Laser-assisted lead extraction: the European experience

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Aims The aim of this study is to investigate the safety and effectiveness of Excimer laser-assisted lead extraction in Europe. The final European multi-centre study experience is presented.

Method and results The Excimer is a cool cutting laser (50°C) with a wavelength of 308 nm. The energy is emitted from the tip of a flexible sheath and is absorbed by proteins and lipids, 64% of the energy is absorbed at a tissue depth of 0.06 mm. The sheath is positioned over the lead, and the fibrosis surrounding the lead is vaporized while advancing the sheath without damaging other leads. From August 1996 to March 2001, 383 leads (170 atrial, 213 ventricular) in 292 patients (mean age 61.6 years, range 13–96) were extracted at 14 European centres. Mean implantation time was 74 months (3–358). Most frequent indications were pocket infection (26%), non-functional leads (21%), patient morbidity (21%), sepsis or endocarditis (14%), erosion (5%), and lead interference (8%). Median extraction time was 15 min (1–300). Complete extraction was achieved in 90.9% of the leads and partial extraction in 3.4%. Extraction failed in 5.7% of the leads. Major complications = perforations caused 10/22 (3.4/5.7%) of the failures. Most partially extracted patients were considered clinically successful, as only minor lead parts without clinical significance were left. Femoral non-laser technique was used to remove 8/12 of the non-complication failures. The total complication rate, including five minor complications (1.7%), was 5.1%. No in-hospital mortality occurred.

Conclusion Pacing and implantable cardioverter–defibrillator leads can safely, effectively, and predictably be extracted. Open-heart extractions can be limited to special cases. The results indicate that the traditional policy of abandoning redundant leads, instead of removing them, may be obsolete in many patients.

KEYWORDS
Extraction; Excimer; Laser Pacemaker leads; ICD leads; Ultraviolet

Introduction

After implantation, pacemaker and implantable cardioverter–defibrillator (ICD) leads undergo a fibrotic encapsulating process by activation of different cellular and humoral mechanisms.¹ The ensuing fibrotic lead adhesions tend to increase over time. For reasons partially unknown, the inter-patient variability is considerable; younger patients, however, seem to develop firm fibrotic adhesions early. Apart from the tip, but equally important, the body of the lead is often encapsulated in scar tissue. Both lead body and tip (Figure 1) can occasionally grow deeply into the surrounding tissue.

Due to the difficulties and risks inherent of extraction, many permanent pacemaker leads are traditionally abandoned and not removed when non-functional. However, transvenous leads associated with systemic infection and transvenous leads with other mandatory indications for removal have traditionally been extracted. Various methods have been used: manual traction, extended weight- or forceps-assisted traction, or mechanical extraction systems employing locking stylets and outer sheaths or open-chest surgery.²–11

Leads with an implantation time of less than a year can often be removed by simple manual traction. A high proportion of leads, having been implanted longer, can also be extracted manually in the hands of experienced physicians by careful and extended traction.¹² With proper experience and the use of locking stylets and outer sheaths success rates of 80–90%²,3,5,7,9 and in limited populations over 90% can be achieved.¹³ Open-chest surgery, with
or without cardiopulmonary bypass, is still required for extraction in a low percentage of special cases (i.e. some coronary sinus leads, non-accessible leads, and leads with large thrombi or vegetation overgrowth or emitting thrombi).

Most of the mentioned procedures, as well as femoral approach extractions, are often very time-consuming and include considerable morbidity. Despite the excellence of a limited number of centres employing traditional and mechanical extraction techniques, new methods allowing widespread high success rate, low complication rate, and more predictable procedure time are needed. Increasing device implantation rates worldwide using existing indications as well as new pacing indications combined with increasing life expectancy steeply increase pacemaker treatment prevalence. The number of patients needing extraction can subsequently be expected to rise considerably. Safe, successful, economical, and predictable methods would also justify the removal of a high proportion of redundant leads, presently abandoned. Laser-assisted lead extraction may be one of the new desirable methods. Investigational use of the Excimer laser sheath in the USA has shown the 12 French (Fr) sheath to be more effective than ‘mechanical’ methods and not associated with additional medical risks for the extraction of chronically implanted leads. In addition, the larger sized laser sheaths have been reported to be as effective as the 12 Fr sheaths. We investigated the efficacy and safety of Excimer laser-assisted lead extraction in Europe. We now report on the final data from this multi-centre study [Pacing Lead Surveillance Study in Europe (PLESSE)]. Previously we have reported on interim results and single-centre experiences.

