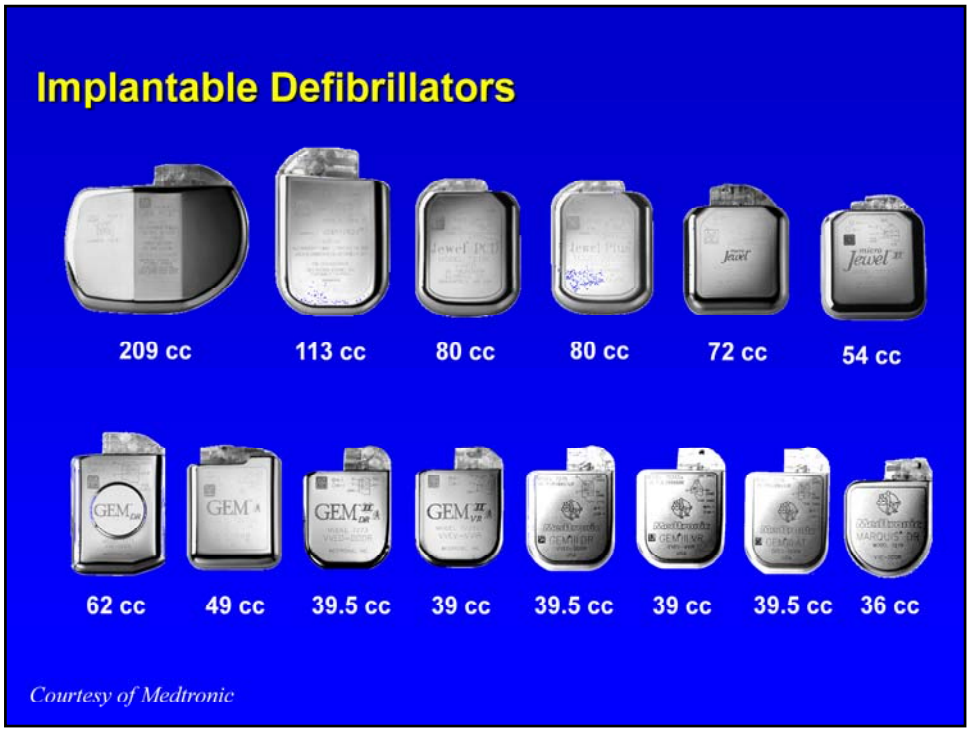
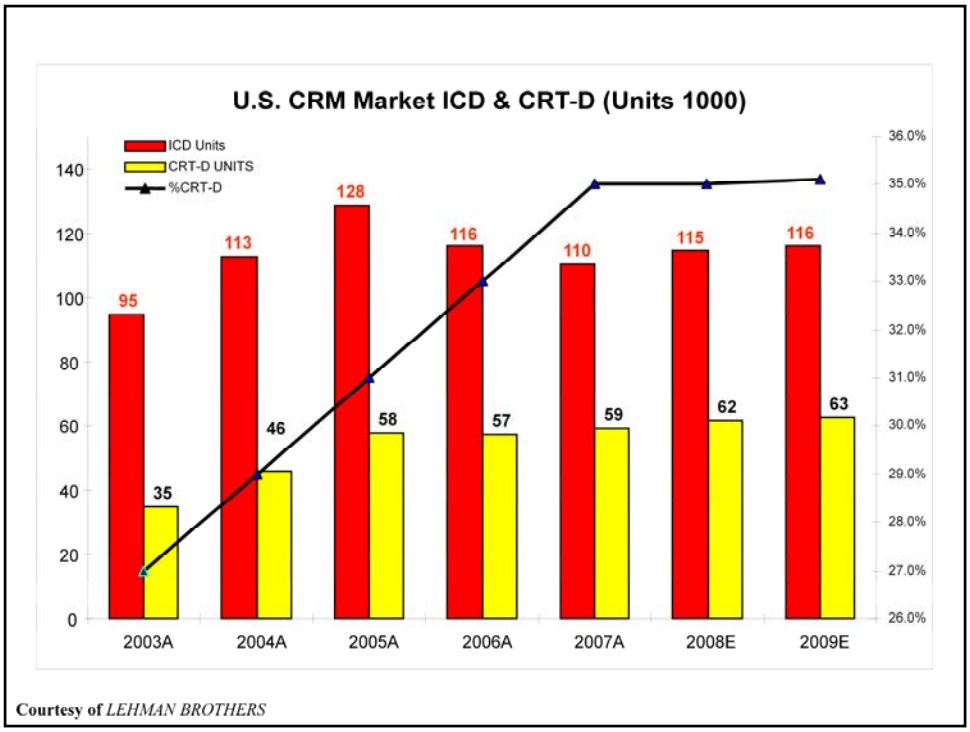
A number of large, randomized, clinical trials have demonstrated that patients left ventricular dysfunction (ejection fraction ≤ 35%) due to either ischemic or non-ischemic cardiomyopathy benefit from ICD implantation.



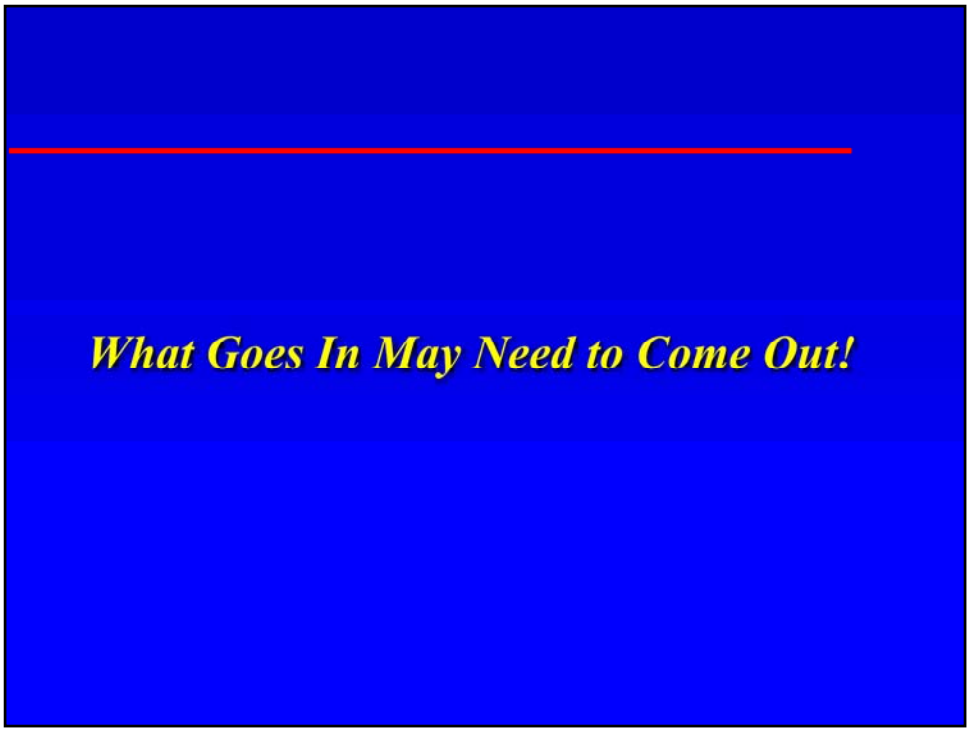
In conjunction with data from randomized clinical trials, dramatic improvements in ICD technology have facilitated an explosive growth in the number of implanted devices being implanted worldwide. One of the major improvements in technology has been the impressive reduction in the size of the ICD generator. 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.

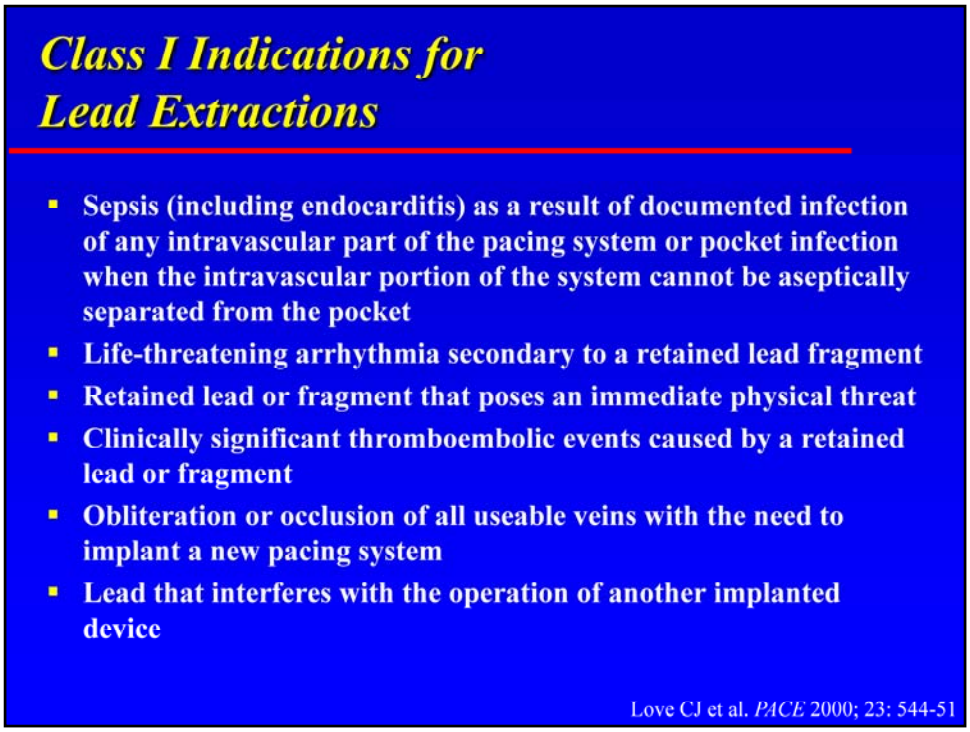


Courtesy of *LEHMAN BROTHERS*

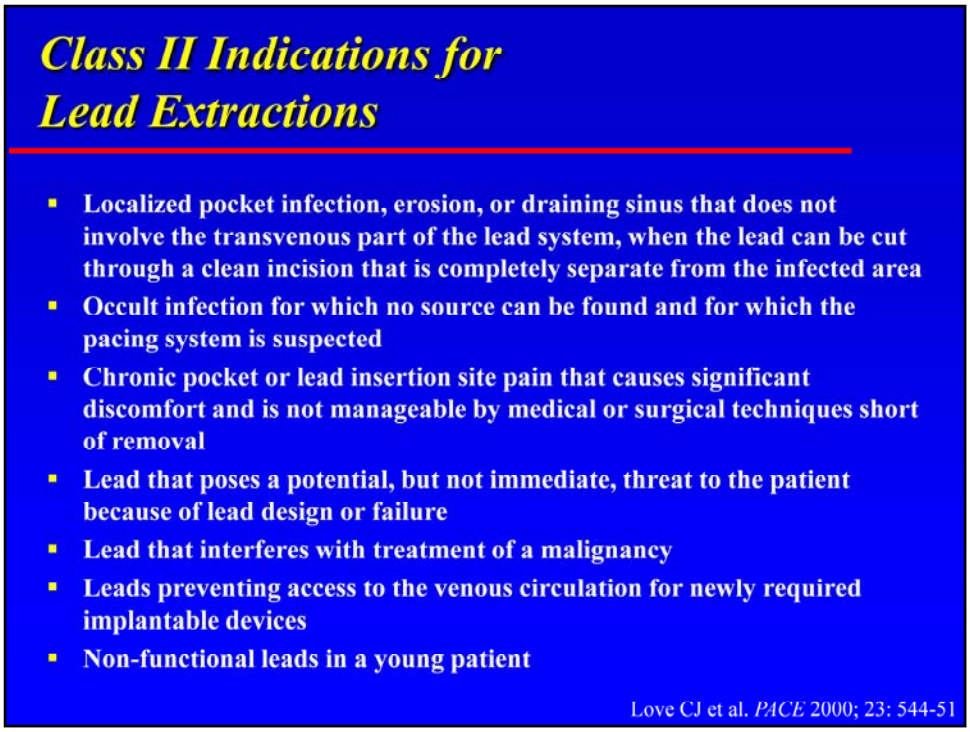
This slides illustrates the maturation of the ICD industry (both with and without CRT capability) over the past 7 years. Nearly 200,000 units are being implanted annually each year in the United States alone. These numbers do not address at all the hundred of thousands of patients undergoing implantation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



