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Excimer Laser for Pacemaker and Defibrillator Lead Extraction: Techniques and Clinical Results

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Abstract. Pacing and defibrillation leads may need to be removed for several reasons including infection, interference with others leads, lack of vascular access or redundancy. However, the removal of chronically implanted leads is a major technical challenge because of the extensive adhesions that develop along the course of the leads over time. The techniques to remove chronic leads have been greatly facilitated by the development of an excimer laser sheath. We undertook an analysis of our experience with laser extraction in the first 50 leads attempted. An excimer laser sheath system, developed by the Spectranetics Corporation, was used to extract 50 chronically implanted leads in 34 patients. The mean patient age was 64 ± 12 years, all were male and the average duration that the leads had been implanted was 5.0 ± 3.9 years. Two-thirds of the leads were pacemaker and one-third were defibrillator leads. There was a 100% clinical success rate and 48 of the 50 leads were completely removed. There were no major complications. There was one minor complication of subclavian vein thrombosis and two haemodynamically non-significant episodes of air embolism. The main limitation observed was failure of the excimer laser sheath to advance in 18% of cases, probably due to the presence of calcified adherences on leads. Two strategies were found useful to deal with this problem: under the clavicle stainless-steel sheaths were used to break up calcified adherences and within the venous system the laser sheath was upsized in order to advance over the calcification on the lead. It was concluded that excimer laser has greatly facilitated the removal of chronically implanted pacemaker and defibrillator leads. There is a high success rate and low complication rate in our experience. The main limitation of laser is the presence of calcified adherences.

Keywords: Defibrillator; Electrophysiology; Excimer; Laser; Lead extraction; Pacemaker; Ultraviolet

INTRODUCTION

Ever since pacemaker and implantable cardioverter defibrillators (ICD) began to be implanted there has been a need to explant leads at a later date in some patients. Infection has always been a major indication for lead removal as device infections are rarely cured by antibiotic treatment alone. Other indications to remove chronic leads include interference with other leads (a particular problem in ICD systems), lack of vascular access for new leads, redundant leads or defective leads which are a risk to the patient [1,2]. The North American Society of Pacing and Electrophysiology has recently published a policy statement listing the indications for lead extraction [3]. The need for removal of chronic leads seems likely to increase in coming years as the implantation rates of pacemakers, and in particular ICDs, increase.

Although recently implanted leads (<3 months) can usually be removed with simple traction, once leads have been in place for many months and especially years, fibrous adhesions develop at the contact points between lead and venous and/or cardiac walls. With time these adhesions become dense, may calcify and extend along the length of the lead. Removal of a densely adherent chronic lead is then a major technical challenge, even with direct surgical exposure, and clearly carries a risk of venous or cardiac perforation [4].

Over the last 15 years, various techniques, both surgical and percutaneous, have been developed to meet the challenge of removing chronically implanted device leads. In the early experience either direct surgical removal

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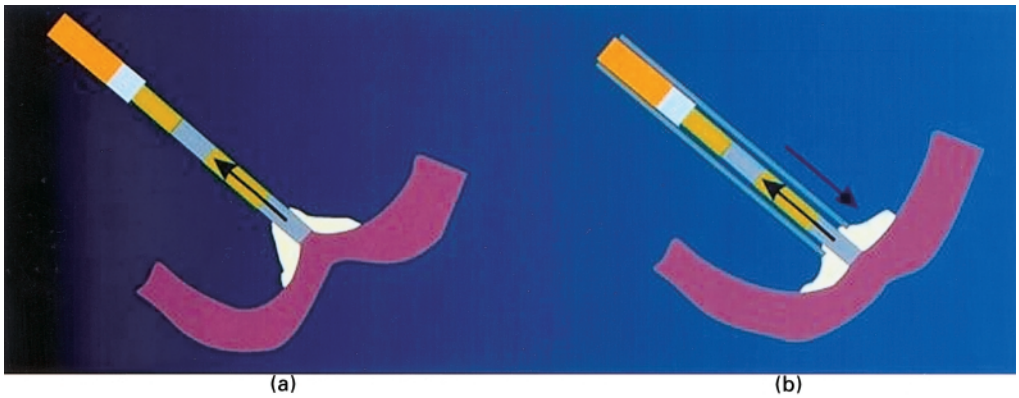

