Excimer Laser assisted extraction of permanent pacemaker and ICD leads: present experiences of a European multi-centre study

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Abstract

Objective: Excimer Laser technique can be used to extract leads. We present the European multi-centre experience. Method: The Spectranetics Excimer Laser is a Xenon-Chloride laser with a wavelength of 308 nm, not visible to the human eye. This cool cutting laser (50°C) has an absorption depth of 0.06 mm. The laser energy is emitted from the tip of flexible 12, 14 or 16 French (Fr) probes and is absorbed by proteins and lipids. The fibrotic sheaths usually surrounding leads can be cut without damaging the endothelial wall or the insulation of other leads. Results: From August 1996 to August 1998, 179 leads (104 atrial, 57 ventricular, one SVC, 17 ICD) in 149 patients (mean age 68.3 years, range 14–94) were extracted in 11 centres. Mean implantation time was 68.3 months (2.8–357.8). Most common indications were patient morbidity, non-function, pocket infection, septicaemia or endocarditis. Median extraction time was 10 min (1–189). Most procedures (78%) were performed in operating rooms. Complete extraction was achieved in 89.5% of the leads, 6% were partially extracted and 4.5% of the extractions failed. In the majority of the partial cases, only minor lead parts without clinical significance were left. Of the failures, 3/8 were completely removed by femoral non-laser approach, 1/8 with a right subclavian approach and 1/8 with thoracotomy. Complications were few but included one ventricular perforation that did not need surgery; two other perforations were related to the reimplantation of leads and required surgery. Mean hospital stay was 3 days and all patients were discharged well and alive. Conclusions: Excimer Laser assisted lead extraction is a safe and efficacious procedure. Open-chest extractions are still necessary but can be limited to very selected cases. These initial results may widen indications from mandatory to include the extraction of many non-functional leads, previously abandoned. © 1999 Elsevier Science B.V. All rights reserved.

Keywords: Excimer Laser; European multi-centre; Pacemaker lead; ICD lead

1. Introduction

Due to the difficulties and risks inherent of extraction, many permanent pacemaker leads are traditionally abandoned when non-functional. Infected leads and leads with other mandatory indications have been extracted by manual traction, extended weight- or forceps-assisted traction or with the use of mechanical extraction systems employing locking stylets and outer sheaths or with open-chest surgery [1–11]. Fibrotic lead adhesion tends to increase with time; however, the inter-patient variability is considerable. Not only the tip, but equally important, the body of the lead may be encapsulated in scar tissue. After a limited time of implantation many leads can be removed by simple manual traction. In addition, experienced physicians are able to extract a high proportion of old leads by using careful and extended traction [11]. Thanks to the increased use of locking stylets and outer sheaths, the rate of successful extractions is often 80–90% [1,2,4–6,8] and, in limited populations, over 90% [12]. Open-chest surgery, with or without cardiopulmonary by-pass is still required for extraction in a certain percentage of complicated cases (i.e. coronary sinus leads, broken leads and leads emitting thrombi). Most of the mentioned procedures, but also femoral approach extraction, often is very time consuming. The need for a more rapid procedure, including a more predictable duration of the extraction and a higher success rate with less complications, inspired Spectranetics Inc. (Colorado Springs, CO, USA) to develop the Excimer Laser technique, in co-operation with Dr. Charles L. Byrd [13]. We now report on the experiences of a European multi-centre study. Previously we have reported on limited, mainly single centre, experiences [14].
2. Materials and methods

2.1. Excimer Laser

The CVX-300 Excimer (excited dimer) Laser is a Xenon Chloride laser emitting light with a wavelength of 308 nm, which is below the limit of visibility of the human eye. The CVX-300 is a cool cutting laser; the temperature of the emitted light is approximately 50°C. At a tissue depth of approximately 0.06 mm, 64% of the energy is absorbed and at 0.18 mm 95% is absorbed. The energy is absorbed by lipids and proteins and not by water which is the main absorption medium for other laser modalities, such as the YAG. Thanks to these characteristics, the Excimer Laser is capable of disrupting the fibrotic sheaths around leads, while not damaging other leads or the blood vessels.