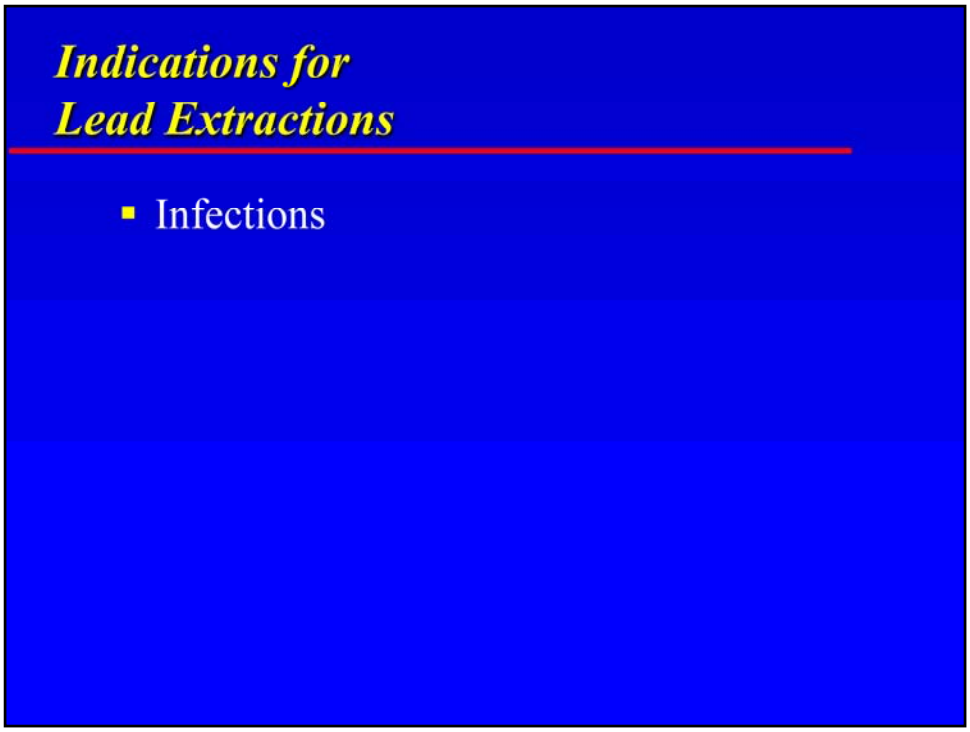
However, when it comes to leads, a central caveat remains…



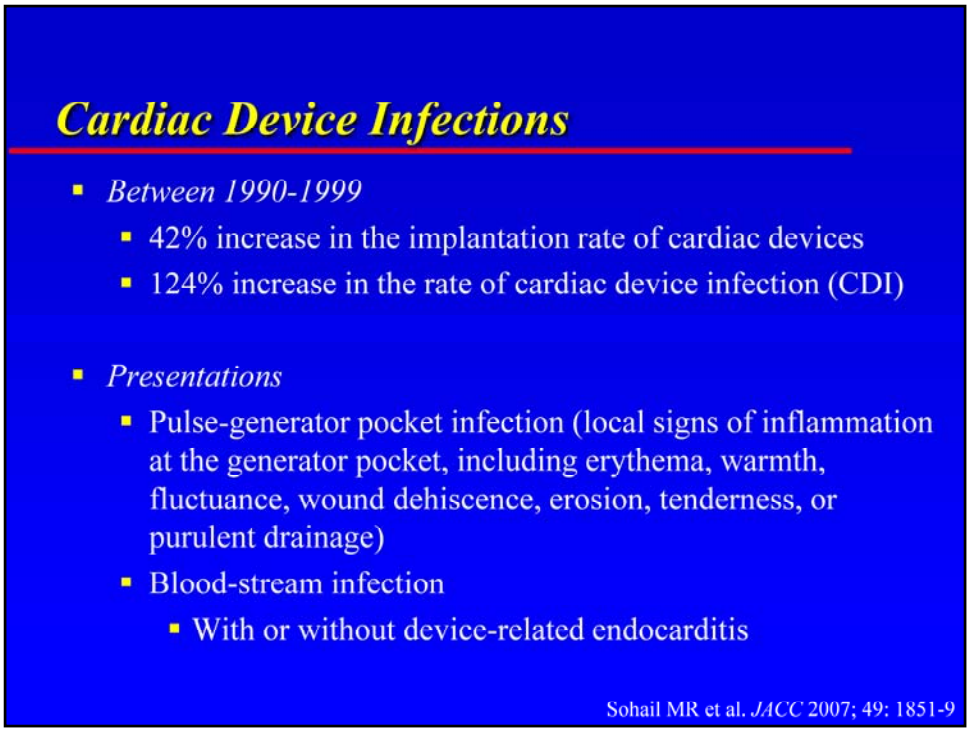
The Heart Rhythm Society has previously identified indications for lead extractions. This document is currently in the process of being updated. Nonetheless, current Class I indications for lead extractions include…



Class II indications for lead extractions include…



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).



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.

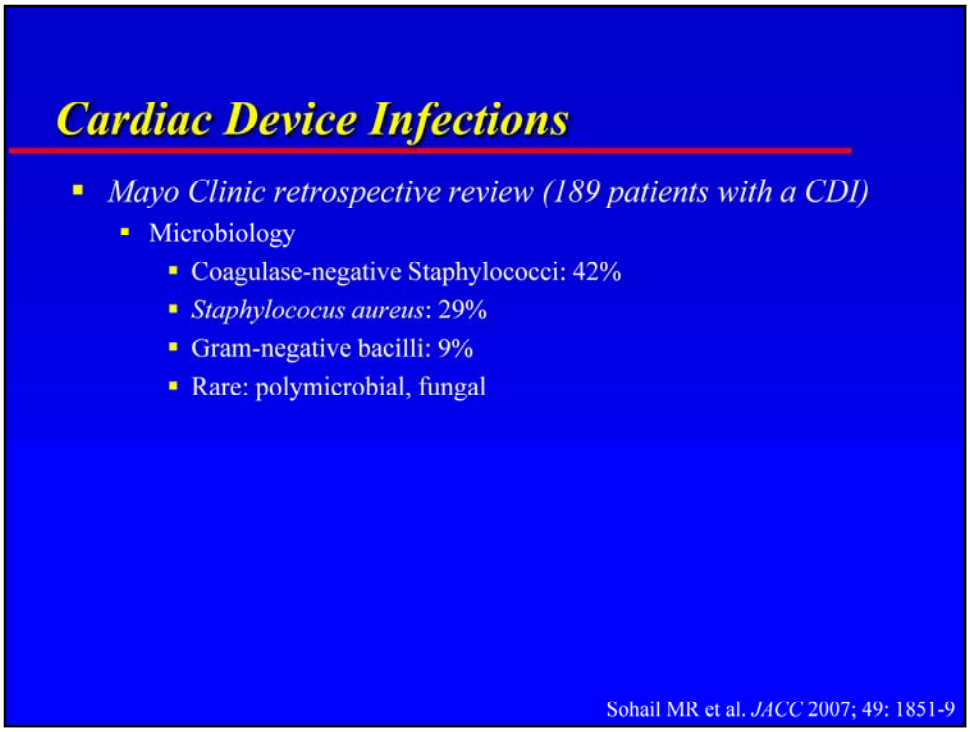
Shown is an example of an infected right infraclavicular ICD. There is marked erythema and swelling at the ICD site.

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).

