Extraction of Transvenous Pacing and ICD Leads

MACY C. SMITH, M.D.* and CHARLES J. LOVE, M.D.†

From the *Division of Cardiovascular Medicine, the Ohio State University Medical Center Columbus, Ohio, and †Cardiac Rhythm Device Services, OSU Division of Cardiovascular Medicine, Columbus, Ohio

The emergence of pacing and implantable cardioverter-defibrillator (ICD) systems, along with expanding indications of these devices (e.g., cardiac resynchronization therapy and sudden cardiac death prevention), increasing infection rates, and device recalls have created the need for removing and upgrading these systems due to various reasons. Removing the pulse generator of a system is generally uncomplicated. Chronically implanted transvenous leads, however, adhere to the venous endothelium and endocardial tissues over time due to fibrosis. Removal of such leads can be a significantly complex procedure requiring tools and techniques that free the lead at fibrotic binding sites. In this article, the state-of-the-art tools and techniques that provide a systematic approach to consistently and safely extract these devices will be reviewed. (PACE 2008; 31:736–752)

Overview

The advent of implantable devices has produced the subsequent need for removal of these devices. Malfunction, erosion, pocket infection, endocarditis, and other unique device-related issues are common reasons for removal. Removal of the subcutaneous or submuscular pulse generator alone is a fairly uncomplicated procedure. However, removal of the chronically implanted transvenous lead system can be a significantly complex procedure.1–5 The major barrier to removal of these leads is fibrosis that progressively grows around the lead body and electrode tip, securing leads to the venous endothelium and to the myocardium. Freeing the lead from these binding sites safely is the goal of tools and techniques that have been developed.

Over the years of lead development, the early large-diameter solidly built wires have been replaced by smaller, more delicate, and structurally complex leads. Many leads implanted in the recent past lack significant tensile strength. When traction is placed on these less-than-robust leads, breakage at almost any part of the lead system may occur. It should be noted that this trend toward fragile construction is not universal to all newer leads. Indeed, anecdotally some of the smallest leads currently on the market have a history of being extractable with manual traction up to 4 years postimplant. Though most current leads are constructed with one or more helical metal alloy conductors with varying configurations, cable conductor construction is becoming increasingly common. Silicone rubber, polyurethane, or newer copolymers provide the insulation and add to the tensile strength of the lead system.

The limiting factor when a physician pulls on a lead (of helical coil construction) by applying simple traction, is the tensile strength of the insulation. If the insulation fails before the lead is pulled free, all that remains is the conductor coil or coils. At this point, the lead system behaves like a spring or a strand of piano wire. Coil deformation and possibly breakage will result from further direct traction. Although direct traction will remove some newly implanted leads, it is not safe or effective for many leads. Tools and techniques have been developed to provide a system and approach to consistently and safely extract these devices.

Definition

The Heart Rhythm Society (formerly NASPE) defines “extraction” as the removal of any transvenous lead implanted in excess of 1 year, a lead that requires tools beyond standard stylets included in the typical implant package, or a lead removed from a route other than via the implant vein.6 To clarify, lead removal is defined as removal of a lead by any technique. Lead explant is the removal of a lead implanted less than 1 year via the implant vein using the tools typically supplied for lead implant.

The success of the extraction can be determined by several criteria. Radiographic success is defined as the removal of all lead components.
This would also be termed a “complete extraction.” Partial extraction is removal of most of the lead, but a small portion (such as the electrode tip and/or a small—less than 2 cm—piece of wire or insulation) is retained in the patient’s heart or venous structure. Clinical success is deemed to have occurred when the clinical objective was achieved, regardless of the degree of radiographic success. For example, in the case of a pocket infection a significant portion of the lead may be retained intravascularly, but the pocket infection is resolved. Another example would be that of an occluded subclavian vein, for which an extraction attempt allowed one to reaccess the circulation, but for which a portion of the old lead was retained.

Indications

Indications for extraction have evolved to encompass more patients and problems as the techniques for extraction have become more refined, safe, and reliable. Dr. Charles Byrd created the first widely used classification scheme related to the indications for lead extraction. This classification (Mandatory, Necessary, and Discretionary) is based on the patient’s clinical status. Mandatory indications include situations where there is significant risk of mortality or morbidity related to or caused by the implanted lead system. Necessary indications lack a current direct threat, though a problem is present or could be anticipated. Discretionary indications are prospectively concluded to be in the patient’s best interest to have the leads removed.

Later, NASPE (now HRS) published a policy statement with the familiar class I, II, and III classification scheme (Appendix). Class I indications are conditions for which there is general agreement that the leads should be removed. Class II indications are conditions for which leads are often removed, but there is some divergence of opinion with respect to the benefit versus risk of removal. Class III indications are conditions for which there is general agreement that removal of leads is unnecessary.

