EP Lab Digest 20 YEARS

A product, news & clinical update for the electrophysiology professional

EP Lab Spotlight

Morristown Medical Center

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In this issue we welcome back Morristown Medical Center, the first EP program to be featured in *EPLD*'s Spotlight Interview, in September 2001.

When was the EP program started at your institution? By whom?

Stephen Winters, MD, initiated a full-time, hospital-based EP program at Atlantic Health System's Morristown Medical Center (MMC) in November 1991. He came from the Mount Sinai Medical Center in New York where he was co-director of the EP program and director of the arrhythmia clinic.

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Lead Extraction: From Traction to Technology

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As we celebrate the 20th year of *EP Lab Digest*, the age-old expression "need necessitates invention" could not be more accurate, and in no field of cardiology is this more evident than the evolution of lead extraction. Within a decade of the initial pacemaker implant in October 1958[1], the need to remove these devices was realized and the concept of lead extraction was born. Case reports of pacemaker lead extraction, for indications such as infection and lead malfunction, began to appear in the literature in the late 1960s.[2] The earliest methods available were surgical intervention and manual traction. Surgical techniques ranged from limited thoracotomy to open chest procedures requiring cardiopulmonary bypass.[3] The surgical approach was usually seen as a final solution given the significant morbidity and prolonged recovery times associated with these procedures.

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Cover Story

History of Ventricular Tachycardia Ablation

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Ventricular arrhythmias can be responsible for worsening heart failure, painful shocks from implanted defibrillators, and sudden death in patients with structural heart disease and inherited channelopathies. Antiarrhythmic drugs often provide incomplete control of ventricular tachycardia (VT), worsen underlying heart failure, and expose the patient to risk of toxicities. For these reasons, catheter ablation for VT has evolved into a critically important part of arrhythmia management for patients with structural heart disease. Figure 1 demonstrates the critical points in the history of VT catheter ablation related to the historical and technological limitations in delivery of ablative strategies to the target tissue of interest, and shows the progress in understanding the underlying mechanisms of arrhythmogenesis.

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HMP Global

Lead Extraction: From Traction to Technology

Shashank Jain, MD[1], and Jude F. Clancy, MD, FHRS[2]

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Manual extraction of pacemaker leads involved simple traction on the lead after the generator was removed and the visible portion of the lead dissected free. While this technique worked well for relatively young leads that were typically less than one year old, it was quickly realized that lead tensile strength and the pathology of lead fibrosis limited the success of this technique for older leads. Implantation of intravascular foreign material, such as pacing or defibrillator leads, initiates an inflammatory response which involves thrombus formation, fibrosis, and ultimately, calcification of the lead(s) to vascular and cardiac structures. This process continues to propagate over time and can result in dense adherence of leads to the vascular wall, myocardium, and tricuspid valve. As a result, the risks of manual traction included myocardial avulsion, vascular tear, and disruption of the tricuspid valve.[4] Therefore, a more continuous traction approach was developed in which a weight was attached by a string and pulley system to the lead (Figure 1). The patient remained in bed until the weight "fell", indicating the lead had pulled free.[5] While this approach was often effective, duration (hours to days), associated risks and morbidities, as well as infection risk at the surgical site, which was open for a prolonged period, limited its success.

In addition, the design and tensile strength of leads are major factors in maintaining the integrity of the lead to allow for complete removal. Acute manual traction often resulted in lead disruption with portions of the lead remaining in the vascular space. The inferior approach was developed to extract lead fragments no longer accessible from a superior approach. Large sheaths are placed in the femoral vein and advanced to the inferior vena cava. A number of vascular tools were then successfully adapted for the purpose of removing retained lead fragments. Tip-deflecting guidewires, snares, bioptomes, pigtail catheters, and retrieval baskets were advanced through the large sheath to grasp the lead or lead fragment and remove it through the femoral sheath with traction.[6-9] Most of these tools are in use today. In a situation where traction alone did not result in lead removal, the portion of the lead which had been grasped was then withdrawn into the large outer femoral sheath (Figure 2). The sheath was advanced to provide countertraction and facilitate safe lead removal. While the femoral approach was initially developed as a bail out when a superior approach was unsuccessful, it remains an important technique in lead extraction and is the preferred method for some extractors.

