

# A single-centre experience of over one thousand lead extractions

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Received 4 November 2008; accepted after revision 2 February 2009; online publish-ahead-of-print 27 March 2009

## Aims

The aim of the study was to present a single-centre experience of pacemaker and implantable cardioverter defibrillator (ICD) lead extraction using different methods, mainly laser-assisted extraction.

## Methods and results

Data from 1032 leads and 647 procedures were gathered. A step-by-step approach using different techniques while performing an ongoing risk–benefit analysis was used. The most common indications were local infection, systemic infection, non-functional lead, elective lead replacement, and J-wire fracture. Mean implantation time for all leads was 69 months and for laser-extracted leads 91 months. Laser technique was used to extract 60% of the leads, 29% were manually extracted, 6% extracted with mechanical tools, 4% were surgically removed, and 0.6% extracted by a femoral approach. Failure rate was 0.7%, and major complication rate was 0.9%. No extraction-related mortality occurred. Median time for laser extraction was 2 min. Long implantation time was not a risk factor for failure or for complication.

## Conclusion

Pacing and ICD leads can safely, successfully, and effectively be extracted. Leads can often be extracted by a superior transvenous approach; however, open-chest and femoral extractions are still required. Laser-assisted lead extraction proved to be a useful technique to extract leads that could not be removed by manual traction. The results indicate that the paradigm of abandoning redundant leads, instead of removing them, may have to be reconsidered.

## Keywords

Lead extraction • Laser • Infection • Non-functional leads • Recalled leads • Risk factors

## Introduction

After implantation, transvenous device leads usually undergo fibrotic encapsulation by activation of different cellular and humoral mechanisms.<sup>1</sup> The ensuing fibrotic lead adhesions tend to increase over time. For reasons partially unknown, the inter-patient variability is considerable. Young patients, however, usually develop fibrotic adhesions earlier than elderly. On the contrary, systemic lead infection seems to counteract or dissolve fibrotic adhesions.

Due to fibrotic encapsulation, early attempts at lead extraction were found to be difficult and associated with high risks. Subsequently, the paradigm of abandoning redundant leads was established. In most centres, only leads associated with systemic infection were indicated for extraction before the 1990s. During

this time period, most leads extracted were removed surgically. Manual traction or methods such as weight and pulley or forceps-assisted traction were often found to be both unsuccessful and prone to complication. Despite improved lead performance, an increasing number of device patients, better life expectancy, more leads per patient, new indications, new types of devices, as well as device and lead recalls strongly increased the need for lead extraction. Subsequently, transvenous extraction methods were developed. Telescoping mechanical sheaths and locking stylets were introduced during the late 1980s and early 1990s. Special tools for femoral lead extraction soon followed. The first laser-assisted lead extraction performed in 1994 was a major breakthrough. Other methods such as electrocautery dissection and revolving sheaths have later been introduced. The number

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of lead extractions has increased exponentially and in 2006, approximately 10 000 patients underwent lead extraction just with laser technique. Several studies from high volume centres have shown that lead extraction can now be performed with high success and low complication rates, employing various extraction methods.<sup>2–5</sup> Long lead implantation time and lack of operator experience have often been associated with extraction failure.<sup>6–8</sup> Due to the low complication rates, accurate risk analysis in the best series is difficult, but long implantation time, lack of operator experience, lead type, female gender (patient size), and implantation route have been discussed as possible risk factors.

The aim of this retrospective, consecutive, single-centre study is to share our experience in removing pacemaker and implantable cardioverter defibrillator (ICD) leads using different extraction techniques, during an early, evolutionary period of lead extraction.

## Materials and methods

### The centre

The Sahlgrenska University (SU) Hospital is a 2300-bed teaching hospital; it is the national referral centre for lead extraction as well as treating patients referred from abroad for lead extraction. Lead extraction is fully reimbursed in Sweden and has been since the start of its clinical introduction in the early 1990s.