Pathophysiology

Thrombus formation on portions of the lead is the initial response to the placement of a lead, which represents an intravascular foreign body. The thrombus eventually organizes with fibrosis occurring predominantly on areas of lead that contact the vascular endothelium or endocardium. Fibrosis propagation occurs along the lead that becomes increasingly dense with time (Fig. 1). The venous entry site, the curve into the superior vena cava (SVC), and in the region from the anode ring to the lead tip are sites most likely to develop severe fibrosis. Calcium may incorporate into the fibrous matrix, especially in young patients and very old leads. Our institutional experience suggests that the quality of the fibrous tissue within the pacemaker pocket, surrounding the pacemaker and lead body, usually represents the characteristics of the intravascular fibrous tissue.

A major assumption to safely performing lead extraction is that the lead is intravascular, and travels to the heart through the venous system exclusively. Unfortunately, there are cases where this is not true. If the lead was placed by the “subclavian stick” technique, the needle and therefore lead could have traveled through the artery before entering the vein. Occult fistulas can occur if the lead erodes through the vein into the artery. A portion of the lead then may become excluded from the vein or even a portion of the myocardium (usually atrial). Vascular emergencies may result in these situations from removal of the lead by direct traction, or by passage of a sheath over the lead.

Figure 1. A pacing lead with fibrous material tightly adherent to it. This tissue was avulsed from the vessel wall during the extraction process.
Indication-Specific Removal Infection

The most common class I indication for pacemaker lead extraction is pocket infection or erosion. Recurrence or failure to resolve a pocket infection is commonly seen if any part of the pacing system (including suturing sleeves, suture, and lead caps) is left in the pocket. Simple debridement of the tissues, irrigating, and moving the same pacing system to an adjacent area yields consistently poor results. In order to achieve the highest possible cure rate, all prosthetic material from the infected area as well as prosthetic material that are present (and therefore colonized) must be removed. The pacemaker or implantable cardioverter defibrillator (ICD), leads, adapters, lead caps, suturing sleeves, and suture must all be removed. In some cases, however, the risks of extraction may be excessive. There are case reports of extensive pocket debridement and sterilization of the leads with antiseptic agents and oral antibiotics being successful. It should be emphasized that this approach is only rarely successful, and no significant prospective data support this approach. Pocket erosions should be treated the same as infection. A common error is to treat erosions differently from a typical pocket infection. In reality, device colonization occurs with erosion, precluding reimplantation of the same system to a new subcutaneous region. Another common misperception is that the guidelines classify all pocket infections as a class-II extraction indication. This is not the case. Any time the infected pocket is adjacent to the venous insertion site (as opposed to an infected pocket in the abdomen with the lead tunneled to the subclavian area), a class-I indication for extraction exists. This will be further clarified in an upcoming revision of the HRS lead extraction guidelines.

Infection of the intravascular portion of a lead may cause sepsis or endocarditis. In the past, some have treated this condition for years with chronic antibiotics. The only way to ensure cure is the complete removal of all of the infected or colonized lead system, as with pocket infections. Cutting the proximal portion of the lead and allowing it to retract into the central circulation such that it is inaccessible via the venous entry site is inappropriate and should be avoided in any situation (pocket infection or endocarditis). Subsequent attempts at lead removal are made far more difficult, often requiring a femoral or transatrial approach. An increasingly common clinical problem is that of vegetations, which can occur with implanted leads. The vegetations can be attached to the myocardium or the lead itself. Though there are a number of reports of uncomplicated extraction in the setting of larger vegetations, it is the opinion of many experts (including this author) that one should consider alternative techniques to the venous entry site extraction approach when vegetations are in excess of 2 cm. Many experts feel that the extraction attempt poses a risk of significant embolization once the vegetation reaches a diameter of 2 cm. Massive pulmonary embolus or complete pulmonary valve occlusion can occur from embolization. Strong consideration of direct removal via atriotomy is suggested with very large vegetations or thrombi. Surgical extraction may also be warranted for retained leads that cannot be removed by transvenous techniques, to remove extraction tools that become trapped within the venous system, for extracting leads inadvertently placed within the left heart to avoid possible embolism, and for leads that are known to have been placed or traverse outside of the venous system.

Multiple Leads

Current pacing systems commonly consist of more than one lead. Indeed in our institutional experience, it is not uncommon to see cases with five or more leads. The degree of difficulty and complication risk is proportional to the number of leads present, as shown by the Lead Extraction Registry and other reports (Table I). In this series by Byrd et al., of the 896 women who underwent attempted extraction of one or two leads, major complications occurred in 1.9%. Yet, major complications were significantly higher in the 58 women who underwent extraction of three or more leads (8.6%; P < 0.005, Yates corrected chi-square). Though a trend was present for males, a significant relationship was not seen (0.7% major complications for one to two leads, 1.5% major complications for three or more leads, P = NS). Fibrosis not only binds leads to vessel walls, but infiltrates between leads binding them together. It is not uncommon to dislodge or damage an adjacent lead when attempting to extract another lead. Further, if one lead is difficult to remove, extracting an adjacent lead may free the former lead to permit removal.