Fig. 1. Diagram showing the principle of counter-traction in lead removal. (A) With traction only on the lead, there is inversion of the right ventricle (shown in purple). (B) A sheath has been advanced over the lead to abut the fibrous tissue and myocardium thus preventing ventricular inversion while the lead tip is freed by traction.

or simple traction strategies were used. Simple traction often failed because either the lead disrupted before adherences gave way or venous (or cardiac) tears occurred [5]. Once the limitations of simple traction were realised a system of counter-traction was developed [6,7]. The principle of the counter-traction technique is that a sheath is advanced over the lead, first to break up adherences and, second to apply pressure on the endocardium around the embedded lead tip [7]. In this way traction can be applied to the lead tip to safely remove it without the risk of myocardial inversion or avulsion (Fig. 1). This traction/counter-traction technique has become the standard approach to lead extraction today.

The limitation of counter-traction systems, however, has been the inability of blunt polymer sheaths to be advanced through dense adhesions surrounding leads. To address this problem an excimer laser sheath was developed by the Spectranetics Corporation (Colorado Springs, Colorado) to be incorporated into the system of traction/counter-traction for removal of chronic leads [8]. The sheath consists of thin outer and inner polymer walls between which a layer of optical fibres has been spirally wrapped. At the 'cutting end' of this hollow sheath the optical fibres present a circumferential ring of light (Fig. 2). The appropriately sized laser sheath is advanced over the lead to be removed and excimer laser energy is delivered at the adhesion sites within the circulation thus freeing the lead (Fig. 3). An outer polymer sheath (non-laser) is advanced progressively behind and over the inner laser sheath. As laser is not performed at the myocardium this outer, non-laser, sheath is advanced the final 1–2 cm to the endocardium to provide counter-traction on the endocardium while the lead tip is pulled free of its myocardial attachments (Fig. 1).

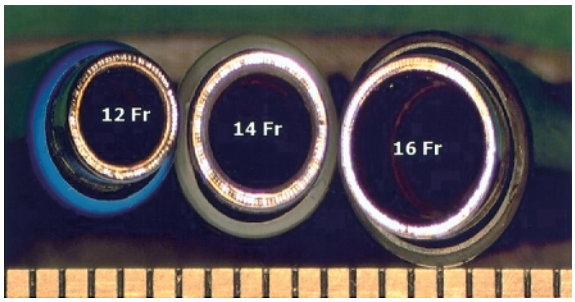

Fig. 2. Photograph showing the distal or 'cutting' end of the three sizes of laser sheath (12F, 14F and 16F). The inner sheath in each case is the laser sheath demonstrating the circumferential ring of optical fibres. The outer sheath in each case is a polymer non-laser sheath.

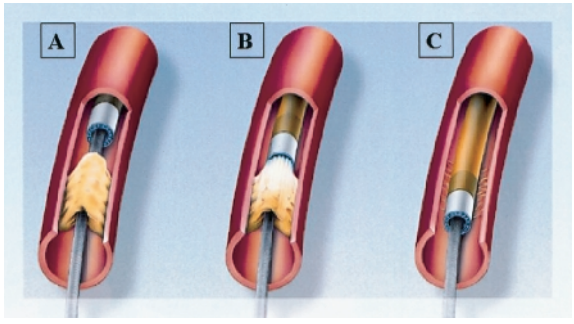

Fig. 3. Diagram illustrating the action of a laser sheath in freeing pacemaker leads from intrvascular adherences due to fibrous scarring. (A) The laser sheath is advanced over the lead until a 'binding site' is reached. (B) excimer laser is delivered to ablate the tissue and free the lead thus allowing the sheath to continue to advance (C).

A number of series have now reported on the use of the excimer laser sheath and one randomised trial has compared the laser assisted to the non-laser lead extraction technique

Table 1. Demographic features of 34 patients undergoing laser lead extraction

Age	64 ± 12
Sex	100% male
Indication for extraction	
Lead interactions[a]	15 pts
Infection	13 pts
Vascular access	4 pts
Other	2 pts
Type of device	
Implantable cardioverter defibrillator	17 pts
Pacemaker	17 pts
Average number of leads per patient	1.7 ± 0.9
Total number of leads per patient	
1 lead	16 pts
2 leads	14 pts
≥3 leads	4 pts
Total number of leads extracted by laser	50 leads

[a]See text for details, pts=patients.