### Patients

592 patients underwent 647 extraction procedures from February 1990 to October 2007; 412 were male (70%). Mean patient age was 62.8 years (range 10–95). The mean age of male patients was 62 years and of females 64.8 years. Several patients underwent more than one extraction during the study duration, mainly due to recalled leads. One patient underwent eight procedures for atrial lead replacement (recalls, dislocations, and dysfunction). The majority of the patients were referred from other hospitals; the remaining were pacemaker and ICD patients from the SU hospital services. Few patients were extracted during the early years of the study period; numbers increased significantly from 1994, largely coinciding with the Telectronics Accufix™ lead recall.

### Indications

The Heart Rhythm Society's (HRS) (NASPE 2000)<sup>9</sup> recommendations were generally adhered to. The recommendations are, however, not quite clear regarding local device infection. The recommendations state that pocket infection should be treated as a Class II indication if the lead can be severed in clean tissue and subsequently as a Class I indication if the lead cannot be severed in clean tissue, which is the typical situation, at least nowadays. The fact that the present recommendations do not clearly address leads infected close to the vascular entry has created confusion. As a result, we treated most localized infections as Class II before 2005 and subsequently many pocket infection patients underwent one revision before undergoing lead extraction. Due to a high recurrence rate (>90% at 2-year follow-up), patients with local device infections were primarily extracted from 2005 on, if no contraindication was present according to the HRS recommendations. Indications were local infection 360 (35%), systemic infection (sepsis and endocarditis) 246 (24%), non-functional lead 108 (10.5%), elective lead replacement 97 (9.4%), J-wire lead fracture 41 (4%), ICD lead interference 25 (2.4%), insulation defect 23 (2.1%), heart transplantation 17 (1.6%), Maze surgery

16 (1.6%), dislocation 14 (1.4%), skin erosion 14 (1.4%), lead fracture 12 (1.2%), and other indications 59 (5.7%). All patients with a Class I indication were subjected to extraction. A low number of patients (<15) with Class II indications were not extracted: the main reasons being high anaesthesia risk, advanced age, long lead implantation time, patient hesitation, or a combination of these factors. If extraction of a non-functional lead led to an upgrade, this was classified as extraction of a non-functional lead, not upgrade, for the purpose of this study.

### Study method

Data were consecutively collected case-by-case and entered into a computerized database and retrospectively analysed. Data on the first 62 patients were gathered retrospectively from patient files and then entered into the database. Files of patients having complications or failures were retrospectively analysed for more details.

### Endpoints

Our definitions of endpoints are based on the intention-to-treat analysis. 'Clinical success' was defined as removing the entire lead or as much of the lead as necessary to successfully treat the indicated condition. Total lead removal including the lead tip was necessary for defining clinical success in Class I indication cases. Clinical success was not achieved if a non-functional or recalled lead was not totally removed (the intention being total removal). 'Partial success' was noted when most of the lead was removed, leaving at most 4 cm of coil and/or insulation and/or the lead tip, when the intention of the procedure was total removal. 'Failure' was scored when previously mentioned endpoints were not achieved. Crossover from one extraction technique to another was performed when necessary as part of the step-by-step approach used. Complications were scored according to the HRS recommendations.<sup>9</sup>

### Definitions

Manual extraction was defined as the removal of a lead without using any tool at all.

Mechanical extraction was defined as the removal of a lead with the help of mechanical sheaths with or without locking stylets or other stylets. One lead extracted with electrosurgical dissection sheath (EDS) technique was included in this group. Crossover from EDS to laser was performed in five leads; these leads were included in the laser group. Laser-assisted lead extraction was defined as the removal of leads using an excimer laser sheath, with or without a locking stylet. Open-chest lead extraction was defined as the removal of leads through a sternotomy or thoracotomy with or without going on bypass. Open-chest extraction was performed either as a standalone procedure or during concomitant heart surgery, mainly heart transplantation or Maze surgery. Primary femoral extraction was defined as the extraction of leads with a femoral approach as the primarily chosen approach (mainly free floating leads). Secondary femoral approach was defined as the removal of leads with a femoral approach when another primary approach failed. Laser extraction time was defined as the time from the start of lasing until the lead and laser sheath were removed from the vessel.