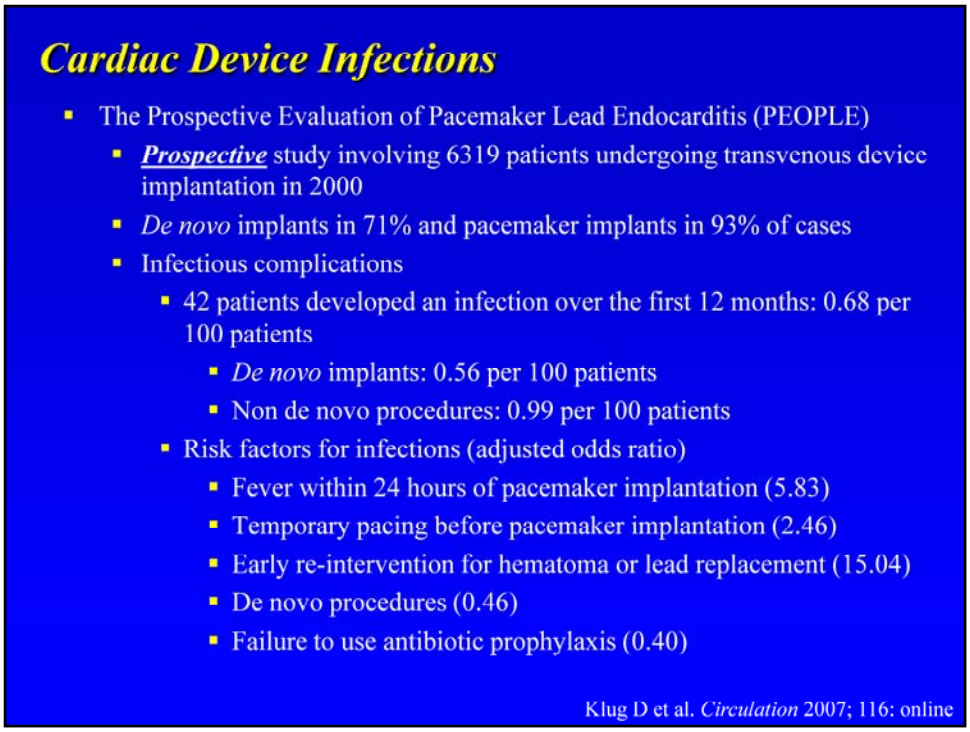
Cardiac Device Infections

- *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%

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

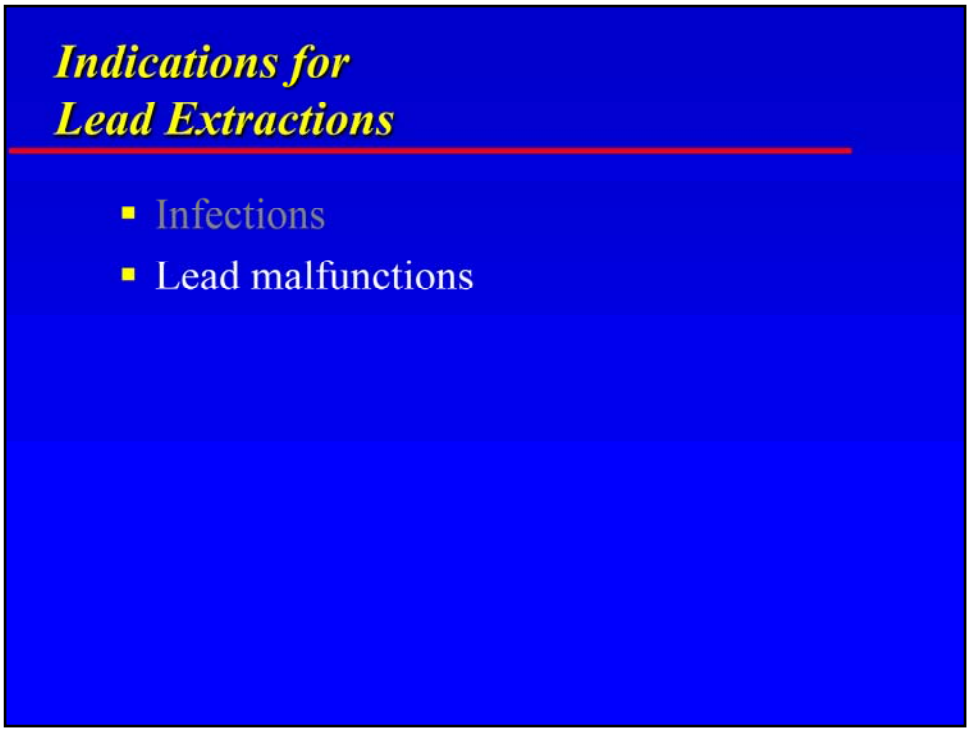


Staphylococcus species (increasingly of the methicillin resistant variety) remain the most important organism in device related infections.

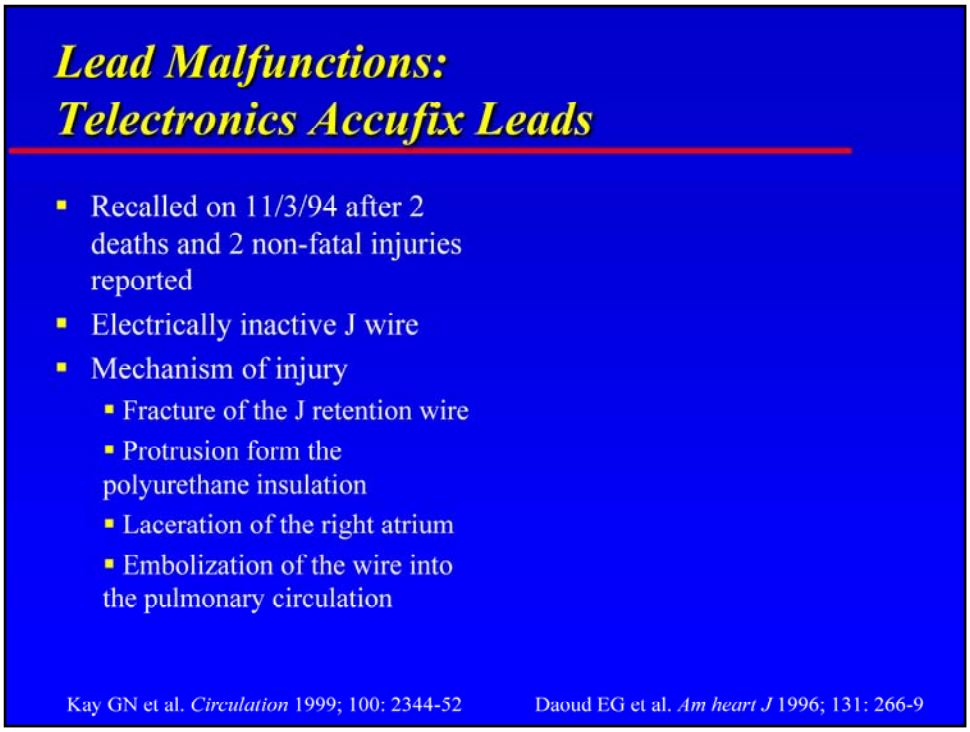


This French study provides a **prospective** look into the issue of device related infections. It should be kept in mind that this study was skewed towards *de novo* pacemaker implants. As such, patients undergoing ICD implants, especially CRT-D devices, were grossly underrepresented. This is important 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.

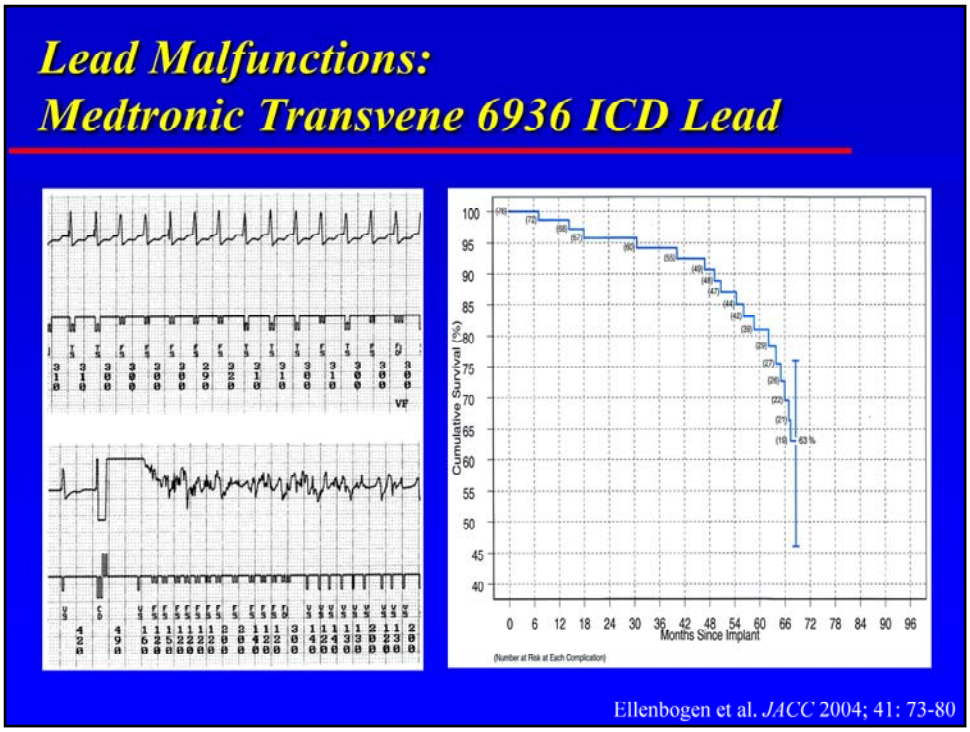


Another important cause for lead extractions is lead malfunction.



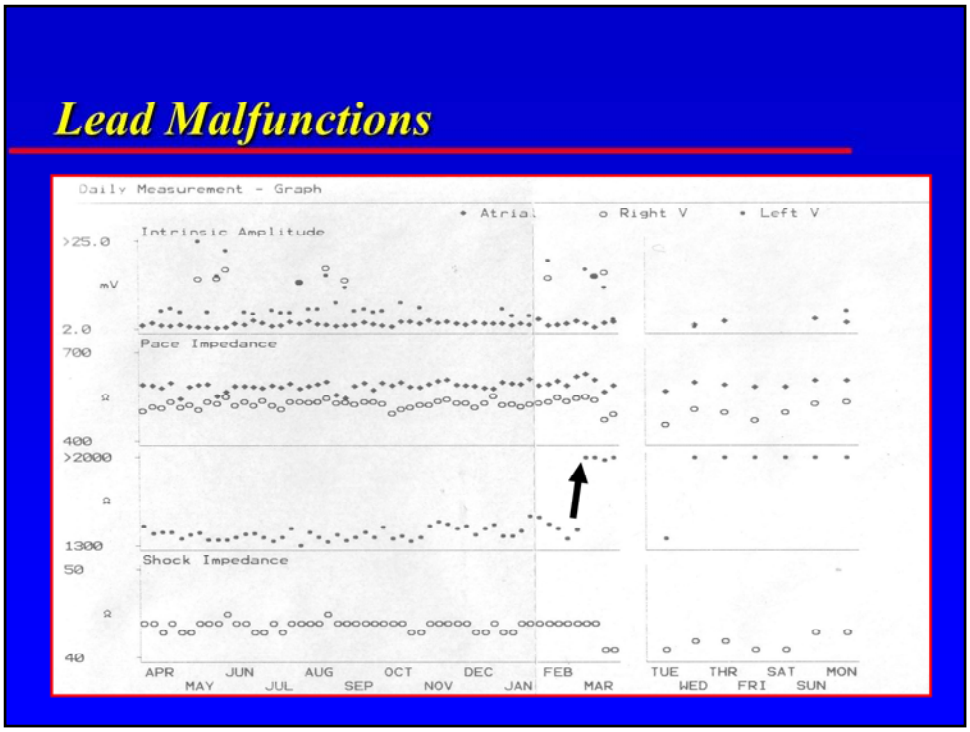
Leads often malfunction due to intrinsic problems with their design. This was learned with the experience with the Telectronics Accufix leads, in which fracture of the J retention wire could results is significant morbidity and mortality.

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

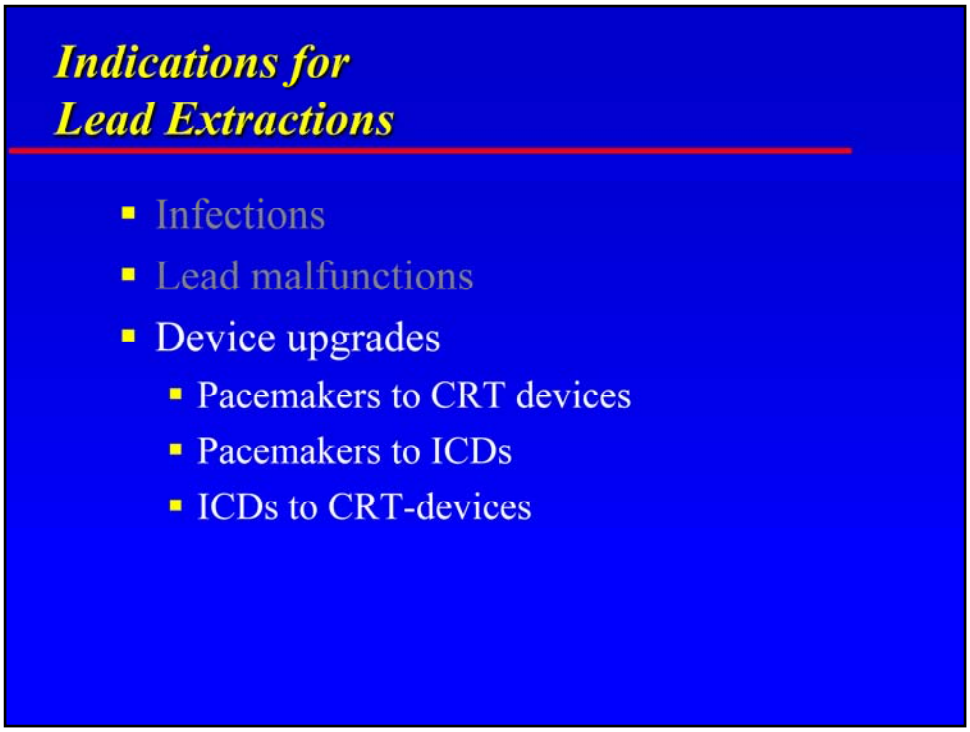


Other leads have had a highly publicized demise. For example, the Medtronic Transvene 6939 lead has had a poor long-term performance record. The lead is subject to metal ion oxidation, which can result in inappropriate detection of non-physiologic signals. On the left is shown detection of node following defibrillation of an episode of monomorphic ventricular tachycardia. On the right is shown a time-dependent decrease in lead survival as observed during follow-up.