The energy is emitted from the rim of the tip of flexible, fiberoptic 12 Fr (inner/outer diameter 2.8/4.1 mm), 14 Fr (inner/outer diameter 3.4/4.8 mm) or 16 Fr (inner/outer diameter 4.2/5.6 mm) sheaths constructed as tubes from 82 fibres (12 Fr sheath), each with a core diameter of 100 μm (Figs. 1 and 2). The sheath is passed over the lead after removal of the pulse generator, making the proximal end of the lead accessible for traction (Fig. 3). The subcutaneous tissue is freed as close as possible to where the lead enters the vessel. The laser sheath is then advanced along the lead up to this point and fluoroscopic guided lasing is started. A smooth alignment of the laser sheath along the track of the lead is essential. There may be difficulties in passing the sheath over tines and wires when the tip of the lead is reached since the laser light does not affect the insulation of leads. Subsequently, for the removal of lead tips, locking stylets and outer Teflon® or polypropylene sheaths are normally used to enable the physician to perform a ‘counter traction procedure’ [6]. Leads with active and passive fixation are extracted with the same technique, as are atrial and ventricular leads. Furthermore, we do not recommend using
the laser sheath at angles close to 90° versus the endothe-
lum, due to the risk of perforation. The 12 Fr sheaths allow
removal of leads with an outer diameter up to 7.5 Fr (2.5
mm). The 16 Fr sheaths are intended for large diameter ICD
leads (max. diameter 11.5, Fr = 3.8mm). Clinical trials in
the US (PLEXES Trial) have shown that the 12 Fr sheath is
more effective than ‘mechanical’ methods and not associ-
ated with additional medical risks, for the extraction of
chronically implanted leads [13]. In addition, the larger
sized sheaths are as effective as the 12 Fr sheaths [15]. In
this study the laser was programmed with a fixed pulse
repetition rate of 40 Hz and a fixed energy setting of 60
mJ/mm². This fixed, maximal energy setting was considered
necessary to obtain the desired results without undue risk of
complication.

2.2. Population

From August 1996 to August 1998, 179 leads (104 atrial
leads, 57 ventricular leads, one SVC lead, 17 ICD leads)
were extracted in 149 patients (52 females, 97 males, mean
age 68.3 years, range 14–94) using the Excimer Laser at 11
European institutions. In the majority of the participating
centres, one physician performed the extractions. Mean
implantation time for all leads was 68.3 months (range
2.8–357.8). Atrial leads had been implanted for 54.8
months, mean (range 9.3–357.8) and ventricular leads
(including 16 ICD leads) for 87.1 months (range 2.8–
329.9). When the 17 passively fixated ICD leads were
excluded, 69 pacemaker leads had active fixation (screw)
and 91 were passively fixated (tines or fines).

2.3. Indications

The indications were categorized as mandatory, neces-
sary and discretionary by the definitions of Dr. Charles L.
Byrd. Mandatory indications were sepsicaemia (6.7%),
endocarditis (4.7%), device interference (2.7%) and oblit-
eration of all usable veins (0.7%). Necessary indications
were patient morbidity (45%, mainly recalled Teletronics’
leads), non-function (24.8%), pocket infection (16.1%),
interference with ICD leads (4%), erosion (2.7%), potential
device interference (2.7%), chronic draining sinus (2.0%),
vein thrombosis (1.3%), lead migration (1.3%). The only
discretionary indication was pain (1.3%).

Patients were only enrolled into the study after it was
found that the lead(s) could not be pulled out by simple
traction. Special care was taken not to risk destroying the
coil(s) or the intravascular insulation of leads.

The local ethics committee approved the study and the
patients gave their informed consent.

3. Results

When the time for implantation of new leads was
excluded, mean extraction time was 22 min (range 1–189)
and the median extraction time was 10 min. Mean time for
use of the laser was 119 s (range 4 s–19 min 28 s). The
number of pulses required freeing a lead varied from 56 to
46 945 with a mean of 4576. Most (78%) of the procedures

Fig. 3. Excimer Laser sheath tip with pacemaker lead.

Fig. 4. Laser extracted, heavily encapsulated distal part of atrial pacing
lead.
were performed in operating rooms. Fibroses were most commonly located to the subcutaneous tissue surrounding the vessels, however the densest fibroses were found in the curve to the brachiocephalic vein (Fig. 4). The majority of lead extractions required only one laser sheath per lead (171/179). In 61% of the leads, the locking stylets reached the lead tip. The stylets locked at the tip in 55% of the leads. A majority (89.4%) of the leads were completely removed. A small portion (6.1%) was partially removed and 4.5% of the extractions failed. A higher proportion was extracted of the atrial leads (98/104) than of the ventricular leads (45/57). A high proportion (15/16) of the ventricular ICD leads was completely removed. Already preoperatively, the intention was not to remove two of the leads completely in the group of partially removed leads. In another eight of the 11 cases with partially removed leads, the outcome was considered clinically successful and no further extraction was attempted. Most of the leads that could not be extracted with laser were removed by femoral, right subclavian or open chest approaches (3/8 with non-laser femoral approach using mechanical extraction systems, 1/8 with thoracotomy, 1/8 with right subclavian approach using a mechanical extraction system). A total of eight additional interventions (six femoral, one thoracotomy, one right subclavian) were performed. The outcome was successful for the majority (97%) of the cases, for which lead replacements were intended. Complications were very few, including one ventricular perforation directly related to the extraction procedure. However, open chest surgery was not required in this case. One ventricular perforation related to the introduction of a new lead necessitated open chest surgery. One patient developed a cardiac tamponade 24 h after the extraction and underwent sternotomy. The bleeding was caused by perforation of the screw tip of an atrial, actively fixed lead, implanted at the extraction. 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 a ventricular arrhythmia.

