Lead Design for Safer Lead Extraction

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KEYWORDS

• Lead • Design • Extraction • Implant • Cardiovascular implantable electronic device

KEY POINTS

- A detailed understanding of lead design is critical to making appropriate implant choices and crucial to safely and effectively extracting each unique lead model.
- Safety in lead extraction depends on the ability to apply sufficient traction to the lead and locking stylet, without disruption, to create a rail to allow the sheath to track the lead.
- A desirable lead design for extraction should encompass the following features: (1) adequate tensile strength to allow minimal lead distortion and stretching with the application of significant traction, (2) the effect of traction is applied to all components evenly (lead control), (3) lead delamination and destruction do not occur with marked traction (maintenance of lead integrity), (4) lumen integrity to allow placement of a locking stylet, (5) isodiametric lead design and designs that minimize ingrowth of scar tissue and lead encapsulation, and (6) a reliably retractable active fixation mechanism.

Video of overcoming an engaged active fixation mechanism accompanies this article at http://www.cardiacep.theclinics.com/

INTRODUCTION

With the advent of subcutaneous implantable cardioverter-defibrillators (ICDs) and the ongoing development of leadless and even biologic pacemakers, the need for transvenous pacing and ICD leads will continue to decrease. However, the future is not here and there are millions of patients currently living with implanted leads. An understanding of lead design and the components of the ideally extractable lead are required to appropriately manage patients with implanted leads and devices. Cardiovascular implantable electronic device (CIED) and lead management starts before implantation and may extend to include the need for lead extraction. A detailed understanding of lead design is critical to making appropriate implant choices and is crucial to safely and effectively extract each unique lead model. CIED use continues to increase rapidly,[1–3] with more than 4.5 million active devices and more than 1 million new leads implanted annually worldwide.[4,5] With expanded indications for device therapy and increased CIED use, observed complications have increased in parallel.[6–14] More frequent device system revisions for complications,[6–8] system upgrade,[15–17] and/or lead malfunction,[9–13] and longer patient life expectancies, have all mandated a paradigm shift toward premeditated lead management strategies, from implantation to removal or replacement. Proactive lead management requires both forethought and conscious decisions at the time of CIED implantation with respect to a variety of factors, including hardware selection.

Lead design and construction are closely connected with the implantability, function, and

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extractability of the lead. The lead must be designed and constructed to withstand several unique applied forces from manipulation at implantation to bending and torqueing with arm and chest movement, to beat-to-beat contraction with each cardiac cycle, to the harsh chemical and oxidative stress of an in vivo environment. In addition, the lead must maintain electrical integrity even in the face of the extremely high voltages seen with ICD leads. Some of the same characteristics required for implant ease and dislodgement prevention may make extraction more challenging. Lead implantation mandates both flexibility and durability to negotiate and withstand these factors. In contrast, extractability depends on the tensile strength and stiffness of the lead. Overcoming areas of fibrotic adhesions necessitates that specific forces be applied to both the lead and sheath; namely counterpressure, traction, and countertraction. Safety in transvenous lead extraction is critically dependent on the ability to apply sufficient traction to the lead and locking stylet, without disruption, to create a rail to allow the sheath to track the lead. A desirable lead design for extraction should encompass the following features: (1) adequate tensile strength to allow minimal lead distortion and stretching with the application of significant traction, (2) the effect of traction is applied to all components evenly (lead control), (3) lead delamination and destruction do not occur with marked traction (maintenance of lead integrity), (4) lumen integrity to allow placement of a locking stylet, (5) isodiametric lead design and designs that minimize ingrowth of scar tissue and lead encapsulation, and (6) a reliably retractable active fixation mechanism. The ideal lead has the optimal balance of all these features. In choosing a lead for an implant, clinicians should consider all of these characteristics. In addition, when faced with extracting a lead, understanding how that specific lead model fails to meet any of the criteria listed earlier helps the extractor plan for obstacles to a safe and effective procedure.

LEAD CONSTRUCTION

The lead consists of the body, conductors, electrodes, insulation, fixation mechanisms, and connectors. Each component has important features that can affect both implantation and extraction procedures.

Older leads can be unipolar with only 1 conductor. These leads have a smaller external diameter, are more flexible for easier manipulation at implantation, and can be more fragile. Although some older unipolar leads are robust, most modern leads are bipolar with lead body constructions that can be coaxial (brady and cardiac resynchronization therapy [CRT] leads), coradial (brady and CRT leads), multilumen (ICD and CRT leads), or lumenless (brady leads) (Fig. 1).

Coaxial lead body design consists of an outer coil to ring electrode that is layered over an inner coil to tip electrode with a central lumen and insulation between the coils, as well as encompassing the lead. This design construction yields a slightly larger diameter and stiffer lead. During traction, the inner and outer coils can begin to delaminate.

Coradial lead assembly features parallel wound insulated coils surrounded by outer insulation and

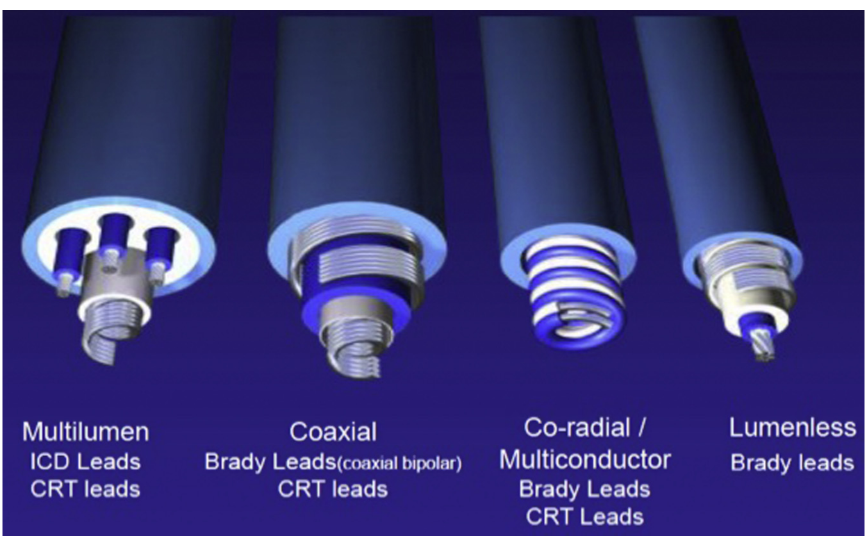

Fig. 1. Different lead designs and the types of leads that use these designs.