Table 2. Characteristics of 50 leads extracted using excimer laser

Mean duration since implant (years)	5.0 ± 3.9
Type of lead	
Pacemaker	33 (66%)
Implantable cardioverter defibrillator	17 (33%)
Chamber in which lead placed	
Right atrium	10 (20%)
Right ventricle	40 (80%)
Type of lead fixation	
Passive (tined)	36 (72%)
Active (screw)	14 (28%)
Type of lead insulation	
Silicone	30 (60%)
Polyurethane	20 (40%)
Venous entry site	
Left subclavian	32 (64%)
Right subclavian	11 (22%)
Cephalic	7 (14%)

[8–11]. The results have been encouraging but concern has remained about success and complication rates. We undertook a review of our own, prospectively collected, single centre experience with laser lead extraction to determine its success in our hands and also to examine its limitations.

PATIENTS AND METHODS

Patients

The study was a review of consecutive patients who underwent laser lead extraction since we first began using this technology in August 1997. There were 50 leads extracted in 34 patients over a 3-year period up to August 2000. In the first year of this experience the laser sheath was investigational and we participated in the US Laser Sheath Registry, a Food and Drug Administration (FDA) approved study sponsored by the Spectranetics Corporation [11]. Subsequently the laser sheath was approved by the FDA and was used as clinically indicated. Table 1 shows the demographic features of the 34 patients. Patients had an average of 1.7 ± 0.9 leads in place. However, only 50 leads required the use of laser for extraction, the other leads were either not removed or were removed by simply unscrewing the fixing mechanism and/or by simple traction. The main indication for lead extraction in this series was that the existing leads were interfering or likely to interfere with new leads in terms of vascular access or electrical function. This indication applied primarily to ICD leads as these leads are large, have the potential for mechanical interaction leading to inappropriate shocks and defibrillation coils adherent to each would be difficult to remove later, therefore it has been our policy not to place two defibrillation leads side by side.

Leads

Table 2 shows the characteristics of the 50 leads, which were extracted using laser. Leads had been implanted for an average of 5 years, one-third were ICD leads and most had tines as the fixation mechanism, all features which make extraction more difficult. It is notable that none of the leads were of the Accufix or Encor type, atrial pacemaker leads in which a re-enforcing wire was prone to break and cause patient injury. These leads form a significant proportion of cases in other lead extraction series from this time period [2,11,12].

Procedure

Patients were consented in detail with regard to the procedure, indications, alternatives and

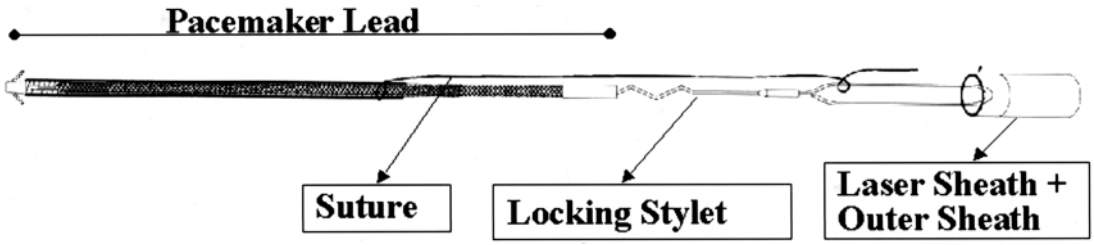

Fig. 4. Diagram showing the preparation of the lead for removal. A 'locking' stylet is advanced through the lead lumen and 'locked' at the lead tip. A suture is tied on the outer insulation to provide traction on the lead body. The laser sheath and a non-laser polymer outer sheath are then advanced over the stylet, suture and lead body.

especially the potential risks. Patients were blood grouped and cross-matched routinely. The procedures were performed in the cardiac electrophysiology laboratory under conscious sedation in 31 patients and general anaesthesia in three. A cardiac surgeon was always on standby within the hospital in case emergency thoracotomy was needed. Echocardiography was always immediately available in case there was concern about cardiac tamponade. An arterial line (usually femoral) and a large bore intravenous line were placed. A transvenous temporary pacemaker wire was routinely placed in the early part of the series, in the latter part only if the patient was pacemaker dependent.