### Extraction techniques

A step-by-step approach using different extraction techniques while performing an ongoing risk–benefit analysis, as described previously, was routinely applied.<sup>10,11</sup> Subsequently, some Class II procedures were stopped if very severe fibrosis was encountered, the complication risk was significant, and clinical success had been achieved.

Laser-assisted lead extraction, EDS extraction, mechanical extraction, femoral extraction, and open-chest extraction were performed as described previously.<sup>10,11</sup> The 14 Fr laser sheath was used for most laser-extracted leads (49%), the 16 Fr sheath was used for 28% of the leads, and the 12 Fr sheath was used for 23% of the leads. Laser extractions were usually (94%) performed with a single sheath technique and with an upgraded sheath size, similar to that recommended for an outer sheath for a certain lead diameter. Characteristics were available for 213 leads to allow us to calculate the difference in diameter between the lead and the inner diameter of the laser sheath used. The mean diameter difference (oversizing) was 4.4 Fr (range 0.5–8.0). One operator (C.K.) performed all transvenous extractions, usually without an assistant. Other operators performed the minority of the dedicated open-chest extractions, but the majority of lead extractions during heart transplantations, Maze procedures, and cardiac surgery for other reasons. Laser technique was used to extract 615 (60%) of all leads, 298 (29%) were manually extracted, 70 (6.8%) with various mechanical tools (including 1 EDS lead), 41 (4%) were surgically removed (33 ECC), and 6 (0.6%) were primarily removed by a femoral approach. One open-chest transatrial extraction was performed with a laser sheath and was classified as a laser case. All procedures were performed in an operating room (OR) with patient preparation and surveillance as described previously.<sup>10,11</sup> Acute complications (perforations) were treated in the OR.

## Leads

Pacing leads accounted for 974 (94%) of 1032 leads, 606 (66%) of the pacing leads were bipolar, and 58 (5.6%) were dedicated ICD leads. Lead tip fixation was passive in 615 leads (60%) and active in 347 leads (34%). Leads implanted from 1 month on were included. Mean implantation time for all leads was 69 months; for laser extracted leads, the mean implantation time was 91 months. Mean implantation time for manually extracted leads was 30 months. The maximum number of leads removed in one patient was five. Locking stylets were used in 59% of the leads. The mean number of leads removed per patient was 1.74.

Table 1 shows the location, numbers, implantation time, fixation mechanism, and polarity of the leads removed.

## Statistics

Categorical data were analysed with frequency tables and continuous variables with mean, median, and standard deviation. Univariate tests between groups were performed using Mann–Whitney *U* test or Fisher's exact test. All *P*-values were two-tailed, and *P* < 0.05 was considered significant. We used SPSS 15.0 for statistical analysis.

The appropriate local authority approved the electronic patient database.

## Results

### Success rate

Clinical success was achieved in 97.6% (1008) of the leads, partial success in 1.7% (17), and the extraction attempt failed in 0.7% (7) of the leads. The mean implantation time for failed extraction leads was 162 months. In the failure group, laser technique was used in 5/7 leads (202 months mean implantation time), 1/7 was attempted with mechanical sheaths (118 months), and 1/7 was attempted with manual traction (7 months), the latter before the laser technique became available. Crossover to another extraction technique was not attempted in 3/7 of these leads (two laser

and one manual) because the indication was not Class I. In another 3/7 of the failures (all laser), extractions were abandoned due to back bleeding from the vessel of implantation. Mechanical extraction failed in the remaining lead (Class I). Of the failures, 4/7 leads were Class I and 3/7 Class II, none of the latter were redundant leads. The failure rates per extraction method were mechanical 1.4%, laser 0.8%, manual 0.3%, primary femoral, and surgical 0%.