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<td>Risk of Complications Related to Number of Leads</td>
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<td>Odds Ratio</td>
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<td>Risk of major complications</td>
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<td>Number of leads 1.6939 2.8935 0.9917 0.054</td>
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<td>Risk of any complication</td>
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<td>Number of leads 1.6659 2.3710 1.1704 &lt;0.005</td>
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Venous Thrombosis

The increasing number of patients being seen at our institution for axillary/subclavian venous thrombosis suggests that this is becoming a more important issue (Fig. 2). This may be related to the increased use of more lateral venous access, such as the extra-thoracic approach, and by the placement of multiple leads in the venous system. Venous occlusion may result in edema of the ipsilateral upper extremity. This may be transient and mild or permanent and severe. The latter case is more likely when thrombosis is more peripheral where collateral drainage is limited. Spontaneous recanalization of the vessel, or dilation of collateral vessels to drain the affected limb, will usually result in resolution of the clinical manifestations. However, symptoms can be extreme. Severe, even life-threatening symptoms can occur if the brachiocephalic vein or superior vena cava is occluded. Leads may be removed and/or thrombolytics given in the acute setting. Stents have been successfully placed into the brachiocephalic and superior vena cava veins to reestablish flow and resolve symptoms. Unfortunately, stents in the more peripheral subclavian or axillary venous regions are likely to thrombose due to the slow blood flow in these areas. If a stent is placed, it is critical that any leads present be extracted prior to deployment of the stent, so that incarceration of the leads between the stent and the vein does not occur. In chronic vein occlusion, introduction of a new lead system may be permitted through the channel created by extraction sheaths. Additionally, if a guidewire can be passed through the area of occlusion, a channel may be created with venoplasty alone or in combination with stent placement. Caution should be exercised concerning placement of a new lead system on the side contralateral to an occluded vein, as subsequent bilateral subclavian vein occlusion could result in a much worse situation for the patient.

Migrated Leads

Arrhythmias can result from fractured or intentionally cut leads that end up free floating in the atrium or ventricle. Ventricular arrhythmias and atrial fibrillation have both been reported. We have seen pulmonary infarcts as a result of leads migrating into distal branches of a pulmonary artery. It is usually possible to snare the leads with a grasping tool and extract it, thus resolving the problem.

Crush

Using the medial subclavian vein approach for venous access is easy, but may place severe stress on the lead, resulting in “subclavian crush.” As such, lead fracture most frequently occurs where the first rib crosses under the clavicle (Fig. 3), though fractures can also occur at other sites. Medial access of the vein can cause the lead to traverse through the costo-clavicular ligament and/or subclavius muscle, placing tremendous force on the lead and producing crush (Fig. 4). This can also occur if the periosteum is penetrated during needle advancement to access the vein. The latter often results in a band of calcification around the lead.
Lead extraction under these circumstances can be difficult, as a great deal of friction and pressure is exerted on the extraction sheaths as they pass through these structures. Retaining a guidewire through the extraction sheath with placement of a new lead along the same path may result in the new lead system being exposed to the same forces that caused the original lead system failure. Thus, this practice should be avoided. In addition, if one lead has fractured and is next to another lead that was placed via the same venous insertion site and technique as the fractured lead, it should similarly be assumed that the second lead is under the same forces. This nonfractured lead is therefore at very high risk for failure as well, and strong consideration should be given to extracting the second (as yet) nonfractured lead. This is particularly true if a single stick with retained guidewire technique was used to place the two leads. It is better for the long-term performance of the new system if a more lateral approach or cephalic vein insertion is used for the new leads. If the venous system is patent at the beginning of the procedure, it is best to obtain the new venous access prior to extracting the old lead system, as venous occlusion and venous tears are not uncommon during extraction.

Counter Pressure and Counter-Traction

A series of tools for lead extraction has been developed to allow for a safe and consistently effective procedure. The purpose of these tools is to reinforce and stabilize the lead while a sheath is passed over the lead to free it from fibrous tissue. Traction is placed on the lead sufficient to allow a sheath to pass over it with counterpressure. Sheaths can disrupt, dilate, include, cut, or vaporize scar tissue. Traction must be sufficient to allow the sheath to follow the lead around the bends of the vascular system. Vascular tears can occur if the sheath fails to follow the lead around bends. If the tensile strength of the scar tissue exceeds that of the vessel wall, a vascular tear may occur regardless of operator care. Operator judgment must determine the amount of pressure to safely use, constantly balancing the amount of forward pressure applied to the sheath with the tension applied to the lead.