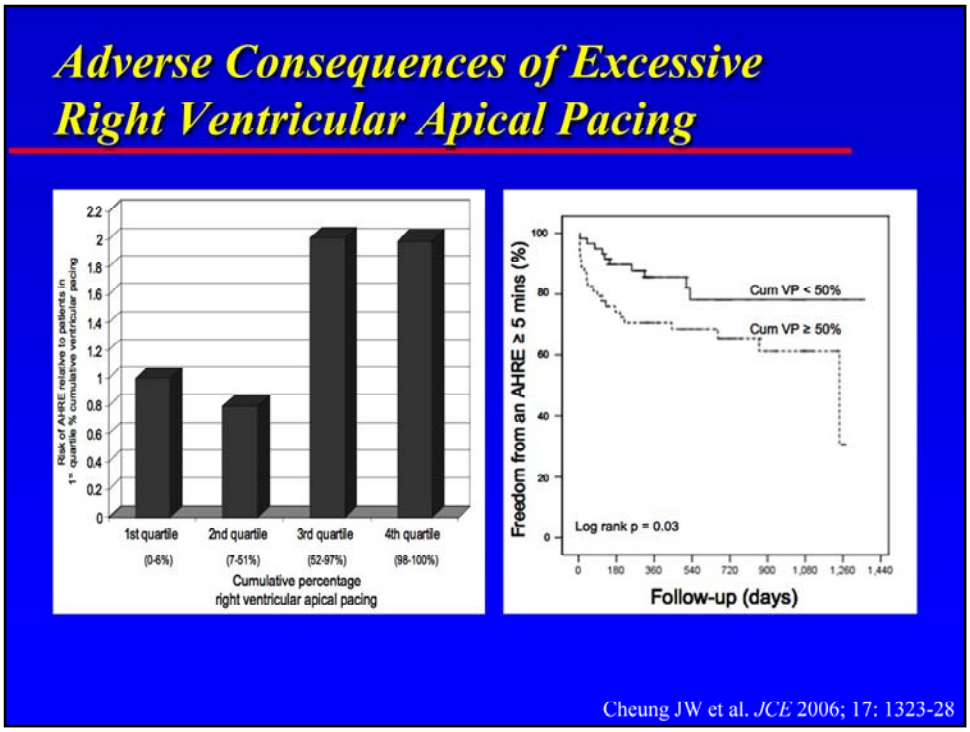
More recently, another Medtronic lead, the Sprint Fidelis lead, has been withdrawn from the market because of an excessive failure rate. This lead is subject to fracture, which results in inappropriate shocks due to detection of non-physiologic signals. With an installed base of nearly 300,000 leads and a current failure rate of 6-7%, a large number of patients will require management of a defective lead. In many patients, lead extraction of the defective lead and replacement with a functional lead will be the management strategy of choice.



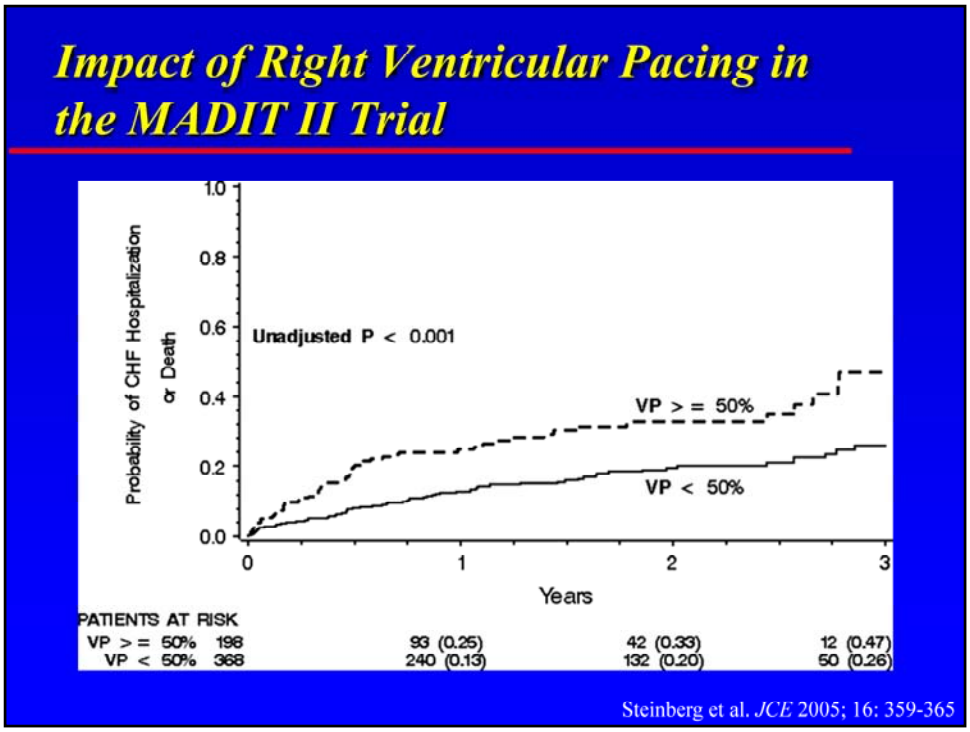
This slide illustrates an abrupt increase (as shown by the black arrow) in left ventricular lead impedance. This is consistent with a lead fracture in a patient with an implanted CRT device. In these patients, it is generally necessary to extract the existing left ventricular lead in order to successfully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



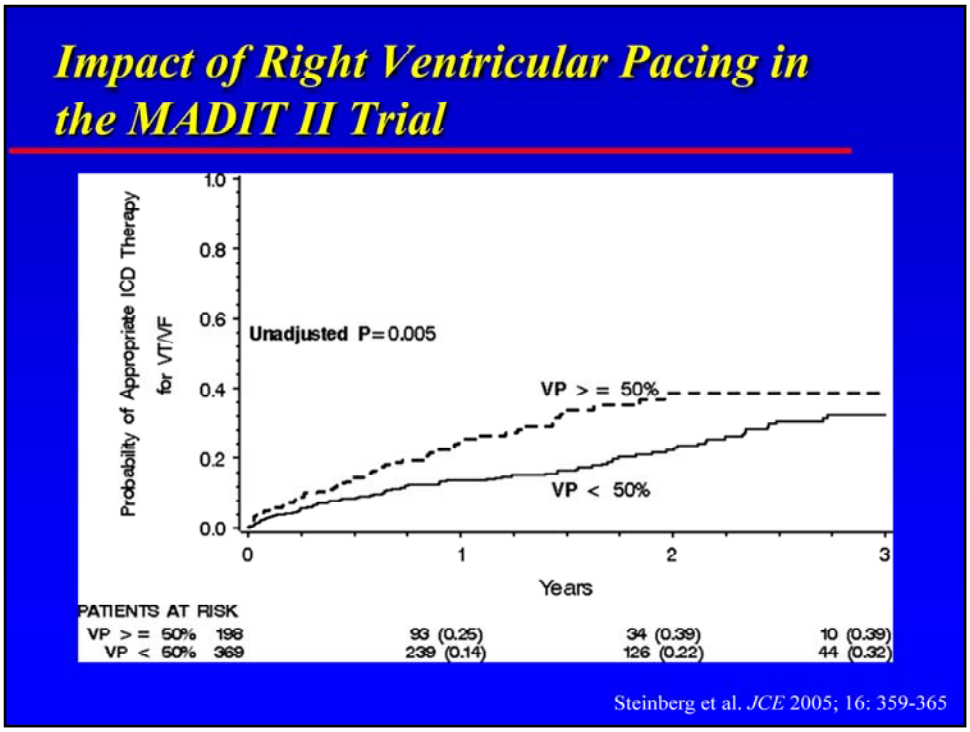
An increasingly important part of electrophysiology practice is that of “device upgrades”. Many of these procedures require lead extractions to overcome problems with lack of vascular access (e.g. occluded veins) and to prevent abandonment of unwanted leads.



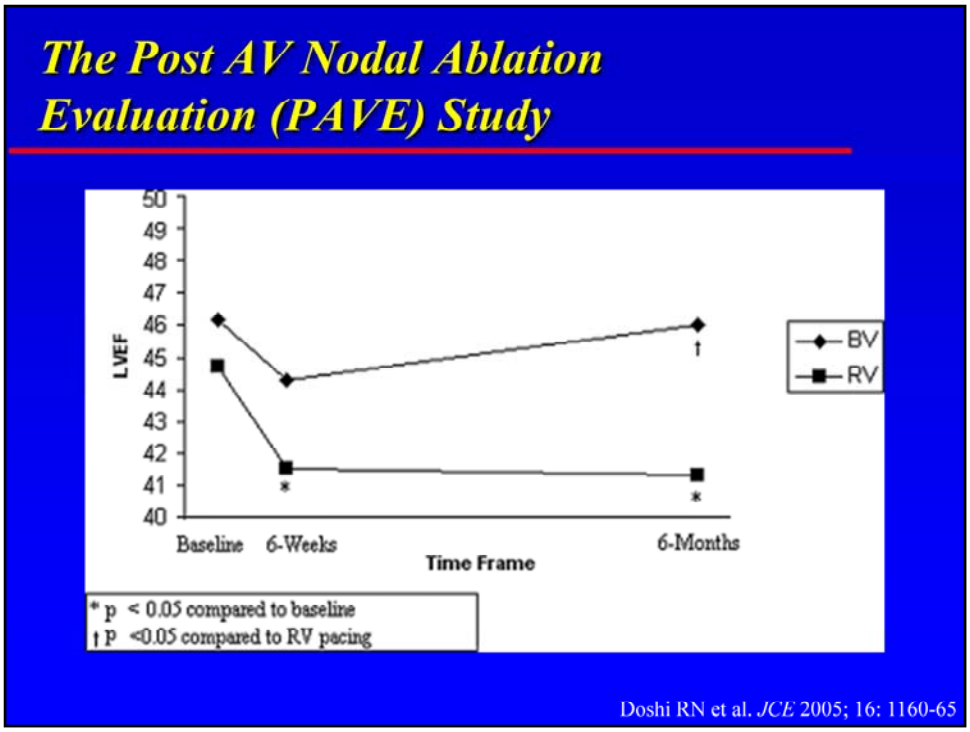
For example, we have learned the adverse consequences of excessive right ventricular pacing. In this study, ≥50% right ventricular pacing was associated with a significantly greater risk of developing at least one atrial high rate episode lasting more than 5 minutes.