All failed extraction leads were standard pacing (5/7 ventricular and 2/7 atrial). In one of the seven failed leads, a previous unsuccessful extraction attempt had been performed at another hospital.

Manual extraction was attempted in 6/17 (mean implantation time 35 months) leads partially removed, 3/17 (77 months) leads were associated with mechanical extraction, and 8/17 (87 months) with attempted laser extraction. Only one ICD lead was partially removed by laser.

Slightly more failures were noted early in the study period; a learning curve reaching statistical significance occurred. Extraction failure was also associated with the absence of locking stylet, young age, and ventricular lead position. Borderline (just above 0.05) significance was noted for non-steroid leads and passive fixation. Failures were not associated with implantation time (for all leads and for laser-extracted leads), previous extraction attempts, laser use, lead/sheath diameter difference, lead polarity, lead material (silicon/polyurethane), patient gender, laser sheath size, or model (SLS I/II). Active leads (127/129) were somewhat easier to successfully extract with manual technique than passive leads (124/137); any difference in implantation time was not accounted for.

## Complications

The major complication rate was 0.9% (four perforations, one tricuspid valve insufficiency, and one late pleural bleeding requiring drainage). Perforation occurred in the ventricle in 2/4 patients and in the atrium/superior vena cava (SVC) in 2/4 patients. One of the latter involved extraction of a dual coil ICD lead. This was the only ICD lead related to complication. The ventricular perforations occurred at the lead tip, passive in both cases. Mean implantation time for leads associated with major complications was 130 months (range 65–284). All patients with a major complication left the hospital well and without sequel. Major complication was not associated with implantation time, fixation type, polarity, locking stylet, insulation material, female gender, ICD lead, or class of indication.

Minor complications occurred in nine patients. Post-operative thrombosis occurred in 3/9 patients: all were non-pulmonary and successfully treated. One of these patients had a retained lead fragment and another had a coagulopathy. Excessive bleeding from the vein entrance occurred in 4/9 patients; in fact, bleeding in two of these four patients caused three of the seven lead extraction failures (failure per lead and complication per patient). Snaring techniques could not remove one lead tip that was severed during extraction and had migrated to the pulmonary vein system. One functional left ventricular lead was fibrosed to a targeted lead and was inadvertently dislocated. Mean implantation time for leads associated with minor complication was 138 months (range 10–317).

No extraction-related mortality occurred. One patient, however, died in hospital after a successful and uncomplicated

**Table 1** Lead characteristics

Leads	n 1032	Time from implant month		Fixation method			Polarity (uni/bicoil ICD)		
		Mean	Range	Active	Passive	Unknown	Bi	Uni	Unknown
Atrial	517	62	1–317	264 (51%)	227 (44%)	26 (5%)	420 (81%)	76 (15%)	21 (4%)
SVC ICD	4	65	54–84		3 (75%)	1 (25%)		4 (100%)	
Ventricular	451	79	1–429	77 (17%)	332 (74%)	42 (9%)	182 (40%)	231 (51%)	38 (9%)
Ventricular ICD	54	58	1–157	6 (11%)	47 (87%)	1 (2%)	40 (74%)	14 (26%)	
LV	6	14	1–47		6 (100%)		4 (67%)	2 (33%)	

open-chest extraction. This patient had severe endocarditis with pannus formation in the right atrium. He was refractory to all antibiotic treatment and accepted for surgical lead removal as a very last resort. He recovered from surgery, but later succumbed to infection. Another patient died at a referring hospital within 30 days due to progressive heart failure. A third patient died suddenly outside hospital after 2 months, probably due to ventricular arrhythmia. One patient partially extracted due to local infection developed late endocarditis possibly related to the original infection.