The technique of counter-traction comes into play once the sheath is advanced to the lead tip at the myocardial interface. The sheath braces the myocardium and localizes the traction force to the scar tissue just around the lead tip (Fig. 5). The forces are therefore localized to the tissues immediately adjacent to the electrode tip rather than
invaginating and jeopardizing a large piece of myocardium.\textsuperscript{29-31} Once the sheath is appropriately positioned, significant traction can be applied to the lead to free it from the heart. At this point, the lead will generally free from the myocardium or break. A common misconception is that counter-traction is a concept that applies only to nonpowered sheath systems, and not to laser or electrosurgical dissection sheaths (EDS). This is patently wrong. The difference in the various sheath systems is simply the method of tissue disruption and dissection as one advances the sheath to the distal end of the lead. Once the sheath is positioned near the myocardium, all sheath-based methods utilize counter-traction to stabilize the myocardium around the lead tip to minimize the risk of tear and avulsion. It is also important to recognize that continued advancement of any type of sheath, or energizing a powered sheath when it is the lead tip, can result in perforation of the myocardium.

**Preparation**

The procedure and risks should be understood by patients undergoing lead extraction, as well as the staff performing the operation. They should also be aware of the less well-defined risks of lead abandonment, and that leads are more difficult to remove if extraction is attempted at a later date. Lead extraction may be performed in an electrophysiology (EP) laboratory, catheterization laboratory, or an operating room. Excellent fluoroscopy is critical to the safe removal of leads. EP and catheterization labs are therefore superior regarding high-quality fluoroscopy rather than portable C-arm units in operating rooms. Operating rooms have the advantage of being a better venue should an emergent thoracotomy be required. However, no matter which venue is chosen for the operation, one must have cardiac surgery available at the institution, and a cardiac surgeon must be present in the hospital. If the extraction is being performed in a setting other than a cardiac operating room, some physicians will keep an operating room ready during the critical phase of the operation. However, other institutions use the same approach as used for percutaneous coronary interventions, with a surgeon notified that the procedure is occurring. Advance notice of a surgeon may not be necessary at larger institutions where back-up is readily available. In certain high-risk cases such as advanced age and anticipated, substantial lead fibrosis, closer cardiac surgical back-up is recommended.

A large bore intravenous line should be placed to administer medications, fluids, and (if needed) blood products. An arterial line may be placed at the discretion of the operator for beat-to-beat blood pressure measurement. If an arterial line is not used, a pulse oximeter with pulse waveform monitoring can be used as an alternative. Having femoral venous and arterial lines present at the beginning of a procedure is an option that can facilitate placement of peripheral cardiopulmonary bypass in a crisis, when this equipment is available. Anesthesia can be administered via general anesthesia with endotrachial intubation or via intravenous moderate sedation. If moderate sedation is routinely used, one may still elect for general anesthesia in younger patients or cases anticipated to be difficult.
Tools for Extraction Stylets

The ability to place direct traction on the lead is dependant on the integrity of the insulation because most leads are constructed with a helical coil of wire surrounded by a layer of insulation. Further traction on the lead after the insulation fails only uncoils the wire, making extraction more difficult. Leads are floppy by design, thus not providing much stiffness to allow a sheath to track along them. The first key element of lead extraction is the locking stylet. Several types of locking stylets have been designed to stabilize and stiffen the lead, and to provide traction near the electrode tip. Though there have been multiple locking stylets distributed in the past, there are currently only two types in common use. The Cook Vascular design (Liberator™, Leechburg, PA, USA) is made from a very thin extruded tube with a thin wire placed within it (Fig. 6A). At the end of the wire is a wound spring. After the stylet is placed through the lumen of the central coil of the lead, the outer tube is advanced forward, which causes the wound spring portion at the end of the stylet to “bunch up” and lock in place. Hence, the Cook stylet provides traction at the tip of a lead. The other locking stylet available is the Lead Locking Device (LLD™), made by Spectranetics (Colorado Springs, CO, USA). A fine wire mesh is stretched over the entire length of a solid stylet (Fig. 6). The mesh appears woven on close inspection. The mesh can be released once the stylet is advanced down the central lumen of the lead, and holds at various points along the length of the lead body from the internal bunching of the wire mesh. This allows the Spectranatics stylet to exert force on multiple areas along the length of the lead.

Some new leads do not have a lumen into which a locking stylet can be placed. These leads incorporate a cable design rather than a helical coil. The cables also allow for the delivery of direct traction to the lead, without the lead falling apart. A new type of tool has been introduced to facilitate traction, and to extend the lead so that it can be pulled into a sheath. This tool is the Bulldog™ (Cook Vascular) and is somewhat similar to a Dottter basket, except it only has two metal strands instead of four (Fig. 6C). The end of the lead and conductors are placed into the loop, and the metal sleeve is advanced over the loop to close it and thus firmly grasp the lead components.