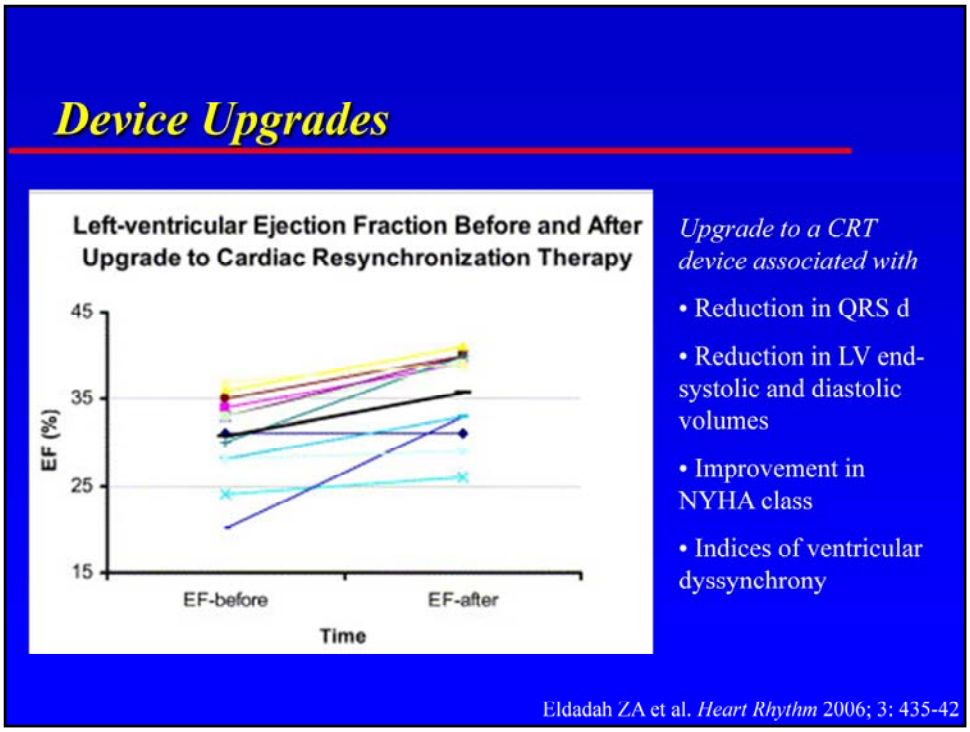
Similarly, in an ICD population, it has been shown that ≥50% right ventricular pacing doubled the composite risk heart failure hospitalization or death.



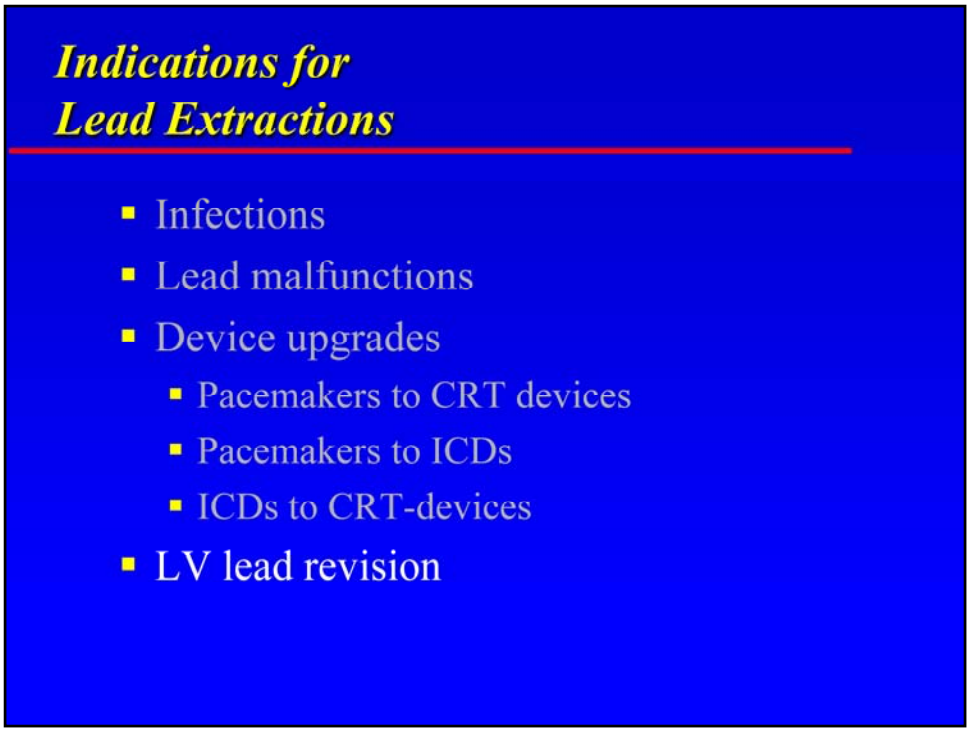
Similarly, excessive right ventricular pacing resulted in a markedly increased risk of receiving an appropriate ICD therapy for management of ventricular tachycardia or fibrillation.



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).

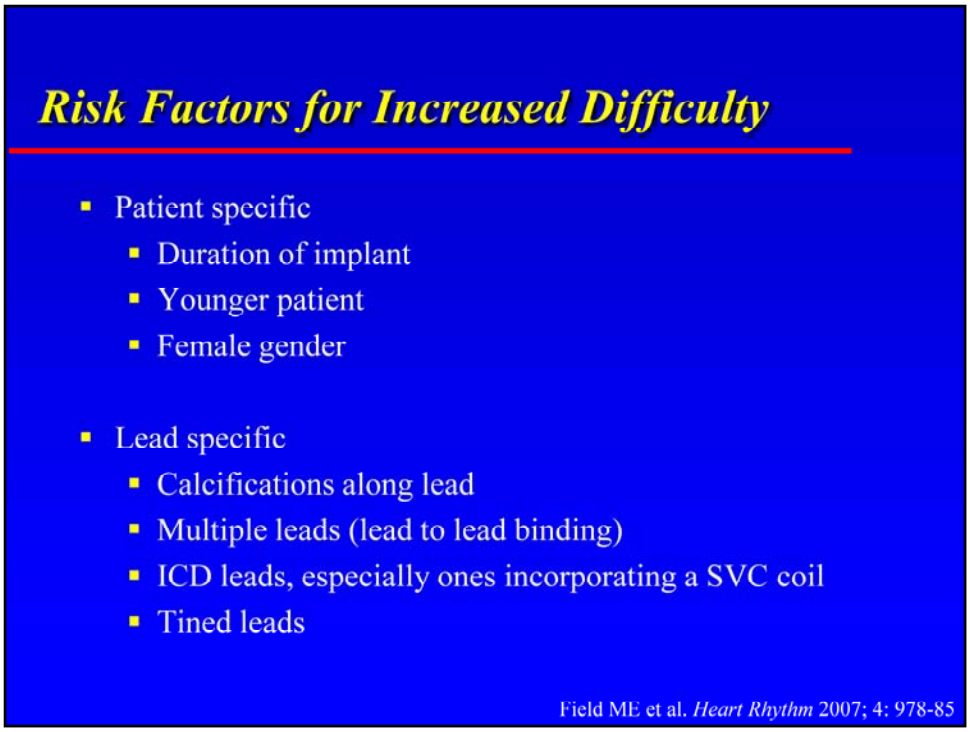


Furthermore, in patient's demonstrating a decrease in left ventricular function in response to obligate right ventricular pacing, upgrade to a biventricular device results in an improvement in clinical symptoms and echocardiographic indices of reverse remodeling.

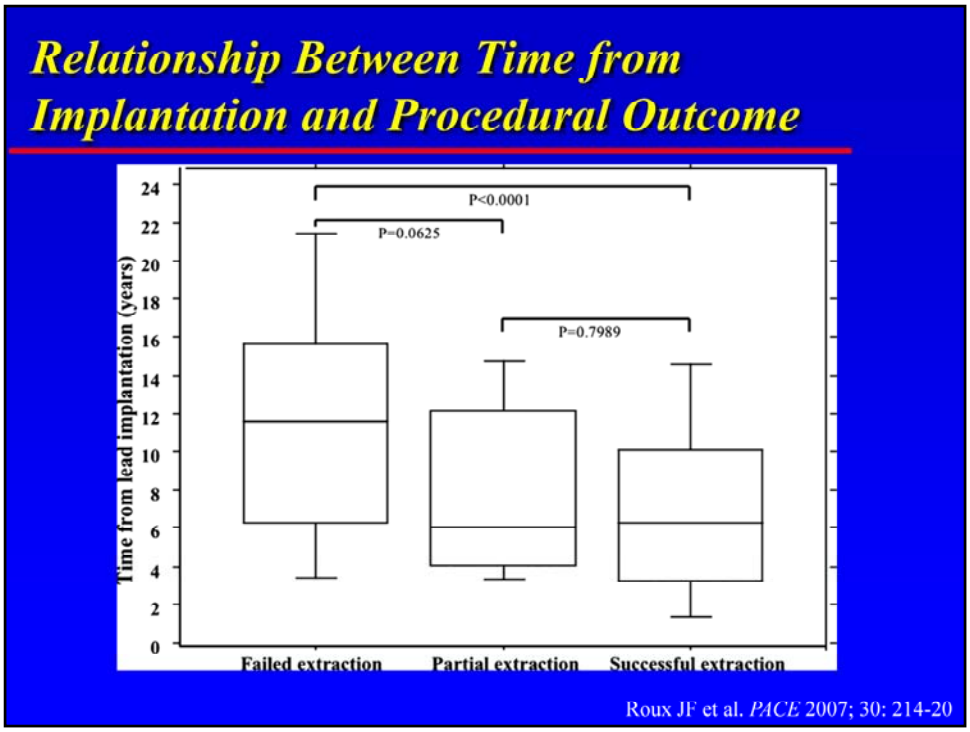


A final reason to consider lead extraction is when a left ventricular lead needs to be revised.

An important reason for why left ventricular leads need o 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.