## Other results

Median extraction time for laser procedures was 2 min (mean 7.2, range 1–55). Fibrosis was most commonly located at the subcutaneous tissue surrounding vessels; however, the densest fibrosis was found in the curve to the brachiocephalic vein. More than one laser sheath was used in 5.7% of the laser cases, usually to achieve more oversizing. Median time in hospital for laser-extracted patients was 3 days.

## Discussion

The various indications in our series have, with the exception of superfluous leads and leads associated with local infection, been stable over time, however, reflecting periodic recalls, mainly of the Teletronics Accufix™ leads. The indications for extraction in this study are similar to those of other recently published major series,<sup>5,12</sup> differing from a third major study with a clearly higher rate of infectious indications.<sup>3</sup> The low implantation rates of ICD and cardiac resynchronization therapy systems in Sweden compared with many other western countries, especially the USA, are reflected in the distribution of the extracted lead types. The results of this study regarding success rate (97.6%), serious complication rate (0.9%), and mean implantation time (5.8 years) are similar to the results of other major series.<sup>2–5,13–17</sup> Bongiorno *et al.*<sup>3</sup> mainly using mechanical sheath techniques achieved a success rate of 98.4%, with a serious complication rate of 0.7%, including three deaths. Mean implantation time was 5.8 years. Epstein and co-workers<sup>5</sup> mainly using laser technique achieved a success rate of 97.5%, with a serious complication rate of 0.4%, without mortality. Mean implantation time was 5.7 years. In detail, comparisons of the results of studies, especially retrospective, employing different extraction techniques are, however, difficult

due to varying indications, different study designs, and different endpoints.

Implantation time was in this study, contrary to several other studies, not associated with failure. The lack of association between implantation time and failure (for all leads and for laser-extracted leads) was surprising and was rechecked. The reason for the lack of association is probably a wide range of implantation times for the failed leads and a very low incidence of failures (7/1032 leads). The trend was, however, strong with a mean implantation time for all leads of 69 months compared with 162 months for failed leads.

This study also failed to show an association between implantation time and the incidence of serious complications, possibly due to the low incidence of serious complications. Extraction from the vein of implantation (the superior approach) was found to be safe and efficient. A high proportion of the leads (29%) could be manually extracted, probably because leads implanted 1 month or longer were included in the study. The high proportion of manually extracted leads may also depend on the experience gained on how much traction lead models can sustain before breaking.

We choose to include leads that had been implanted from 1 month on, as we wanted to include a few leads that stuck in the tricuspid valve at implantation and subsequently were referred for extraction. This also allowed inclusion of several leads that required laser extraction (mainly in young patients) that had been implanted less than 1 year. Active leads were somewhat easier to successfully extract with manual technique than passive leads, any difference in implantation time was not accounted for. The explanation is probably that most active fixation leads are isodiametric, at least pacing ones.

Laser-assisted lead extraction was, in our hands, a successful, safe, and quick technique. The median extraction and fluoroscopic times (not reported) of this procedure were relatively short and facilitated scheduling patients. Contrary to the originally described extraction technique employing double telescoping mechanical sheaths and matching inner sheath size close to the lead diameter, we found single sheath laser technique and a certain amount of laser sheath oversizing essential for success, especially regarding heavily fibrosed leads. Initially, only 12 Fr laser sheaths were available. Subsequently, the percentage (23%) of leads extracted with this size of sheath is skewed, and the percentage clearly decreased over time. When performing laser extraction, we found the

increased sheaths stiffness associated with using a mechanical outer sheath to be a major disadvantage and a potential risk factor for perforation. This applies especially when freeing leads at the brachiocephalic curve and when targeting tortuous leads. The major obstacles for extraction in our hands were dense fibrosis and calcification (mainly at the vascular entrance, at the brachiocephalic curve, and in the ventricle) and tortuous lead configuration. Surprisingly, we found that previous extraction attempts were not predictive of failure. Less surprisingly, leads in which locking stylets could not be used were associated with extraction failure.