Sheaths

The second key element for safe and effective extraction is the sheath. Removing adhesive tissues and providing counter-traction are key functions of the sheath. Sheaths are divided into non-powered and powered types (Fig. 7). Nonpowered sheaths are tubes made of various compounds including Teflon™, polypropylene, and stainless steel. Teflon is very flexible but cuts through tissue poorly. Polypropylene is stiffer than Teflon, and therefore better for cutting and disrupting scar tissue, but must be used with greater care to avoid damaging vessel walls. The use of a pin-vise on the plastic sheaths acts as a grip on the sheath, making advancement and torque application easier for the operator. Stainless steel sheaths are used exclusively for entering the venous system from the subclavian approach. They effectively cut through dense fibrous tissues and even calcified areas that other sheaths cannot traverse. Steel sheaths cannot be advanced beyond any curve in the vein due to their stiffness. If not kept perfectly in line with the lead, the steel sheaths are more likely to sever the lead than their more flexible counterparts. Flexible metal sheaths were produced at one time, but were never widely used.

The newest iteration of the nonpowered sheath is the Evolution™ marketed by Cook Vascular. This is a flexible plastic sheath with a threaded metal distal tip. The sheath is attached to a handle that rotates the sheath and allows the threaded metal end to bore through adhesions. Our institutional experience and that of several other centers has shown that this device can be helpful with calcified lesions though there are no published data as of yet. A second iteration of this sheath is now being produced and will be marketed as the “Shorty™.” This shortened version can be used to enter the venous circulation when heavy fibrosis or calcification are present, clearing the way for use of other types of sheaths.

Powered sheaths enable one to advance sheaths along the lead body with reduced traction and counter pressure.34 The Excimer Laser system marketed by Spectranetics is an ultraviolet laser that vaporizes tissues in contact with the tip of the sheath where the optical fibers terminate. The sheath is a flexible composite with multiple glass fibers aligned in a circle and terminating at the distal end. Laser energy is applied when the sheath encounters a binding site. Only tissue that is in direct contact with the end of the sheath is ablated since the laser has a very short penetration depth (100 microns). Though very useful and highly effective, the Excimer laser is expensive to purchase, maintain, and use relative to other options. In addition, there are currently no studies to suggest that laser is safer than nonpowered sheaths. However, due to the reduced force needed in many situations, the laser sheath remains very popular, highly useful, and quite effective.

The Electrosurgical Dissection Sheath utilizes radiofrequency energy produced by a standard electrosurgical unit (ESU) to cut through fibrous...
Figure 6. (A) Liberator™ locking stylet. The spring is compressed by the outer tubular sheath, locking it into the end of the lead. (B) LLD™ locking stylet. The wire mesh expands to lock the stylet into the lead. (C) Bulldog™ clasp. The proximal end of the lead is placed into the loop, and the metal sleeve advanced to compress the loop around the lead coils or cables. This allows one to exert traction on the lead externally in the event there is no inner conductor coil in which to place a locking stylet.
Figure 7. (A) Telescoping teflon, polypropylene, and stainless steel sheaths. (B) Evolution™ sheath. This is a flexible plastic sheath with a distal threaded metal tip. A handle is attached to the plastic sheath proximally that rotates the sheath, allowing the threaded metal end to bore through adhesions. (C) The Eximer Laser Sheath is a flexible composite with multiple glass fibers aligned in a circle and terminating distally that vaporize tissue.
tissues within the vasculature. A flexible plastic sheath that has 2 tightly spaced tungsten electrodes are exposed at the cutting end, and energized using pulses of energy from the ESU. This allows linear dissection of the material encasing the lead body. The sheath can be rotated to cut circumferentially, or held at a single angle to direct the energy away from weaker areas of the vasculature. It is notable that neither of the powered sheath systems can cut through calcified adhesions effectively. The EDS is very effective, but can cause some patients discomfort during the extraction process when the phrenic nerve is stimulated as the sheath passes close to it. This is transient, and terminates once the sheath is beyond the region where the vein and nerve are in close proximity.

Note that no one sheath will work on all leads in all patients in all situations. It is often necessary to change from one technology to another, and then even change back again as the operation evolves. It is wise to have as many tools available when one begins a procedure on hand as practical, as this will allow a higher rate of success.