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

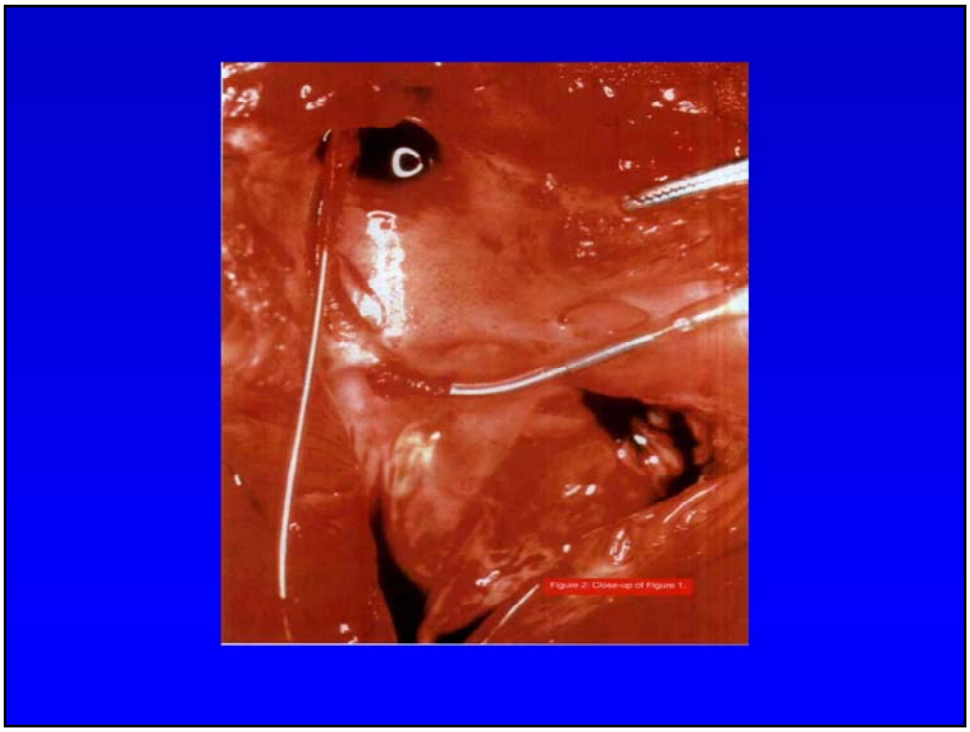


Clearly, one of the most important variables is the time from implantation to extraction.

Why Do Implanted Leads Not Come Out With Gentle Pulling?

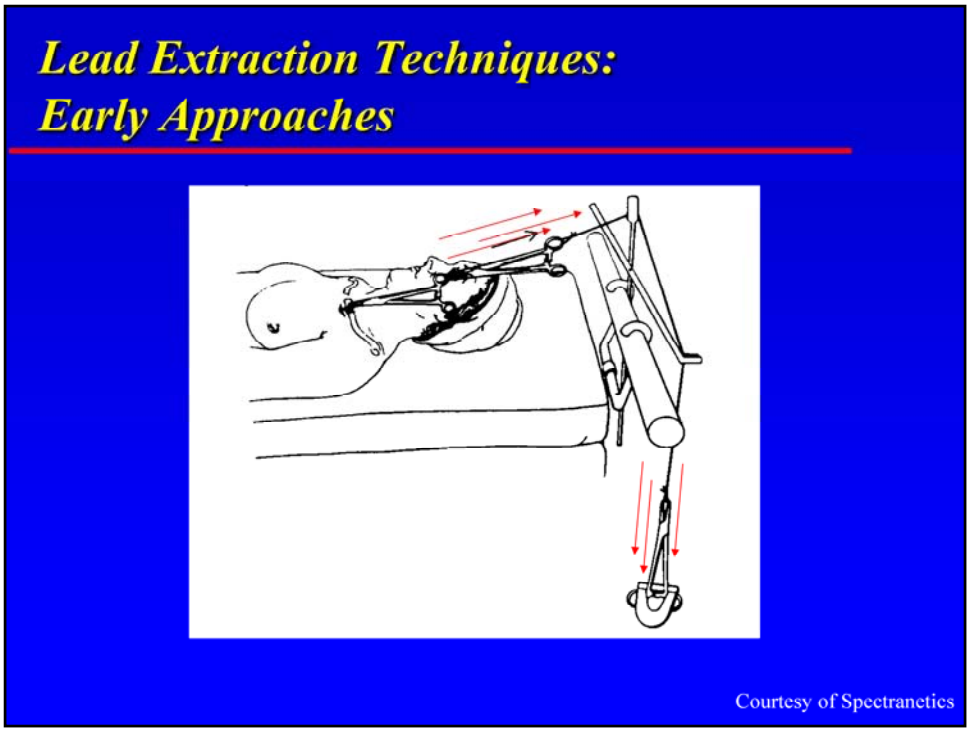
- Mechanism for binding
  - Thrombus form over a new lead
  - Form points of fibrous attachment to intravascular and cardiac structures
- Common binding sites
  - Site of entry of the lead into the vein
  - Passage of the lead under the clavicle
  - The superior vena cava-right atrial junction
  - The distal electrode-myocardium interface

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

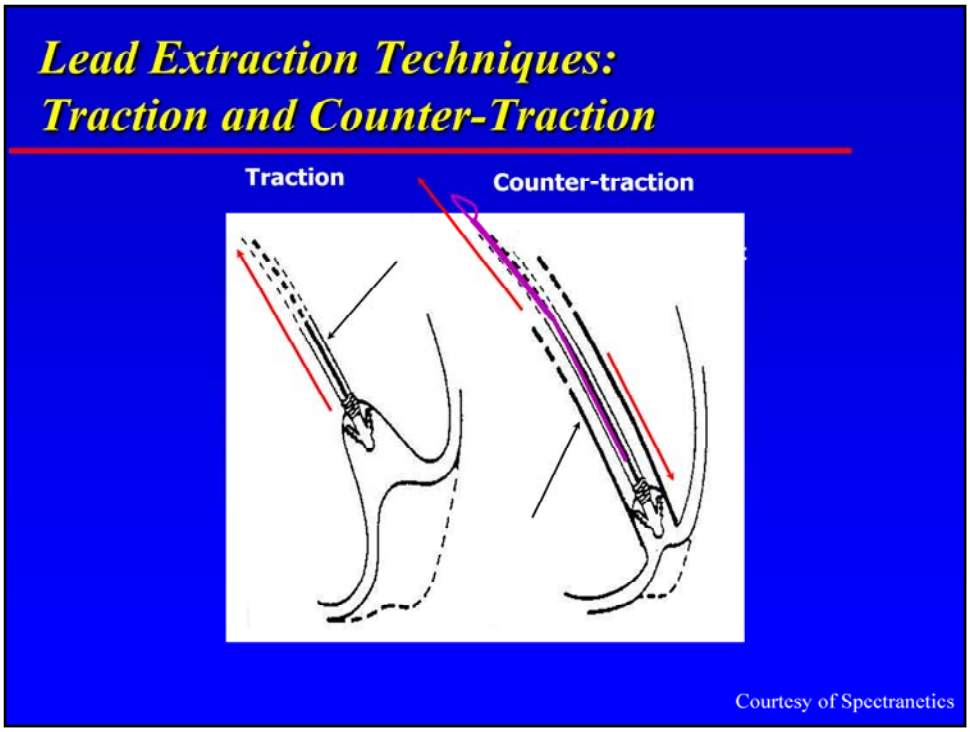


This illustrates the challenge associated with lead extraction. As can be seen, a portion of the lead has been “endothelialized”, thus making it difficult to extract the lead without causing significant damage to the cardiac structures.

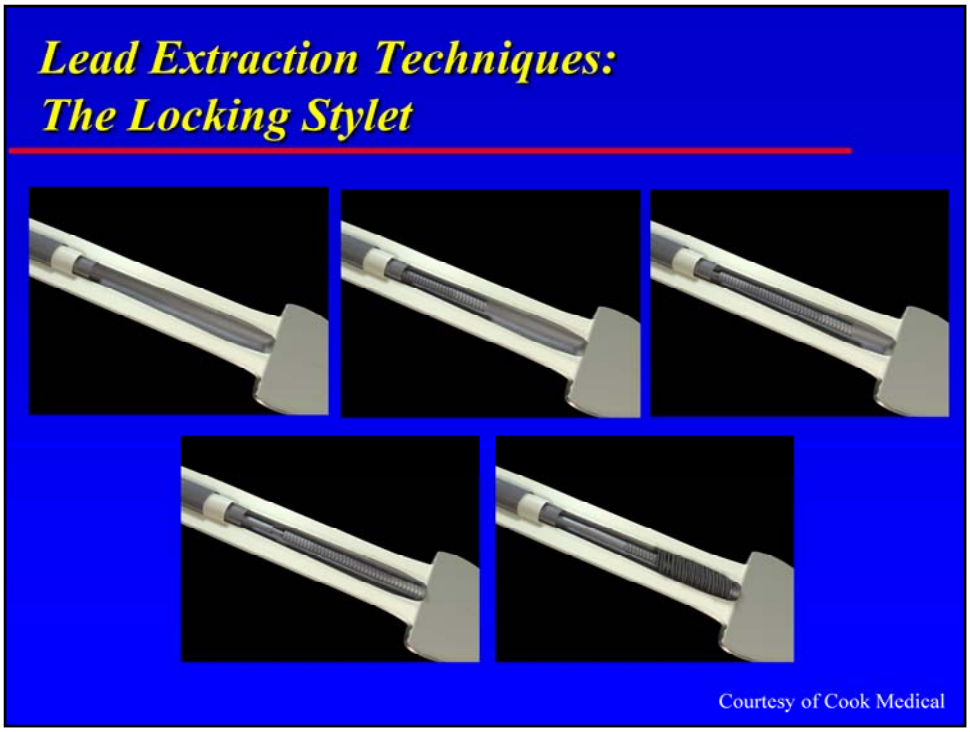
In this extracted lead, one can appreciate the dense amount of fibrosis present along a long segment of the lead.



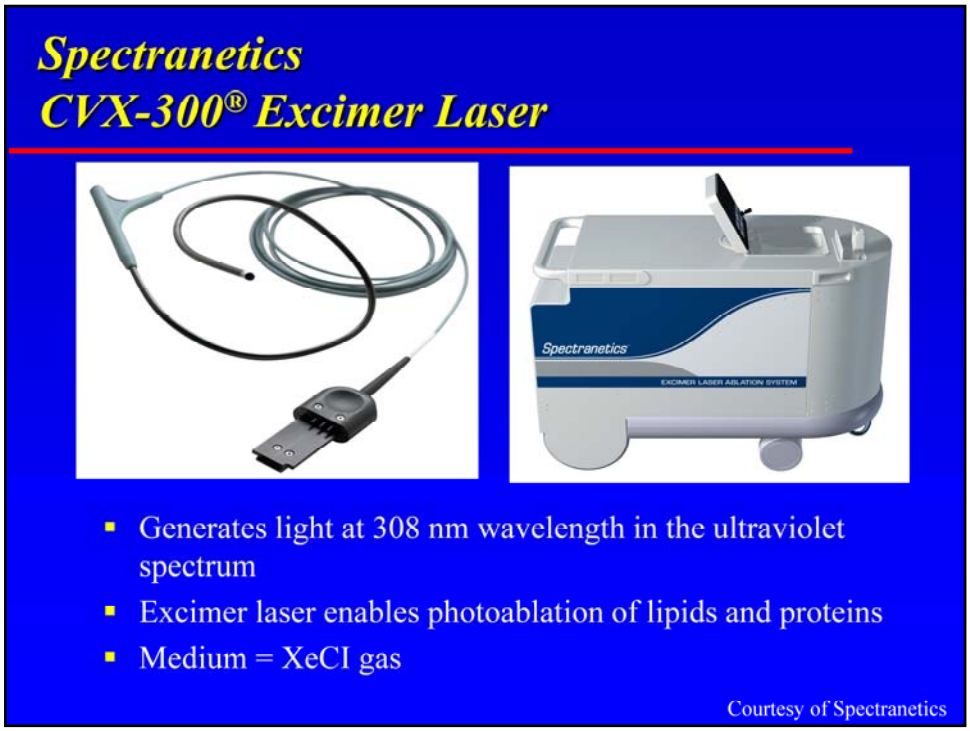
Techniques for lead extraction have gradually evolved over time. The initial approach involved traction on an exposed portion of the lead. One waited to her the “thud” of the weight fall to the ground. At that point, the lead was usually out; one had to hope that essential cardiac structures did not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