Laser Lead Extraction Technique

The technique used has been previously described in detail [10,11]. In brief the lead to be removed was exposed by dissection, the lead was cut and the patency of the lumen was tested. A 'locking' stylet was advanced through the lumen of the lead as far distally as possibly and locked. This allowed for traction on the tip of the lead. During the study period three different types of locking stylets were used as the technology changed. In the initial phase Cook locking stylets were used (Cook Vascular Inc., Leechburg, Pennsylvania), in the middle phase 'Wilkoff' stylets were used (Cook Vascular Inc., Leechburg, Pennsylvania) and in the third phase the LLD system from Spectranetics was used (Spectranetics Corporation, Colorado Springs, Colorado) (Fig. 4). In addition to the locking stylet, a suture was tied on the lead insulation and used to apply traction to the lead body (Fig. 4). Then the appropriately sized laser sheath was advanced over the lead; three laser sheaths sizes are available, 12F, 14F or 16F (Fig. 2), for different diameter leads. Using fluoroscopy the inner laser sheath was advanced over the lead (Fig. 3). Excimer laser energy was delivered from a XeCl excimer laser (CVX-300, Spectranetics Corporation) at a repetition rate of 40 Hz and a fluence output of 60 mJ/mm^2. Laser energy was delivered in 5-s bursts. Lasing was virtually always required to obtain entry to the venous system, where there was usually dense fibrosis. Lasing was then performed as required to free the lead from adhesions in the veins and advance the sheath over the lead to within 1–2 cm of the endocardium. Lasing was not performed at the endocardium; rather the outer non-laser sheath was advanced over the laser sheath to the endocardium to provide counter-traction as traction was applied to free the tip of the lead.

Post-Procedure and Follow-Up

Following successful lead extraction venous access was maintained if needed for implant of a new lead, by placing a guide wire though the laser sheath and then exchanging the laser sheath for an alternative sheath. If indicated the new lead(s) and device were implanted during the same procedure. However, in cases of device infection re-implantation was typically postponed for 2–7 days. Patients were observed on telemetry overnight. Haemoglobin levels and chest radiography were performed the following morning to detect any sign of late or slow bleeding. Patients were discharged to home later that day. Patients were followed-up at 1 week and at 6 weeks post-procedure when any late complications could be detected. Thereafter patients were followed as necessary for their implanted device.

Data Collection and Analysis

The results presented here represent analysis of data derived from a prospectively maintained database, the US Lead Extraction

Table 3. Results of excimer laser lead extraction of 50 leads in 34 patients

Complete extraction success	48 (96%)
Partial extraction success	2 (4%)
Clinical success	50 (100%)
Complications	
Major	0
Minor	
Subclavian vein thrombosis (arm oedema)	1
Observations	
Air embolism without haemodynamic compromise	2
Avulsion of portion of tricuspid valve without sequelae	1

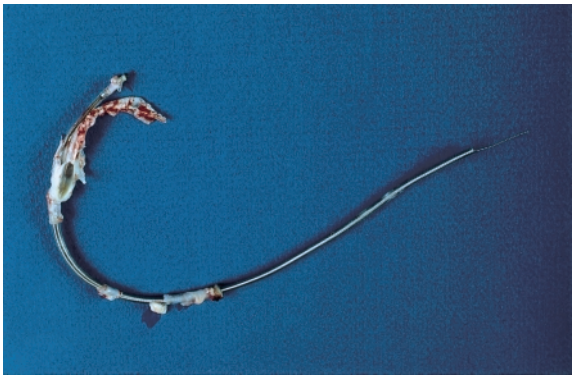

Fig. 5. This extracted ventricular pacemaker lead shows tissue attached to the distal part of the lead that is compatible with partial avulsion of a tricuspid valve leaflet. The patient had no adverse sequelae, see text for details.