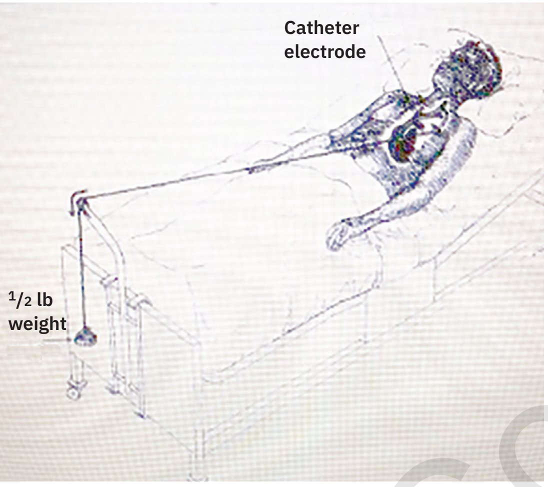

Figure 1. **Manual traction with weight and pulley system.**

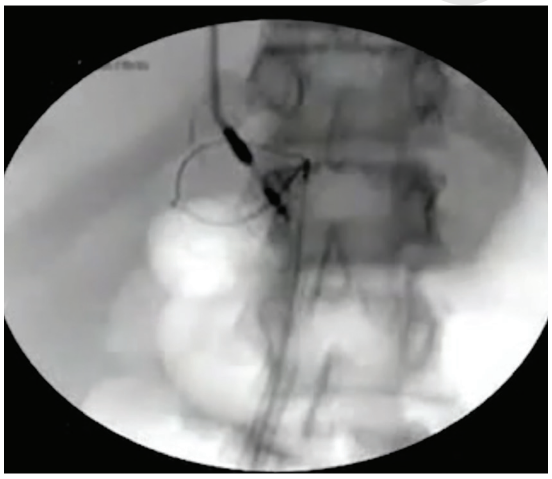

Figure 2. **Fluoroscopic clip showing a snare tool being used from a femoral approach to remove the pacing lead during an extraction procedure.** ***(Video available on eplabdigest.com)***