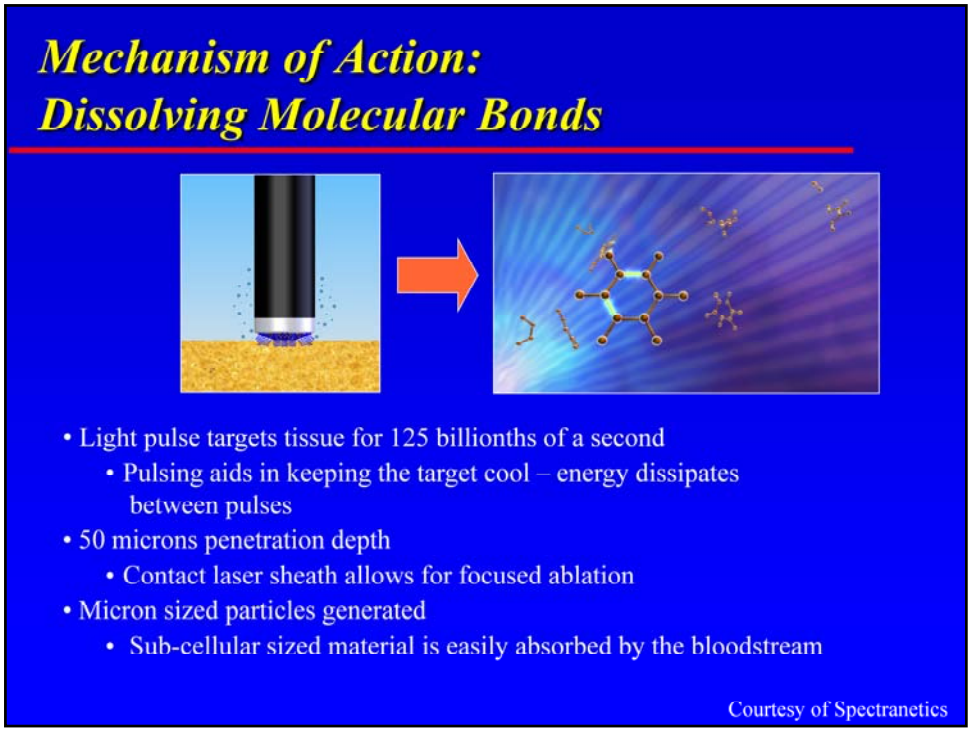
Today, a technique using traction **and** counter-traction is generally used in the lead extraction process.



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.



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

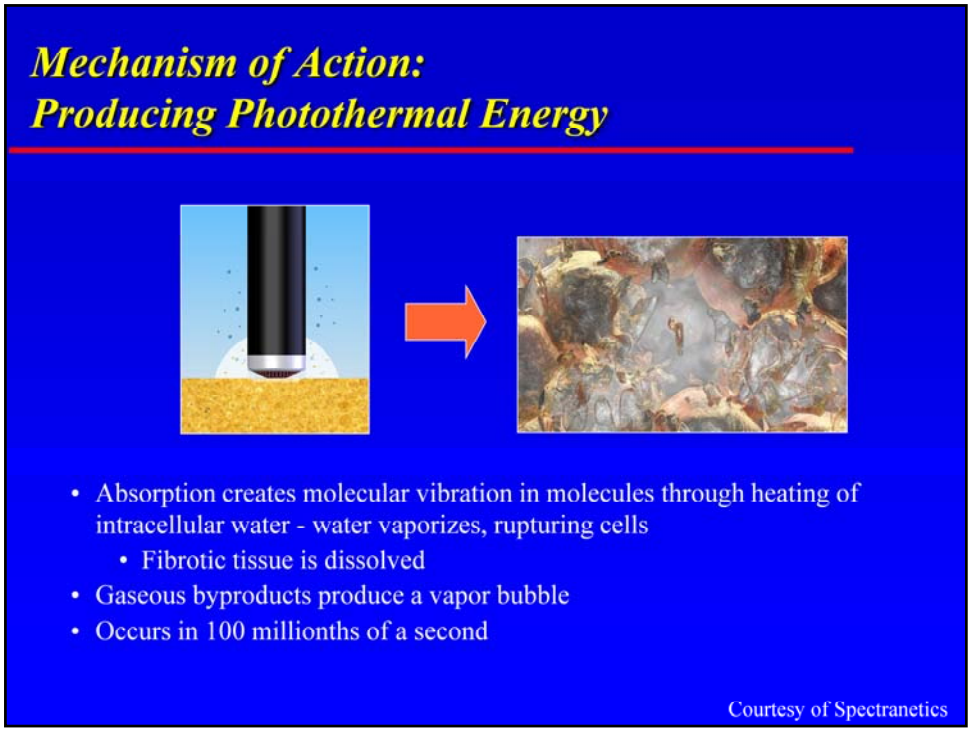


Time scale : 0 -125 nanosecond (ns) – billionth of a second

- 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.



Time scale: 100 millionths of a second

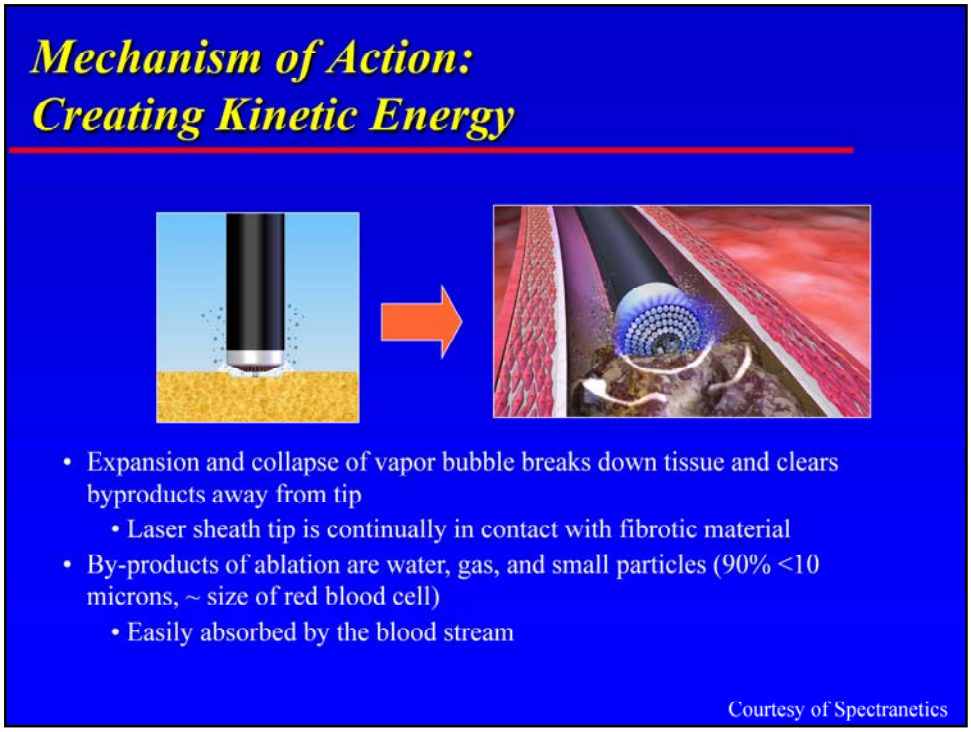
- Ultraviolet light is absorbed and produces fast vibration of molecular bonds in the tissue

- Vibration heats the intracelluar 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.



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

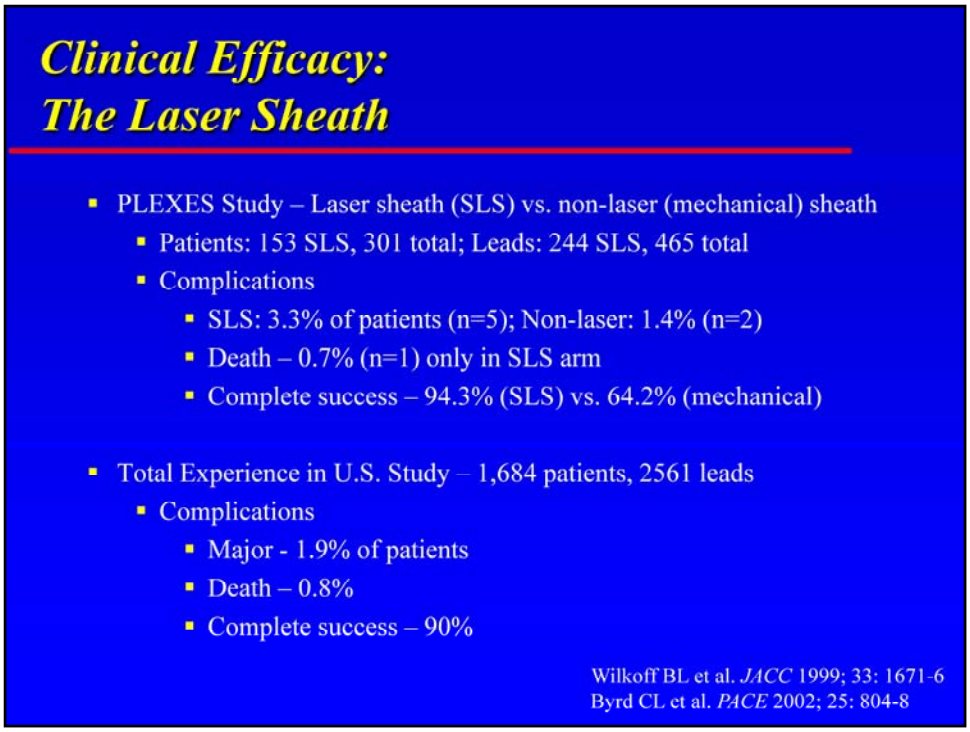
- The fast expansion and implosion of the steam bubble produces cavitation and pressure effects that further break down tissue and assists in sweeping ablated debris from the face of the catheter.