**Materials and methods**

**Extraction technique**

The CVX-300 Excimer laser (Spectranetics, Colorado Springs, CO, USA) is a xenon chloride laser with a wavelength of 308 nm, which delivers pulsed light at a maximum fluence of 60 mJ/mm. In this study, a 40 Hz repetition rate was used. The Excimer is a cool cutting laser; the temperature of the emitted light is \( \sim 50 \) °C. At a tissue depth of \( \sim 0.06 \) mm, 64% of the emitted energy is absorbed, and at 0.18 mm 95% is absorbed. The energy is absorbed by tissue lipids and proteins but not by water, in contrast to other lasers. The laser acts by breaking intracellular tissue bonds. Due to these characteristics, the Excimer laser can vaporize fibrotic sheaths surrounding targeted leads, while not damaging other leads.

The energy is emitted from the rim of the tip of flexible, fiberoptic 12, 14, or 16 Fr (inner/outer diameter, respectively, 2.8/4.1, 3.4/4.8, or 4.2/5.6 mm) sheaths. The sheaths are tubular constructions made of 82 fibres (12 Fr sheath) with a core diameter of 100 \( \mu \)m, sandwiched between inner and outer polymer layers. After the removal of the pulse generator, the subcutaneous tissue around the lead is dissected close to the vessel entry. The lead connector is then severed, and a locking stylet is inserted into the inner coil and locked with the leading end as close as possible to the tip of the lead. The laser sheath is then passed over the lead and locking stylet, making the proximal end of the lead accessible for traction. When judged necessary, a tightly fitting Teflon™ or polypropylene sheath is mounted on the outside of the laser sheath to allow mechanical disruption of fibrotic bonds, in addition to the laser effect. The laser sheath (with or without outer sheath) is then advanced along the lead to the venous entry. A straight alignment of the laser sheath along the track of the lead is essential. For this purpose, a light pulling force is applied to the lead and locking stylet. Lasing is started and the sheath(es) advanced during fluoroscopic guiding. The outer sheath, if mounted, is advanced with...
Laser-assisted lead extraction

Figure 4 Excimer laser sheath tip with outer sheath and pacemaker lead. Published with permission by Spectranetics Inc.

Table 1 Lead types, fixation methods, and implantation time

<table>
<thead>
<tr>
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<th>Time from implant (months)</th>
<th>Fixation method</th>
<th>N = 383</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Range</td>
<td>Median</td>
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<tr>
<td>Atrial</td>
<td>67</td>
<td>3–358</td>
<td>53</td>
</tr>
<tr>
<td>Atrial ICD</td>
<td>46</td>
<td>11–85</td>
<td>53</td>
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<tr>
<td>Ventricular</td>
<td>79</td>
<td>3–330</td>
<td>60</td>
</tr>
<tr>
<td>Ventricular ICD</td>
<td>40</td>
<td>3–151</td>
<td>36</td>
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ICD, implantable cardioverter-defibrillator.
number of leads extracted. Locking stylets were used in 96% of the leads; 77% of the locking stylets were various models manufactured by Cook (Cook Inc., Lecceburg, PA, USA). When used, they reached the lead tip in 67% and locked at the tip or elsewhere in 91% of the leads. VascoMed (VascoMed, Weil am Rhein, Germany) supplied 12% of the locking stylets (two models); 88% of these reached the tip and 93% locked at the tip or elsewhere. Finally, Spectranetics (LLD locking stylets, three sizes) supplied 11% of the locking stylets; all of these reached the lead tip and locked.