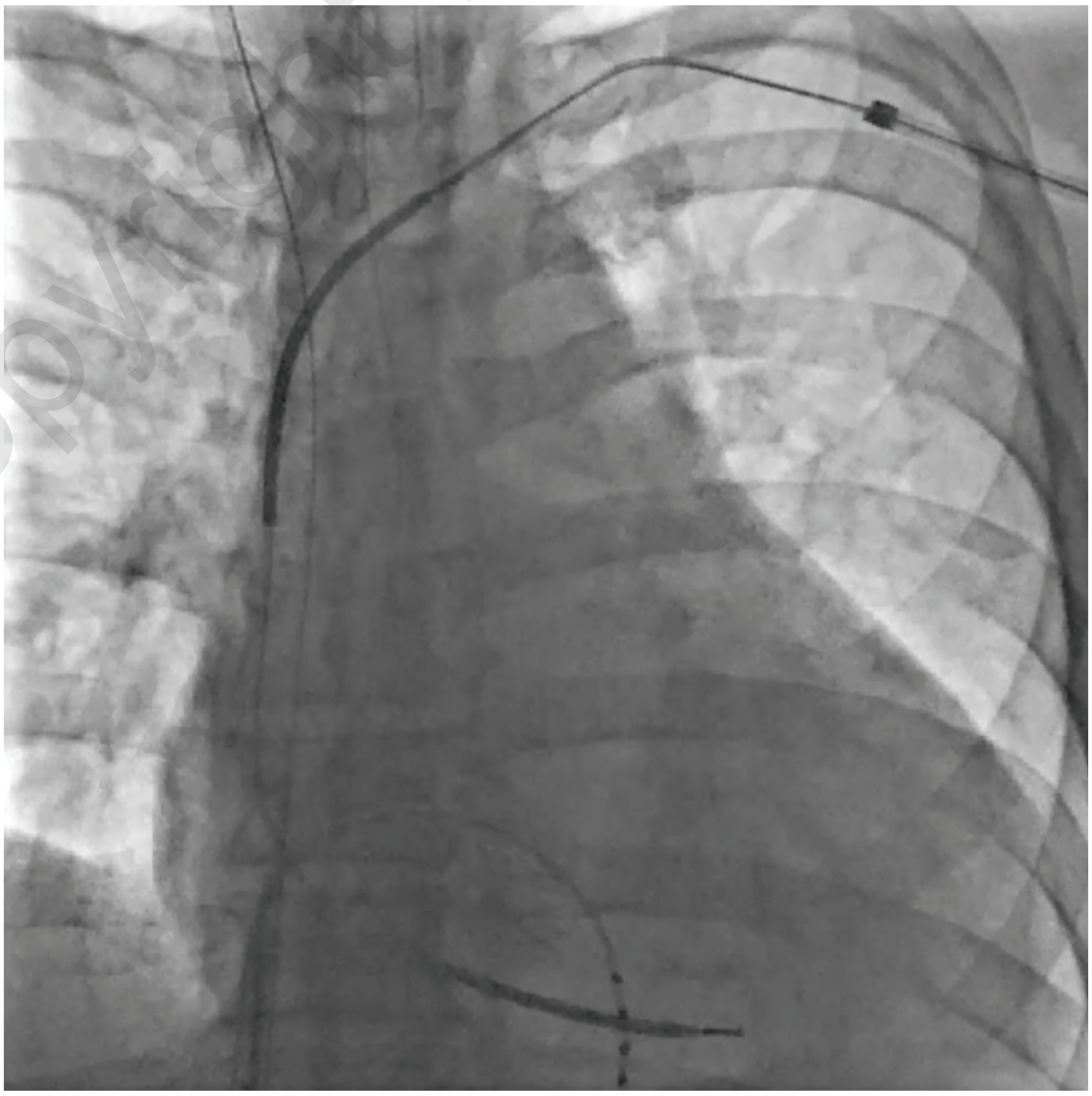

Figure 3. **Laser sheath and outer sheath used during extraction of a right ventricular ICD lead. Figure courtesy of Robert Schaller, MD.** ***(Video available on eplabdigest.com)***

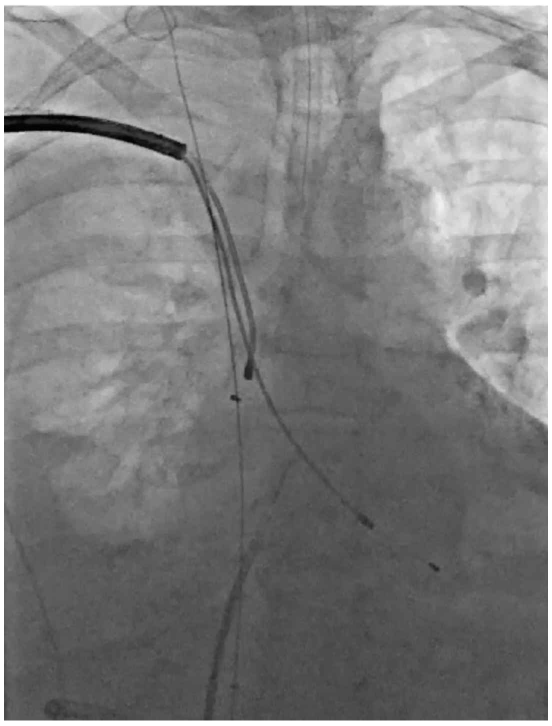

Figure 4. Mechanical sheath being used during the extraction of a right ventricular lead. Figure courtesy of Robert Schaller, MD. ***(Video available on eplabdigest.com)***

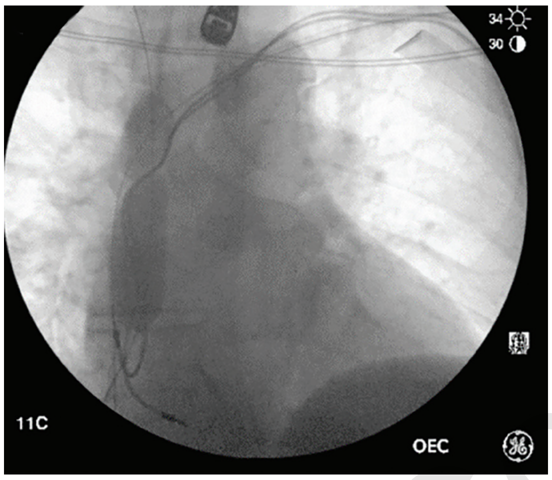

Figure 5. Endovascular rescue balloon deployed in the SVC. The compliant nature of the balloon allows it to conform to vascular geometry.