**Femoral Tools**

Not all leads are accessible from the original venous entry site. Leads that have been cut or fractured can retract into the vein, and may even prolapse into the heart. Some operators may also prefer the femoral approach. The current approach to femoral extraction utilizes a 16-French (internal diameter) sheath with a hemostatic valve (Byrd Femoral Workstation, Cook Vascular). This workstation is placed via the femoral vein and advanced to the inferior vena cava and into the atrium to maintain venous access and provide counter-traction. Any number of positioning and grasping tools can be used with this conduit. A Needle’s Eye snare, deflecting tip guidewire with a Dotter helical basket retriever, Amplatzer gooseneck snare, and Curry loop snares are some of the tools that can be used to position and grasp the lead (Fig. 8A–C). Once snared, the lead is drawn into the sheath with the sheath advanced to the myocardial interface providing counter-traction and safe lead removal. The major disadvantage to these sheaths is the lack of cutting ability. Thus, if there is heavy fibrosis around the lead, it may not be possible to advance the sheath far enough to achieve true counter-traction.

**Venous Insertion Site Approach**

The lead body must be initially freed from the fibrous tissues of the pacemaker pocket. Though some prefer to do a sharp dissection along the length of the lead, electrocautery can safely remove the fibrous tissues from the lead body once the pacemaker is removed from the pocket. Contrary to what many assume, unless heating of the adjacent tissues is excessive or the ECU setting is too high, electrocautery will not damage the lead. In addition, some of the very thin leads now being used are actually very likely to sustain damage unless the utmost care is taken with either electrocautery or manual dissection techniques. This is, however, unwise if there is evidence of insulation failure with exposure of the metal conductor. It is essential that all prosthetic material including sutures, suturing sleeves, lead caps, and adapters be removed from the pocket at this point. Future infection or a chronic draining sinus may result from failure to remove all items, especially in an infected pocket. If there is a retractable screw mechanism, an attempt should be made to retract the helix. Once the lead is dissected down to the site of venous entry, lead removal can be attempted with gentle and constant direct traction. Use of counter-clockwise rotation is often useful as well. A standard stylet can be used to stabilize the lead, and to clear debris from inside of the lead during this attempt. If direct traction fails, one prepares for counter-traction removal. The lead insulation is cut with a scalpel near the connector end. The conductor coil(s) are cut cleanly with a sharp wire cutter in order not to cause a crimp in the coil. If the lead is coaxial bipolar or triaxial, the inner conductor is exposed by pulling and unraveling the outer coil and cutting the excess outer coil away. A locking stylet is then placed within the inner coil and advanced into the lead as far as possible (Fig. 9A). The stylet is locked and suture is tied around the lead body to compress the conductor coils and insulation near the cut end (Fig. 9B). This prevents uncoiling of the conductor, and keeps the insulation from bunching in front of the sheaths as they are advanced, thus keeping the lead as a single unit (Fig. 9C).

The sheath is now ready to be advanced over the lead. A steel sheath, Shorty™, or powered sheath may be used to enter the vessel if a plastic sheath will not easily enter. Manual or powered disruption of the fibrous tissue advances the sheath en route to the myocardium. The operator must carefully advance the sheath and follow the lead’s course down the venous path, diligently staying in line with the lead. The junction of the superior vena cava with the atrium and other areas of acute vein angulation are common sites of vascular tear, and must be approached with extreme care. Once the sheath is within 1 or 2 cm of the electrode tip, the lead is pushed to the sheath while applying counter-traction until the lead releases from the myocardium (Fig. 5). The patient must be vigilantly monitored for heart rate and blood pressure changes during the entire intravascular
Figure 8. (A) Byrd Femoral Workstation™. This is a 16F internal diameter sheath with a hemostatic valve, through which various inner sheaths and snares may be passed. (B) Needle’s Eye™ Snare. This may be used to grasp and pull on leads. It provides a reversible grip on the lead once the lead is clasped. (C) Dotter helical basket and deflecting tip guidewire. The deflecting guidewire can be used to loop around a lead, then the Dotter helical basket may be used to snare the free end of the lead. Alternatively, the basket can be used to snare the free end of the guidewire once the latter is looped around the lead, to provide additional traction to pull the lead down into the femoral vein.
procedure, and especially when the lead pulls free from the myocardium. Vagal reactions are common and must be quickly differentiated from pericardial tamponade and extra-vascular hemorrhage. The freed lead can now be pulled through the sheath. If the lead is removed and the sheath is retained for venous access, care must be taken to avoid air embolism due to the large internal diameter of the extraction sheath. A guidewire can be placed through the sheath if one wishes to implant a new lead in the same insertion site. Moreover, a guidewire can alternatively facilitate placement of a large bore catheter should rapid fluid administration be required. Use of longer introducer sheaths in association with this type of retained guidewire technique will reduce the problems of advancing the new lead through the proximal portion of the venous system and SVC junction, which may have been disrupted by the extraction process.