Database. This is a voluntary database contributed to by multiple US lead extraction centres and is run by Med Institute Incorporated (West Lafayette, Indiana) and sponsored by the Cook Corporation (Cook Vascular Inc., Leechburg, Pennsylvnia) [1,2]. At the time of the performance of each case a US Lead Extraction Database form was completed which included information on the patient, leads and the procedure. Any late post-procedure complications (within 30 days) were subsequently sought and the database updated at regular intervals. For the present analysis Med Institute Inc provided the data for our single centre experience in Microsoft Excel spreadsheet form. This was supplemented where necessary by review of medical records.

RESULTS

Success Rate and Complications

Table 3 shows the overall results for the extraction of 50 leads in 34 patients. There was complete extraction success, i.e. the lead was removed entirely, in 48 of the 50 cases. In two leads there was incomplete extraction. In one case the tip of the lead remained embedded in the myocardium. In this case the indication for extraction was a failed ICD lead (not infected) and the residual lead tip has not been of clinical significance during 1 year of follow-up. The second case was a ventricular pacemaker lead, which had been partly removed at open-heart surgery for tricuspid valve replacement. The surgeon had only been able to remove the distal part of the lead and had cut the lead in the superior vena cava. At subsequent pacemaker implantation, extraction of the lead was attempted in order to remove the exposed conductor coil in the superior vena cava (SVC). The conductor coils of the lead were removed with the outer insulation only remaining in the right subclavian vein and upper SVC and this was considered a clinical success.

There were no major acute complications (Table 3). A postoperative minor complication occurred in one patient, namely subclavian vein thrombosis manifested by arm oedema. In this patient there had been extensive adhesions with calcification between the leads in the subclavian and inominate veins. Lead extraction had required the use of additional polymer and steel sheaths to break adhesions within veins. Post-procedure subclavian vein thrombosis was treated with anticoagulation with a good clinical result. There were two episodes of air embolism, which were visible radiographically but were not associated with haemodynamic compromise and resolved on high flow oxygen without sequelae. There was one case of avulsion of a portion of the tricuspid valve (Fig. 5). This patient, with pacing system infection, had three chronic leads one of which had been abandoned at the time of implant 5 years earlier because it had become entangled in the tricuspid valve. After freeing this lead from adherences in the venous system using laser the lead came free from the heart with traction/counter-traction. On removal, a portion of tricuspid valve leaflet remained attached (Fig. 5). The patient suffered no adverse sequelae. Follow-up echocardiography could not identify any structural abnormality of the tricuspid valve and Doppler showed moderate tricuspid regurgitation which had been present on studies before extraction.

Table 4. Details of laser extraction procedure for 50 leads

Size of LASER SHEATH Used	
12 F	12 (24%)
14 F	18 (36%)
16 F	20 (40%)
Sites of intravascular adherences	
Subclavian vein	48 (96%)
Superior vena cava	28 (56%)
Right atrium	22 (46%)
Tricuspid valve	10 (20%)
Right ventricle	20 (40%)
Other leads	13 (26%)
Outer sheath advanced to endocardium	19 (38%)
Failure to advance – calcified adherences	9 (18%)
Need to upsize laser sheath	5 (10%)
Need to use steel dilator sheaths	4 (8%)

Fig. 6. This extracted atrial pacemaker lead shows a cuff of calcified fibrous tissue surrounding the distal end. During extraction of this lead, despite sheath upsizing, the laser sheath could not pass over this calcified area located in the SVC. The calcified cuff of tissue was pushed to the tip of the lead by the sheath and extracted on the lead as shown.

Adherences and Calcifications

Table 4 details the sites at which significant intravascular adherences were observed and lasing was necessary. Dense adherences were universally found at the entrance to the venous system and then frequently within the venous system and at the endocardium. Adhesions were not only common between the vein wall and lead but also between leads when more than one lead was present. Adherences were particularly prominent between defibrillator lead coils and other leads. In 18% of cases the appropriately sized laser sheath failed to make progress beyond a certain point, presumably due to the presence of calcified adherences. These were identified either radiologically by intraoperative, high magnification fluoroscopy, or by the feeling of hard resistance to sheath advancement with failure of the laser sheath to advance. In five cases it was found that upsizing of the laser sheath (i.e. 12Fr to 14Fr or 14Fr to 16Fr) resulted in the ability to 'go over' the calcification. In one of these cases the atrial pacemaker lead was extracted with a large calcified cuff of fibrous tissue, which had been pushed to the lead tip (Fig. 6). In another case the calcified tissue on the lead was able to be withdrawn until visible at the venous entry site and was manually dissected off so that the laser sheath could be advanced. In four cases it was necessary to use 'telescoping' steel dilator sheaths to break up the calcified adhesions at the venous entry site under the clavicle.