4. Discussion

The laser sheaths handled well and were structurally strong enough to withstand the wear of extraction. This notion is supported by the fact that two sheaths were required in only eight of 179 leads. Earlier versions of the larger sheaths were slightly stiff when encountering sharp bends in the vessel system; softer versions combined with more experience have solved this problem. The laser source performed well technically and was easy to operate. In order to achieve success in laser extractions, it is critical to reach the tip of the lead with the locking stylet. It is equally essential to obtain a firm fixation of the stylet at the lead tip in order to achieve good counter traction. The performance of the locking stylets (various models from the lead-manufacturers) was somewhat disappointing and an improvement would lead to better results all over. The outer sheaths allowed countertraction and facilitated the implantation of replacement leads. However, the direct implantation of a new lead through the outer sheath and the preformed fibrotic channel proved sometimes difficult. It is advisable to introduce a guide wire, to remove the outer sheath and then use an extra long introducer over the guide wire, in order to avoid getting the tip of the new lead entangled in fibrotic tissue. The alternative is a new venous entry combined with a long introducer. No infections were found which might be attributed to the antibiotic prophylactics and to the short extraction times. Sufficiently large laser sheaths are essential. If too little spacing is allowed between the lead and the sheath, fibrotic tissue may create a ‘snow-plough’ effect in front of the sheath tip, which stops further advancement. The larger laser sheath sizes do not seem to be associated with more complications than the 12 Fr sheath, however, the number of 14 and 16 Fr sheaths used is still low. Another situation that can prohibit advancement is when damaged insulation material (not affected by Excimer Laser light) folds back. This creates an outer diameter of the lead, which the sheath can not cope with. The higher success rate for atrial leads compared to ventricular leads may be due to the shorter duration of their implantation but may also depend on that a majority of the atrial leads were isodiamic (Accufix leads). From a clinical point of view, most of the leads classified as partial extractions were successful. The minor lead parts which were left to remain in the patients have not created problems so far, except for in a case of endocarditis. Most of the failures occurred with old leads or with leads that were damaged by previous extraction attempts. Patients not subjected to previous extraction attempts have an increased possibility to success.

The learning curve for the use of the Excimer Laser can be shortened by previous extraction experience. We recommend thorough training before starting laser assisted lead extraction; the majority of the noted complications were experienced early by several centres. The support given by the manufacturer during the early cases is essential and may help to avoid potentially fatal complications. In order to uphold the reputation of the method, only two patients in this study have been extracted according to discretionary indications. In the beginning of the study, only mandatory and some necessary indications were used. Subsequently, also non-functional leads have been extracted. Lead models known to be fragile with non-laser extraction technique were, also with laser aid, found to be fragile. The unnatural policy of leaving non-functional leads to remain in the body may change in the near future when new methods, such as laser assisted extraction, gain wider acceptance. However, a prerequisite is that the good results achieved so far are maintained. In addition the costs have to be acceptable to the medical community.

In conclusion, we found Excimer Laser assisted lead extraction to be efficient and associated with few complica-
tions. Even though today only moderately more successful than the best traditional methods, it is less time consuming, the outcome is more predictable and the complication rate is probably lower. The Excimer Laser can be applied to most lead problems but open chest surgery is still required for special cases and for complications.

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References


Appendix A. Conference discussion

Dr Y. Louagie (Mont Yvoir, Belgium): You mentioned that you had to extract leads in septic cases. I operated on two patients referred for infected leads. I had to do it under extracorporeal circulation with a right atrial approach since echocardiography disclosed huge potentially infected thrombi. At surgery we found giant granulomas that had to be removed surgically. I would like you to elaborate on that subject and to precise the indications and contraindications for your technique of endovenous extraction.

Dr Kennergren: This is a quite interesting issue which hasn’t been answered properly yet. There is a quite recent paper from Canada discussing this. In my own experience and in the experience of this study, we have had no neurological complications using laser; however, seeing those large vegetations is sometimes very frustrating, and if you are in doubt, I would say there is definitely still a case for open heart surgery. If using the laser technique a large diameter sheath is recommended.

Dr F. Wellens (Aalst, Belgium): In my local experience, I have found clinical pulmonary embolism in 20% of the cases, so I decided to anticoagulate all the patients for at least 3 months after this procedure. Can you comment on that?

Dr Kennergren: Well, such a short period of anticoagulation is probably not associated with increased bleeding complications, so it is a good precaution, I would say. In this study we did however not recommend compulsory anticoagulation after the extraction. In my centre we did not use it if the patient didn’t have other indications for anticoagulation. As mentioned, no neurological complications were reported in the study.