A majority (90.9%) of the leads was completely removed. A small portion (3.4%) was partially removed and 5.7% of the attempted lead extractions failed. Major complications were classified as failures; the failure rate excluding complications was 2.3%. A higher proportion of the atrial leads (93.5%) than of the ventricular leads (88.7%) was completely extracted (NS). The partial success rate and the failure rate for atrial leads were 1.8 and 4.7%, respectively. The partial success rate and the failure rate for ventricular leads were 1.8 and 4.7%, respectively. In two of the partially removed leads, the pre-operative intention was not complete lead removal. In another 8 of the 13 cases of partially removed leads, the outcome was considered clinically successful and no further extraction was attempted. Complete removal was achieved in 88% of all ICD leads, 2% were partially removed and the failure rate for ICD leads was 10%.

Long implantation time was associated with procedure failure ($P = 0.005$ by $t$-test). The odds of failure for leads $>8$ years old was 4.0 times that of younger leads (95% confidence interval: 1.6-10.6). Lead location, gender, fixation type, and laser sheath size did not statistically correlate with procedure failure.

Major complications caused 10 of the 22 failures; the leads in these 10 cases were all removed surgically when treating the complications. These 10 major complications were all perforations either of the vessels concerned or of the heart wall. Femoral non-laser technique was used to remove 8 of the 12 remaining failures (due to leads falling apart), 1/12 was extracted with a thoracotomy, and 1/12 with a right subclavian approach using a mechanical extraction system. Lead replacement was successful in the vast majority of cases when intended (97%). Total complication rate was 5.1%, 3.4% were perforations. The five (1.7%) other complications were two cases of pulmonary embolism that were successfully treated, one suspected post-operative infection, and two cases of haemothorax, one of which required drainage. One major complication not related to extraction but to the implantation of new leads occurred. After having had four ICD leads and one atrial lead successfully extracted, the patient post-operatively (24 h) developed a cardiac tamponade and underwent sternotomy. The bleeding was caused by perforation of the screw-in tip of an atrial, active fixation lead, implanted after extraction. The lead tip was not judged to be in a region of the atrial wall affected by previous lead extraction.

Gender did not correlate with complications, as it has in other reports. Also, lead location and fixation type did not correlate with complications. Complications were seen in a higher percentage of 16 Fr cases ($P = 0.007$); the odds of a complication with a 16 Fr device was 4.8 (1.4-16) times that of smaller sheaths. Use of the 16 Fr device was, however, also closely associated with defibrillator leads.

Mean time in hospital was 5.5 days (median 4, range 0–45) but included treatment for all causes. All patients left the hospitals alive and well. One patient died in another institution within 30 days due to progressive heart failure. Another patient died suddenly after 2 months, probably due to ventricular arrhythmia.

**Discussion**

The laser sheaths handled well and were structurally durable enough to withstand the strains of extraction. This notion is supported by the results and the fact that two sheaths were required in only 13 of 292 cases. Early versions of the larger size sheaths were found to be stiff when encountering sharp bends in the vessel system; later versions with a softer distal section combined with more operator experience have partially solved this problem. The laser source performed well technically and was easy to operate. Reaching the tip of the leads with the locking stylets was important in order to achieve success. Sharp bends of the lead or damaged coils due to previous unsuccessful lead extraction attempts prevented locking stylets from being advanced to the lead tips in a minority of leads. It was also considered essential to obtain a firm locking of the stylet at the lead tip in order to achieve good counter traction. The performance of the locking stylets was generally somewhat disappointing and an improved function would most likely lead to a higher success rate.