As the early pioneers of lead extraction continued to develop tools and techniques to improve safety and efficacy, the concept of countertraction was applied to the superior approach of lead extraction. Countertraction is a technique in which direct traction on a lead is countered by the pressure exerted by an extraction sheath advanced over the lead to the myocardium.[10,11] To overcome disruption of lead integrity and breaking of leads seen with prior manual traction, locking stylets were developed. These fine wires had various designs which, when advanced down the central lumen of the lead and deployed, resulted in "locking" of the wire in the central lumen. Ideally, the stylet was advanced to the distal tip of the lead stiffening the lead and allowing traction on the lead to be distributed along the lead, and in particular, the distal tip. Locking stylets remain an important tool in lead extraction today. Improved control along the length of the lead allowed for the development and use of sheaths. Sheaths are a key component in the safe and successful extraction of pacemaker and defibrillator leads. They provide the capability to disrupt fibrotic tissue responsible for lead-lead and lead-vessel binding, as well as countertraction at the lead-myocardium interface. The technique involved advancing the inner sheath with clockwise and counterclockwise rotation along short lengths of the lead surface. The outer sheath was then advanced over the inner sheath. Careful traction-countertraction was applied at the myocardial interface to free the fibrotic lead tip and prevent invagination of the myocardium to minimize the risk of myocardial avulsion. Initial standard sheaths were long telescoping tubes of various diameters made from several different materials, including Teflon, polypropylene, and stainless steel. Polypropylene is a stiffer material than Teflon and more efficient at disrupting fibrotic adhesions; however, there is greater concern for injury to vessel walls. Stainless steel sheaths were used specifically at the entry site of the lead, between the clavicle and first rib, often a site of heavy calcification and fibrosis. Once the sheath was advanced through this region, it was exchanged for a polypropylene or Teflon sheath to complete the extraction. The lead was freed and removed through the sheath, allowing for retained access to reimplant if necessary. Using these techniques and tools, success rates of 71%-97% for complete extraction of pacemaker leads were reported.[10-14]

As the need for extraction increased, so did the need for additional tools. The introduction of the implantable cardioverter-defibrillator (ICD) resulted in larger diameter leads with metal coils which created more pronounced fibrotic reaction due to the metal material and invaginated surfaces, potentially making these leads more difficult to extract than pacemaker leads. In addition, mechanical sheaths and traction-countertraction, although successful, worked by tearing and mechanical disruption of fibrotic tissue. Therefore, in an attempt to improve safety and efficacy, the first powered sheath was introduced in the mid 1990s. This sheath, an ultraviolet, excimer, cool-cutting laser dissolved tissue to a depth of 50 µm, minimizing risk to vascular and cardiac structures (Figure 3). The first European experience, published in 1998[15], and the first clinical study in the U.S., the PLEXES trial[16], showed use of the laser sheath resulted in higher success in complete lead removal and also decreased time to successful extraction when compared to nonlaser extraction. Use of the laser, however, was associated with increased risk of potentially life-threatening venous or cardiac tear. These data were further refined by a consecutive study in 2010, the LExICon study.[17] This multicenter study demonstrated laser-assisted lead extraction had a high success rate (97.7% clinical success) and overall low procedural complication rate (1.4%). As more experience was gained with the laser, there developed a need for a powered sheath that would cut through dense, calcified adhesions. Mechanical sheaths, hand-powered tools with rotational stainless steel teeth, were introduced in 2008[18] (Figure 4). Over time, mechanical sheaths were modified to include bidirectional cutting capability, a shielded blade, and a flexible shaft. The various mechanical powered sheaths have added important tools to extract complex leads with success rates of 95.7%-100%[19] and no significant difference in clinical or procedural success between these mechanical sheaths.

With the continued development of tools and an increasing need for extractions, the focus shifted to driving the procedural mortality to zero. Although major complications such as myocardial or vascular tear occur in only 0.8%-2% of cases, mortality from these complications can be significant.[16,20-22] The most common injury during lead extraction is superior vena cava (SVC) tear, which typically results in sudden hemodynamic compromise and requires emergent open surgical repair.[17,20] Despite appropriate surgical repair, mortality of an SVC tear approaches 50%.[20,21] An endovascular occlusion balloon was developed to reduce blood loss, maintain hemodynamic compromise, and serve as a bridge to surgical rescue[23] (Figure 5). Clinical data in follow-up, after release of the balloon in 2016, demonstrated a significant improvement in survival from SVC tear (88.2%) with appropriate use of the balloon when compared to no balloon or inappropriate use (56.9%).[24]

The field of lead extraction, born out of necessity, continues to evolve to better care for patients with implantable cardiac devices. Novel ideas of today's extractors, passionate about lead extraction, based in the principles established by pioneers, will continue to improve the safety and efficacy of the

The field of lead extraction, born out of necessity, continues to evolve to better care for patients with implantable cardiac devices. Novel ideas of today's extractors, passionate about lead extraction, based in the principles established by pioneers, will continue to improve the safety and efficacy of the procedure.