Of note, the outer sheath system was advanced to the endocardium for countertraction in 38% of the cases, which indicated that these leads were firmly embedded at the tip and needed to be removed from the myocardium by traction.

DISCUSSION

Our series confirms that excimer laser has a valuable role to play in the extraction of chronic pacemaker and defibrillator leads. In the extraction of 50 leads implanted for an average of 5 years we had a 100% clinical success rate without a major complication.

Success Rate of Laser Lead Extraction

Prior to the introduction of the laser sheath, extraction of leads was performed either from the superior approach using polymer sheaths to mechanically disrupt fibrous adhesions or from a femoral approach using basket catheters and other devices to snare and extract the leads [6,7,13,14]. Although the published data on these techniques suggested that as of 1996 the success rate for complete lead removal was 93% [2] the procedures were technically challenging and time consuming. The use of the excimer laser sheath was first reported in 1996 [8] and subsequent small reports indicated that the success rate of laser lead extraction varied from 81% to 100% [9,15–17], the difference being explained at least in part by a learning curve [16].

The most convincing evidence that excimer laser has a superior success rate for lead

extraction compared with mechanical techniques comes from the 'PLEXES' Trial [10]. In this trial, 301 patients with 465 leads were randomised to extraction using a 12F-laser sheath or using a standard Teflon polymer sheath. The results showed a 94% success rate of complete lead removal in the laser group versus a 64% rate in the non-laser group ($p=0.001$) [10]. Failed non-laser extractions crossed over to the laser group and 88% were successful. The use of excimer laser also reduced the duration of the procedure compared to non-laser sheaths, 10 ± 11 min versus 13 ± 19 min ($p<0.04$) [10].

Subsequent to the PLEXES trial, the US Laser Sheath Registry, in which our centre participated, reported on the multicentre experience with all three sheath sizes, 12F, 14F and 16F sheaths [11]. The clinical success rate for lead extraction was 92% in 863 patients with 1285 leads undergoing laser lead extraction at 52 centres [11]. In a European multicentre study in 149 patients with 179 leads complete extraction was achieved in 90% and complete or partial extraction in 96% [18]. Thus the large multicentre experience supports our single centre results that the laser sheath is a highly effective new tool to deal with the challenging problem of lead extraction.

Complications of Laser Lead Extraction

We did not have any major complications in our series. It is estimated that the risk of major complications with lead extraction is approximately 2% [1,2] and such an incidence is within the confidence limits for our small series. Major complications with lead extraction are primarily bleeding due to vascular perforation or avulsion of myocardium. Recognised risk factors for complications include longer duration of lead implant, multiple leads, female sex and possibly younger patients because of a tendency to more fibrous scarring [2]. Although the duration of implant was relatively long at an average of 5 years and 53% of patients had more than one lead in our series, there were no females and this may be one reason to explain the absence of major complications.

It is unlikely that laser reduces the risk of lead extraction procedures and there has been a suggestion that laser might be associated with increased risk [10]. In the PLEXES Trial there was a trend towards higher risk in the laser cases, 2.2% versus 1% in non-laser cases [10]. In the large US registry the complication rate was 3.6% with a perioperative mortality of 0.8% [11]. Complications were primarily due to cardiac tamponade (1.5%) and SVC perforation (0.6%), this latter complication being associated with trauma from new lead implant [11]. The complication risk was independent of sheath size. The level of risk in these laser lead extraction series and the type of complications seen are comparable to the risks described for lead extraction generally [2]. The most reasonable interpretation of the literature to date seems to be that lead extraction carries an approximately 2% risk of major complication regardless of whether laser is used or not.