The outer sheaths allowed counter traction and facilitated the implantation of replacement leads. Outer sheaths were used for a majority of the extracted leads. However, the direct implantation of a new lead through an outer sheath and through the preformed fibrotic channel sometimes proved difficult. It was found useful to introduce a guidewire through the outer sheath, then to remove the outer sheath and put an extra long, flexible, introducer over the guidewire, in order to avoid getting the tip of the new lead entangled in fibrotic tissue. An alternative procedure for re-implantation was to perform a new venous puncture combined with a long introducer. No confirmed post-operative, procedure-related, infections were found, most likely due to antibiotic prophylaxis and short extraction times. Sufficiently large laser sheaths were...
found to be essential. If too little spacing was allowed between the lead and the sheath, fibrotic tissue could create a ‘snow-plough’ effect in front of the sheath tip, which could stop further advancement of the sheath.

The 16 Fr sheath was associated with more complications than the smaller sheath sizes but also with extraction of ICD leads. Early large diameter ICD lead models were very close in size to what the 16 Fr sheath could accommodate, allowing less clearance between the lead and extraction sheath than desirable. The subsequent tight fit in addition to heavily serrated defibrillation coils, likely to cause deep tissue in growth, most likely increases the risk of complication. The rate for major complications associated with ICD lead extraction was 12% (including one case of atrial screw lead perforation not classed as a failure of ICD lead extraction); this accounted in fact for 6/10 of all the perforations. The specific major complication rate for pacing leads was 1%, 4/6 ICD perforations were associated with passive leads, 2/6 were Guidant Endotak C leads, and 2/6 were Guidant Endotak DSPs. The two active fixation leads associated with perforations were Medtronic leads of two different models.

Damaged insulation material (not affected by Excimer laser light) can fold back, as the sheath is advanced. This can create an outer diameter of the lead, which is too big for the laser sheath to accommodate. In such a situation, an outer mechanical sheath is essential for further advancement. Damaged insulation and calcification of leads seem to be the most common causes for stopping sheath advancement. The non-significant higher success rate for atrial lead extraction, compared with ventricular lead extraction, may depend on the shorter implantation time of the atrial leads, but may also depend on the fact that a majority of the atrial leads were isodiamic (Accufix leads). From a clinical standpoint, most of the leads classified as partial extractions were successful. The minor lead parts, which were left in these patients, have, to our knowledge, not created problems except in one case of late endocarditis. Lead models known to be fragile with non-laser extraction technique were found to easily fall apart also using laser technique. Most of the failures occurred with old leads or with leads that were damaged by previous extraction attempts. It seems essential to avoid deleterious extraction attempts in centres without the necessary equipment and experience.

Our impression is that the learning curve for use of the Excimer laser can be shortened by previous extraction experience. Appropriate training is, however, strongly recommended before laser-assisted lead extraction is undertaken. This recommendation is supported by the fact that the majority of the complications in this study were experienced early. The support provided by the manufacturer during the first number of cases is essential and may help avoid potentially fatal complications.

In order to uphold the reputation of the method, only two patients in this study have been extracted according to emergent situations. The lack of deaths observed in this case series is a tribute to the preparedness of the PLESSE investigators to deal with emergent situations.

The common but questionable policy of leaving redundant leads in the body instead of removing them may change in the near future when new extraction methods with high success and low complication rates, such as laser-assisted extraction, gain wider acceptance. However, a pre-requisite for this is that the results achieved so far are maintained. In addition, costs, mainly of the laser pulse generator, have to be reduced to be acceptable in many centres.

In conclusion, we have found Excimer laser-assisted lead extraction to be efficient and associated with few complications. Even if very experienced centres can achieve similar results with mechanical tools, the laser method is less time-consuming and the outcome is more predictable regarding procedure time. Laser-assisted extraction of ICD leads is about 10 times more risky than extracting pacing leads. This fact should be kept in mind when comparing the success and complication rates of laser-assisted lead extraction with other methods less often used for ICD lead extraction. The laser technique can be used for the vast majority of lead extractions, but open-chest surgery is still required for special cases and for treating complications.

Conflict of interest: C.K. is a medical advisor to Spectranetics.

References