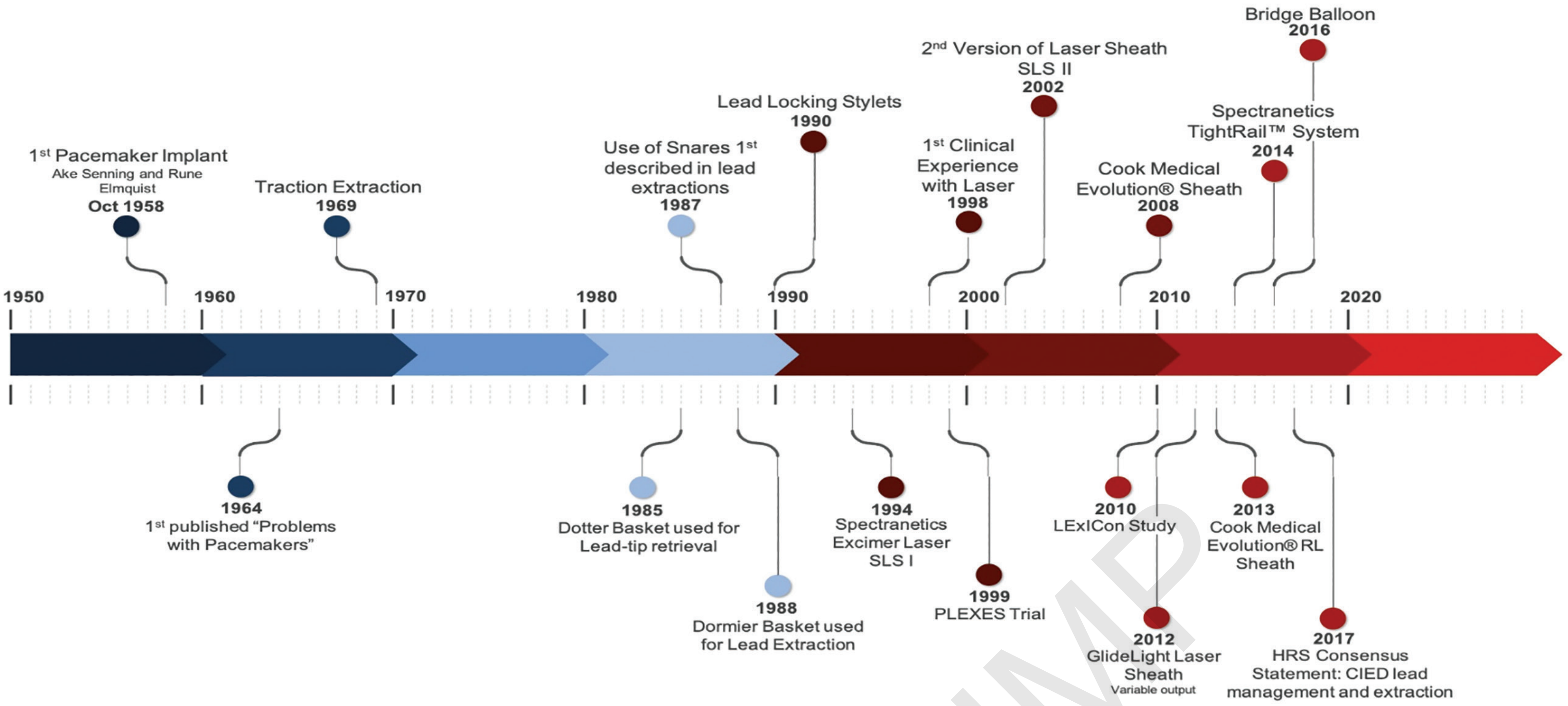

Figure 6. **Timeline of development of lead extraction from beginning to present.**

procedure. Additional powered sheaths, new tools for femoral approach, and use of imaging to predict degree and location of fibrosis, will have a major impact in the future development of this field. We are confident the 20th year celebration of *EP Lab Digest* will attest to this. ■

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Disclosures: The authors have no conflicts of interest to report regarding the content herein. Outside the submitted work, Dr. Clancy reports support from Philips for proctoring new extractors.

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