The performance of the various locking stylet models from different manufacturers improved over the study period (better trackability, better ability to reach the lead tip, and better locking). The EDS extraction technique was evaluated in a limited number of leads and was found to be less efficient than the laser (crossover to laser with subsequent success was performed in 5/6 of these leads). A femoral or right jugular vein approach was used for free floating leads. The vast majority of the leads with vegetations (up to ~4 cm if not very pedunculated) were successfully extracted with transvenous laser technique. The 16 Fr laser sheath was used in most of these cases. Open-chest techniques were used to extract 4% of the leads; the vast majority of these leads were extracted during otherwise indicated heart surgery.

All patients with a Class I indication for extraction were treated: 4/7 of the failed leads were Class I, 3/7 Class II, and none of the latter were redundant leads. It should be noted that the majority of the partial success cases involved leaving a passive lead tip entrapped between the clavicle and the first rib, most likely as a result of medial subclavian punctures. From a practical standpoint, most of the leads classified as partial extractions were clinically 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. We find it essential in lead extraction to apply an ongoing risk–benefit analysis and to avoid forcing extraction in cases of discretionary indications. Trying to achieve radiographic complete success in all Class II indication cases may not be in the patients' best interest. A good proportion of the successfully extracted leads were superfluous and the proportion of such leads increased over the study period, reflecting an increasing demand for extraction of such leads and an increasing extractor confidence. Our results extracting superfluous leads should, however, not be used as a recommendation to low volume centres to embark on extracting such leads without doing a serious individual risk–benefit analysis and being very well prepared to treat complications.

The four perforations that occurred required immediate sternotomy in the OR; the two atrial/SVC perforations were associated with massive bleeding and required putting the patients on bypass. These two patients would probably not have survived transferal to another room for treatment. The tricuspid valve had to be replaced in one patient (on the first post-operative day) due to damage during extraction. The lead was found to have been fully encapsulated into the centre of one cusp, probably as a result of a previous infection. This condition was not diagnosed by intraoperative transoesophageal echocardiography prior to extraction. Similar to several other series we found a learning curve affecting the failure rate.

## Study limitations

The lack of association with failure and complication for most of the factors analysed should be interpreted with some caution due to the relatively low number of failures and complications in the study. When comparing the failure rate of the extraction methods used in this study, the difference in implantation times should be noted.

This retrospective study suffers from the inherent limitations of such studies. Only patients treated and leads extracted consecutively have been analysed; no systematic registration of potential extraction patients not treated was done. Two kinds of selection bias may therefore affect the results of this study. First, patients may not have been referred to our centre for various reasons. Secondly, a small number of patients did not undergo extraction, because of their high risk. Further, patients with local infection were for part of the study period not primarily extracted but underwent one revision before extraction. This policy, however, probably did not improve the results. Finally, the low risk in this study may be affected by the small number of dual coil ICD leads extracted.

## Conclusions

Pacing and ICD leads can safely, successfully, and effectively be extracted. Leads can often be extracted by a superior transvenous approach; open-chest and femoral extractions are, however, still needed. Laser-assisted lead extraction proved to be a useful technique to extract leads that could not be removed by manual traction. The results indicate that the paradigm of abandoning redundant leads, instead of removing them, may have to be reconsidered.

**Conflict of interest:** C.B. and J.G. have no disclosures. R.W. had no disclosures until being employed by CardioNord in 2001. CardioNord is the local representative of Spectranetics Inc. C.K. has presented on behalf of, performed studies with, or advised Biotronic, Boston Scientific, Ela Medical, Guidant, Medtronic, Spectranetics, St Jude, and Vitatron.

## Funding

Partial funding was provided by Biotronic, CardioNord (Boston Scientific), Ela Medical, Medtronic, and St Jude. Funding to pay the Open Access publication charges for this article was provided by Spectranetic Inc.

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