Many ICD leads suffer from conductor fractures and insulation failures. To prevent current shunting from the newer shock coil into the older coil, and to prevent noise from the metal components of the leads touching each other, removal of inactive ICD coils is frequently performed.39 “Make-break” electrical signals can also occur, caused by metal-to-metal interaction from the contact of old and new leads.40 An ICD may misinterpret these signals as ventricular tachycardia with subsequent inappropriate shocks possible. Though older ICD leads are substantially larger than pacing leads, removal is performed in an identical manner. This size difference is due to the large shock coils used in ICD leads, which also frequently results in a non-isodiametric lead. Though ICD lead removal often requires a larger (and thus stiffer) sheath, newer ICD leads are now in the same size range as standard bradycardia leads. In general, ICD leads (especially older models) are more difficult to extract because of their larger size, aggressive fibrosis around the coils, and non-isodiametric structure.

Coronary Sinus and Cardiac Venous Leads
Leads placed via the coronary sinus (CS) for biventricular pacing systems have created new challenges for those performing lead extraction. Like their counterparts, CS leads can stimulate significant fibrosis in the venous system. Human and animal models have demonstrated the occurrence of significant adhesions attached to the pacing lead in the CS. The latter is most noted when shock coils are placed in the CS. This raises concern as the CS is a rather thin structure that can be easily torn, dissected, or perforated, especially when exposed to aggressive instrumentation. Nonetheless, several studies have demonstrated that coronary sinus leads can be removed effectively and safely. Tyers et al.41 demonstrated successful removal in 14 patients without major complications. It should be noted that five of these leads were in place less than 6 months. All leads in place greater than 6 months were extracted with manual or powered sheaths as well as two of the leads in place less than 6 months. Kasravi et al.42 successfully extracted 14 CS leads without major complications. All leads were removed with direct traction and locking stylets without the use of dilating or laser sheaths. However, three leads required the femoral vein technique due to fibrous attachment of the CS lead body to other pacing leads. Laser CS lead extraction was reported by Burke et al.43 All 10 leads were successfully extracted without procedural complication with four leads extracted by laser extraction and six via direct traction. Though these studies are promising, our experience with chronic CS lead extraction is just beginning, and more experience is needed to gain additional insight into safely removing these leads that have been in place for longer durations. In addition, at least one “active fixation” design has been released outside of the United States (Medtronic 4195 “Starfix,” Minneapolis, MN, USA). Early extraction experience in animals and humans has been inconclusive as to how difficult this design will be to extract (personal communication). Finally, though the CS may be entered with an extraction sheath, it is currently not considered safe to attempt to enter the cardiac venous branches due to the high risk of tears and tamponade.

Efficacy and Safety
As new tools are introduced, lead extraction continues to evolve. There are many variations
on how extraction can be performed utilizing the now-established techniques. Effectively removing leads is influenced by several factors. The duration of the implant is clearly an important factor. Leads in place longer are more difficult to remove. Indeed, there is a linear increase in difficulty over time. Multiple leads become bound together by fibrous tissue making removal even

Figure 9. (A) Locking stylet being placed into the exposed inner conductor coil of a pacing lead. (B) Stylet placed into the lead, and suture on the lead to secure the insulation onto the conductor coils. (C) Telescoping sheath placed over the lead, which is then advanced through the vascular system to provide counter-traction.
more difficult. Younger patients develop more robust fibrous tissue and are more likely to progress to a calcified fibrosis. Compared to atrial leads, ventricular leads contact more tissue from their longer length that makes extraction more difficult. Tined and other non-isodiametric leads are felt to be more difficult to extract by some, though data from the extraction registry do not support this. Finally, efficacy depends significantly on operator experience.37,44,45

The type of sheath system being used may play a role in efficacy as well. The PLEXES trial randomized patients to excimer laser or nonpowered sheaths.46–51 The study concluded that the laser was significantly more effective (94% vs 64%, P = 0.001) and reduced the extraction time (10.1 ± 11.5 minutes vs 12.9 ± 19.2 minutes, P < .04). Four life-threatening complications (including one death) occurred in the laser group (153 patients total), whereas none occurred in the nonlaser group. This difference, however, was not statistically significant given the small overall numbers. One problem with the study was that crossover was permitted if the nonpowered sheaths were felt to be ineffective. Moreover, the efficacy for nonpowered sheaths as documented in the lead extraction registry was significantly higher (>90%) than that reported in PLEXES.