-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

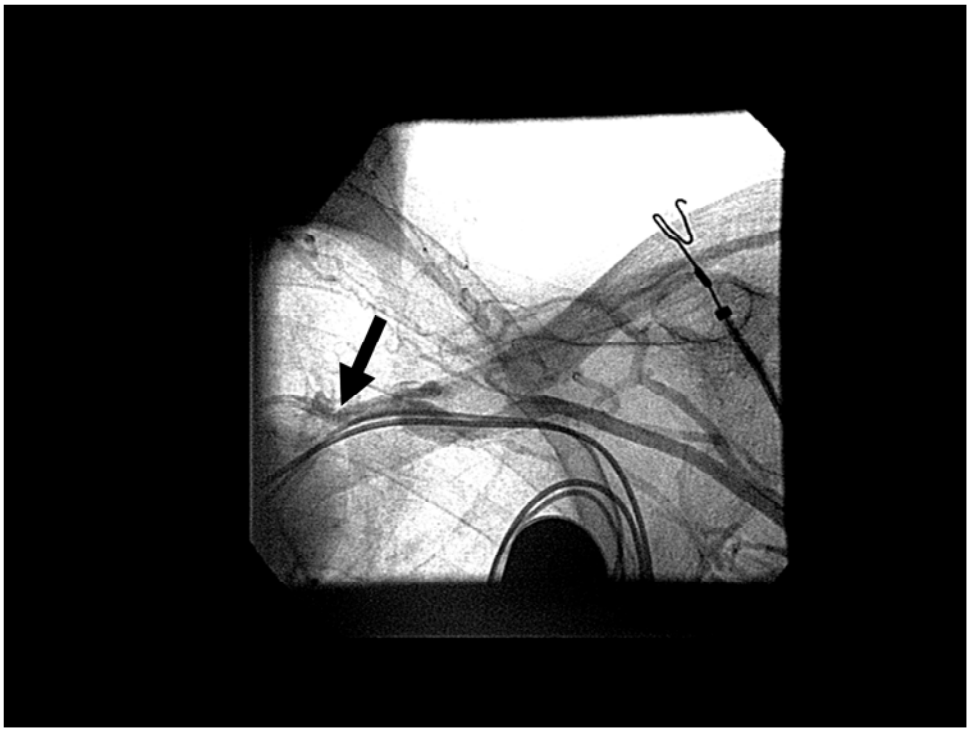


The experience to date with the laser lead extraction system demonstrates a high degree of success (with respect to complete extraction of the lead) with an acceptable rate of complications. However, the risks and benefits of lead extraction must be carefully weighed in **each** patient as the procedure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

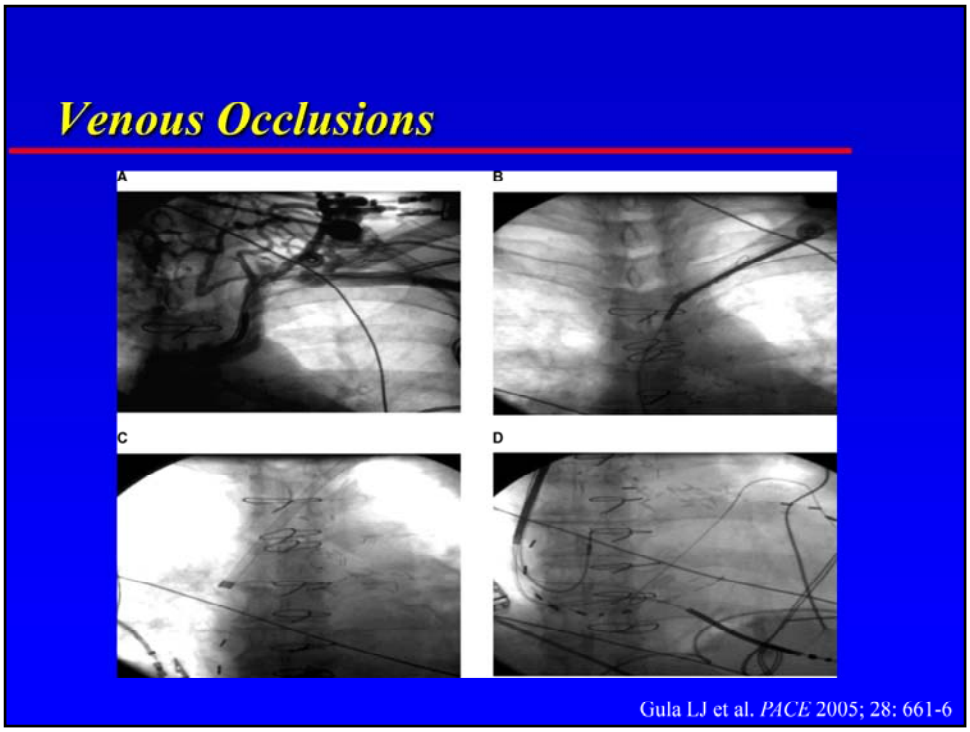
Venous Occlusions

- 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

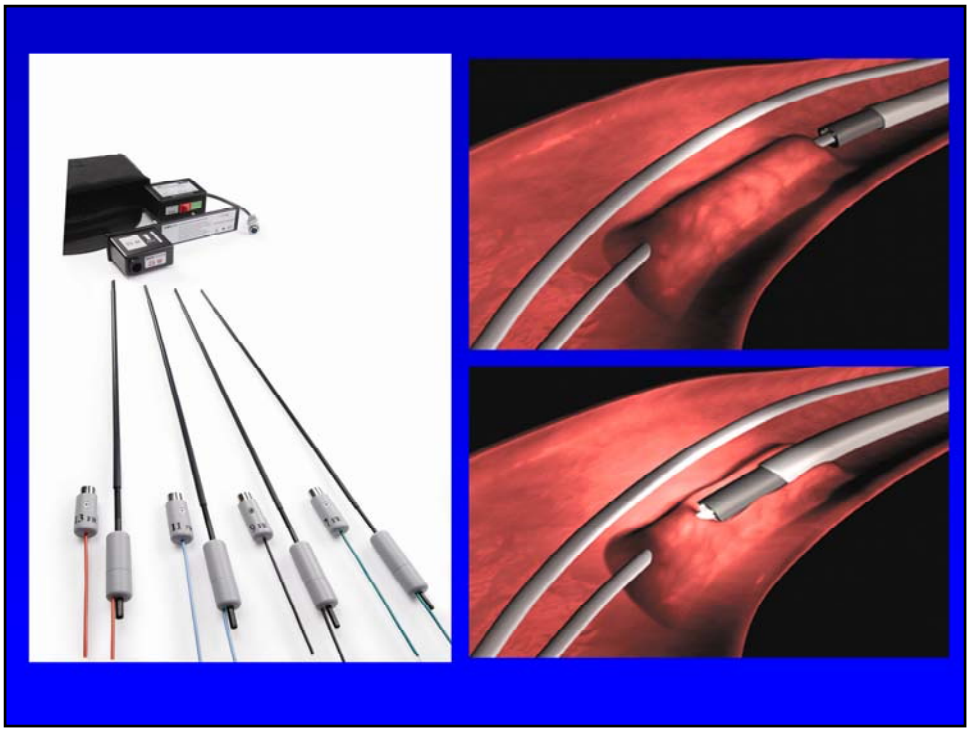
Korley VJ et al. *JICE* 2000; 4:523-8
Lickfett L et al. *Europace* 2004; 6: 25-31



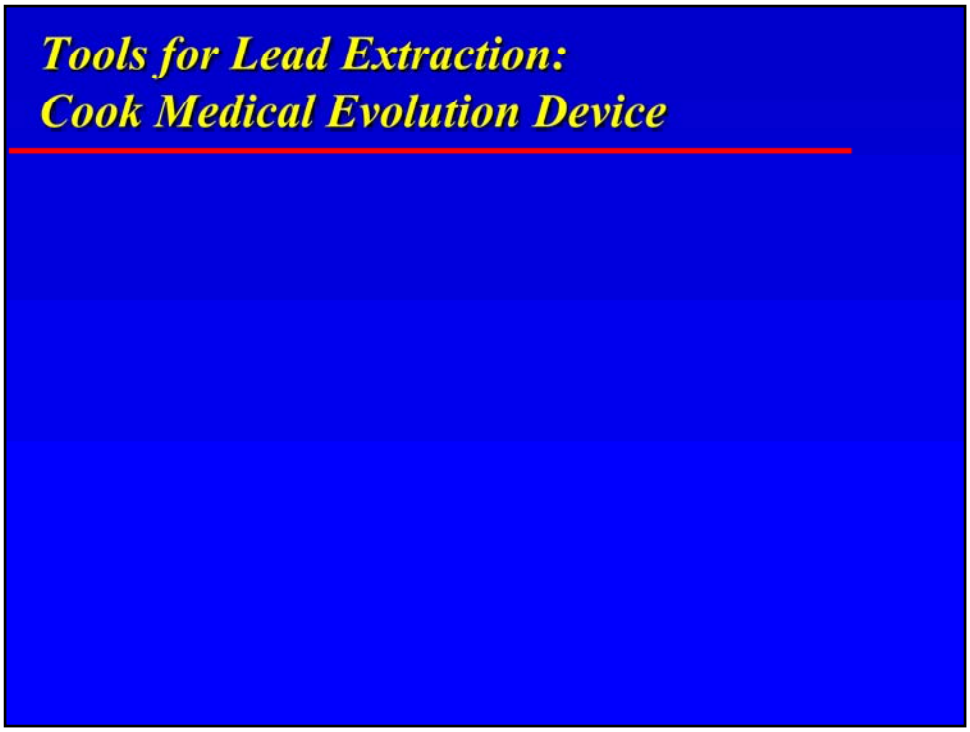
This venogram of the left subclavian vein was obtained during a procedure in which there was a need to add a left ventricular pacing lead (i.e. upgrade from a dual chamber to biventricular system). Note that the left subclavian vein was entirely occluded (black arrow) at the point where the prior leads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



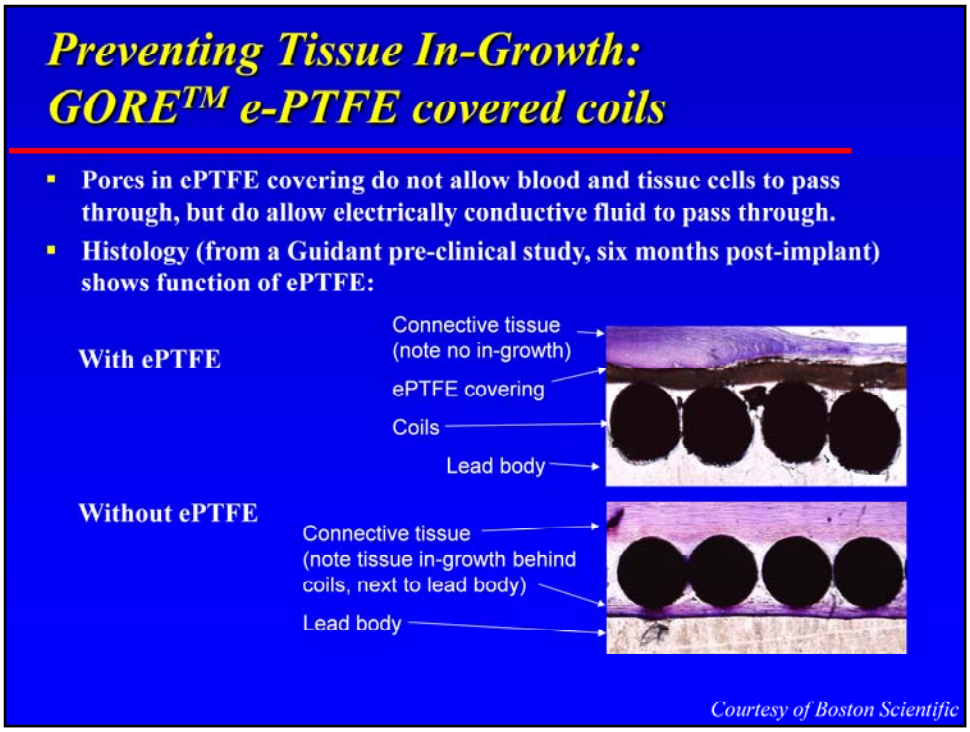
In patients with venous occlusions (panel a), it is possible to “cross’ the occlusion with a laser sheath (panel b), remove the existing leads (panel c), and use the channels created to implant an entirely new multi-lead system (panel d).



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



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



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.

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