Although we did not have any major complications in our series we did observe that there is a risk for air embolism as a result of this technique, especially using the larger sheaths. These sheaths are non-compressible, thus at the time of removal of the lead and the placement of a guide wire to retain access through the laser sheath, great care should be taken to minimise the risk for air embolism. The complication of subclavian vein thrombosis which we observed has been described in other series [10] and was not unexpected in our particular patient because of the extensive intravascular manipulation which was needed to remove the chronic leads. Partial avulsion of the tricuspid valve has also been described [19] but in our case this was clearly related to an original implant complication and was not associated with long-term sequelae.

Limitations and Challenges in Laser Lead Extraction: Calcification, etc

We found that the primary limitation of the excimer laser sheath was failure to advance beyond a certain point in some patients. This appeared to be due to the presence of dense adherences containing calcium. On fluoroscopy it was not always possible to identify the presence of calcium and often failure to advance the sheath with a feeling of hard resistance suggested to us that calcium was present. This is a significant limitation as many leads appear to develop some calcified adherences over years. We found that a number of strategies were useful in dealing with this problem. Upsizing of the sheath to go over the calcified area allowed laser to

continue to be used [11]. This was our preferred choice when the adhesion was intravascular. The clavicle-first rib junction or venous entry site was another point at which dense calcified adhesions were often present. If the laser failed to cross here the outer polymer sheath was initially used with its 'cutting edge'. If this failed polypropylene and finally stainless steel dilator sheaths were used [7].

We also found that one of the critical aspects of the procedure is advancement of the locking stylet to the tip of the lead. If this cannot be achieved then it greatly reduces the chance of success, because the lead tends to disintegrate if traction cannot be applied to the tip. This observation emphasised that the laser is only one component of the technique and other aspects of equipment and technique are equally important for good results.

One of the other major factors in increasing the duration and complexity of the procedure was the presence of multiple leads [2]. Usually leads, especially if they travel along the same course, have multiple fibrous adherences, which may be denser than the adherences to the vascular wall. In this situation, the laser sheath has sometimes to be placed on one lead to make some progress and then changed over to the other lead, alternating back and forth to make progress in freeing the leads.

Defibrillator versus Pacemaker Leads

Our series includes a large proportion of defibrillation leads as has been observed in other recent series [11,15,18]. This is despite the fact that ICD leads are prone to form extensive adherences at the site of their exposed coils in the SVC and right ventricle [20]. There are a number of reasons for an increasing trend to extraction of defibrillator leads. First, defibrillators have only been widely implanted for the past several years and thus are only now beginning to return with lead problems. Second, many patients who had initial abdominal ICD implants are now requiring revision of these systems to newer pectoral systems. Third, defibrillation leads are large and tend to impede access for new leads. Fourth, mechanical interaction on ICD leads could lead to ICD 'noise' and inappropriate shocks. Finally defibrillation leads have large coils that once adhered together would be exceptionally difficult to remove. For these reasons we have tried to avoid placing defibrillation leads alongside each other and if a new defibrillation lead is required, we have opted to extract the old lead using laser. Our experience with laser extraction of ICD leads has been good. Although these leads are large, they are more robust than pacemaker leads and less likely to disintegrate with traction/counter-traction. Although fibrous adherences can be extensive, the laser has proved valuable in freeing these leads [11,15,18].

Future Trends in Lead Extraction

It is our impression that the availability of laser has tended to reduce the threshold before attempting removal of chronic leads. In our earlier experience leads were primarily removed because of infection. In recent years, leads have been removed increasingly because of redundancy, limited vascular access and the potential for mechanical interaction of multiple leads [2,11]. The ability to remove chronic leads more predictably with laser has been a factor in this trend. Ideally improved reliability of leads might reduce the need for extraction however, it is likely that there will always be a significant need for removal of chronic leads [21,22] and that laser will play an important role.

CONCLUSIONS

The excimer laser sheath is a very important recent addition to the tools available for extraction of chronically implanted leads. Excimer laser has made the procedure more predictable in terms of success and of shorter duration. Limitations remain, due to the presence of calcium in particular, and there continues to be a small risk of serious complications. For these reasons extraction procedures should be performed in experienced centres by experienced operators in order to obtain the best results.

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