Lead extraction complications are divided into categories of major, minor, and observation. Major complications are those that create a life-threatening situation or require a major intervention to resolve. Minor complications are not life-threatening but require an intervention to resolve, such as medication. An observation has no significant consequence for the patient but was an event that should be noted. It is notable that significantly lower complication rates exist at high-volume centers where more than 300 extractions have been performed (Table II).19

Extraction Conscious Implantation

As noted previously, a consequence to the implantable device era was the need for lead extraction. Further, expanding indications for implantable devices continue to increase the need for lead extraction. With this in mind, it is reasonable to approach device implantation with the awareness that lead extraction may one day be necessary for the leads currently being implanted. Thus, one should consider lead implantation techniques and hardware that lend themselves to easier extractions. As noted before, the larger ICD coils result in aggressive fibrosis. This is particularly problematic with a superior vena cava (SVC) coil that will not only stimulate aggressive fibrosis, but will also do so at an area of high risk for vascular tear (the
Table II.
Complication Rates Relative to Operator Experience

<table>
<thead>
<tr>
<th>Complication</th>
<th>&gt;300 Procedures</th>
<th>20–120 Procedures</th>
<th>Not Fully Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0%</td>
<td>0%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Sternotomy/thoracotomy</td>
<td>0.4%</td>
<td>0.8%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Transfusions</td>
<td>0%</td>
<td>0.6%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Pericardiocentesis/chest tube</td>
<td>0.6%</td>
<td>0.2%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Other major complications</td>
<td>0%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Total major complications</td>
<td>1.0%</td>
<td>1.8%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Minor complications</td>
<td>1.2%</td>
<td>2.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Total complications</td>
<td>2.2%</td>
<td>4.4%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

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high SVC). Therefore, we generally implant single-coil ICD leads at our institution to decrease the risk and difficulty of possible future lead extraction. Since recent studies have documented that the proximal coil usually does not lower the defibrillation threshold significantly, we have abandoned their use in most patients.52 Dual-coil leads are still used occasionally, but reserved for patients with high-risk features for atrial arrhythmias in whom we would like to increase the efficacy of atrial defibrillation. Mediasternal vein approaches are also discouraged due to the risk of crush requiring subsequent and likely difficult extraction. Use of leads that are appropriately sized for the patient will reduce the amount of extra lead left in the pocket that may need to be dissected. Leads that are constructed well so as not to fall apart easily, and leads that are isodiametric with active fixation, are likely to be more easily and completely removed. If passive fixation leads are to be used, shorter time length will make extraction easier. As the IS-4 standard becomes widely available for ICD leads, this will eliminate the “yoke” on these leads, making dissection easier as well. The use of ICD leads that use coils backfilled with medical adhesive, or that are covered with Gortex™ markedly reduces the tissue ingrowth and facilitates easier and safer extraction.53

**Conclusion**

Lead extraction has matured into a series of defined steps that allow nearly all leads to be removed safely and completely. Adherence to the basic principle of counter-traction is essential to the success and safety of this procedure. A well-trained and experienced operator performing the procedure in a well-equipped setting with good staff is also critical. No single tool is sufficient to achieve a high success rate. Rather, having an array of different sheaths and stylets will allow the greatest opportunity to remove a lead entirely. We should continue to see the introduction of new tools that will allow us to manage new lead systems (such as cable type conductor leads), and to deal with old problems (such as calcifications) effectively and safely.

**Appendix**

**HRS Indications**

**Class I** (conditions for which there is a general agreement that leads should be removed):

a. Sepsis (including endocarditis) as a result of documented infection of any intravascular part of the pacing system, or as a result of a pacemaker pocket infection when the intravascular portion of the lead system cannot be aseptically separated from the pocket.

b. Life-threatening arrhythmias secondary to a retained lead fragment.

c. A retained lead, lead fragment, or extraction hardware that poses an immediate or imminent physical threat to the patient.

d. Clinically significant thromboembolic events caused by a retained lead or lead fragment.

e. Obliteration or occlusion of all usable veins, with the need to implant a new transvenous pacing system.

f. A lead that interferes with the operation of another implanted device (e.g., pacemaker or defibrillator).

**Class 2** (conditions for which leads are often removed, but there is some divergence of opinion with respect to the benefit vs risk of removal):
a. Localized pocket infection, erosion, or chronic draining sinus that does not involve the transvenous portion of the lead system, when the lead can be cut through a clean incision that is totally separate from the infected area.

b. An occult infection for which no source can be found, and for which the pacing system is suspected.

c. Chronic pain at the pocket or lead insertion site that causes significant discomfort for the patient, is not manageable by medical or surgical technique without lead removal, and for which there is no acceptable alternative.

d. A lead that, because of its design or failure, may pose a threat to the patient that is not immediate or imminent if left in place.

e. A lead that interferes with the treatment of a malignancy.

f. A traumatic injury to the entry site of the lead for which the lead may interfere with reconstruction of the site.

g. Leads preventing access to the venous circulation for newly required implantable devices.

h. Nonfunctional leads in a young patient.

Class 3 (conditions for which there is general agreement that removal of leads is unnecessary):

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