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CLINICAL RESEARCH

Safety and efficacy of the new bidirectional rotational Evolution® mechanical lead extraction sheath: results from a multicentre Italian registry

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Aims The aim of this prospective multicentre study is to evaluate safety and efficacy of the new bidirectional rotational mechanical lead extraction (LE) sheath (Evolution RL, Cook Medical, USA) in chronically implanted leads (>1-year-old leads).

Methods and results Between September 2013 and June 2016, a total of 238 leads in 124 consecutive patients were removed by using the new Evolution RL rotational mechanical sheath. Indications for LE were cardiac device infection in 63 (50.8%) cases, lead malfunction in 41 (33.1%), upgrade in 1 (0.8%) case and for other reasons in the remaining 19 cases (15.3%). Ninety-one leads (38.2%) were implantable cardioverter defibrillator leads (81 dual coil vs. 10 single coil), 38 (16%) right ventricular leads, 86 (36.1%) right atrial leads, and 23 (9.7%) coronary sinus leads. The mean implant duration was 92.2 ± 52.9 months (range 12–336). 91.6% of the leads (218/238) were extracted completely with the Evolution RL alone, with the complete success rate rising to 98.7% (235/238 leads) with combined use of a snare. Overall clinical success rate was 100%. No Evolution sheath-related complications were noted. There were no deaths or major complications. Five minor complications (4%) were encountered. In cases of companion leads no wrapping or lead damage were observed.

Conclusion On the basis of our prospective multicentre study, the new hand-powered bidirectional rotational mechanical LE sheath is an effective and safe tool for the extraction of chronically implanted leads without major complications and lead wrapping or lead damage.

Keywords Evolution RL rotational sheath • Implantable cardioverter defibrillator • Lead extraction • Pacemaker

Introduction

Despite improvements to extraction techniques, transvenous lead removal is still a challenging procedure, especially when leads are chronically implanted, and is associated with potential procedural failure, morbidity, and life-threatening complications.[1–5] Chronically implanted leads develop fibrous adhesions around surrounding structures and thus require different extraction sheaths, such as mechanical sheaths, laser sheaths, or electrosurgical dissection sheaths.[6–9] A rotational mechanical extraction device (Evolution, Cook Medical, USA) has

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What's new?

- The second generation Evolution RL bidirectional rotational mechanical sheath (Cook Medical, USA) is a novel tool for lead extraction (LE).
- This is the first multicentre Italian registry evaluating the efficacy and safety of this mechanical extraction system.
- The new Evolution sheath with its bidirectional rotational mechanism and the design change of the tip is an effective and safe LE tool in chronically implanted leads.

been shown to be an effective and safe tool for extracting chronically implanted leads.[10–14] However, due to the device's unidirectional rotation mechanism, it has been found to cause a phenomenon known as 'lead wrapping', especially in the presence of companion leads.

A second-generation Evolution device (Evolution RL, Cook Medical, USA) has been designed to address this issue. The sheath has been fitted with a bidirectional rotational mechanism and a less aggressive tip, reducing the risk of damage to leads, vascular structures, and myocardial tissue.

Recently, initial single-centre experiences with the new bidirectional rotational mechanical lead extraction (LE) sheath have shown that the device is efficient, has high success rates and is safe for use with chronically implanted leads.[15–17] However, this new extraction tool needs further clinical validation in larger-scale studies.

The aim of this multicentre study was to evaluate the effectiveness and safety of the new bidirectional rotational mechanical LE sheath with chronically implanted leads that require advanced extraction tools.

Methods

Study population

Our study population comprised consecutive patients undergoing LE procedures using the new Evolution RL rotational sheath (Cook Medical, USA) at four centres (San Raffaele Hospital, Milano, Italy; Department of Cardiac, Thoracic and Vascular Sciences, University of Padova, Italy; Cà Foncello, Civil Hospital, Treviso, Italy; and S. Maria della Misericordia Hospital, University of Udine, Italy) from September 2013 to June 2016. Patients with recently implanted leads (implant duration < 12 months) and patients whose leads had been explanted by simple traction without using the Evolution system were excluded from the analysis. Potential indications for LE were classified as infection, lead malfunction, upgrade of a pre-existing system and other factors. The underlying type, number and fixation modality of each lead were also included among the recorded variables. Informed consent was obtained from every patient before enrolment. The study was conducted in compliance with the principles outlined in the Declaration of Helsinki.

Extraction procedure

All of the patients underwent LE in electrophysiology laboratories, with continuous electrocardiographic and arterial blood pressure monitoring. The procedure was performed under sedation or general anaesthesia, depending on patient status and physician preference. In patients dependent on bradycardia support, a temporary pacemaker (PM) was inserted from the femoral vein. Standby cardiac surgery for the treatment of emergency complications was always available. LE was performed using a standard stepwise approach for all patients, as previously reported.[13] After the leads were dissected free from the scar tissue in the pocket, the suture sleeves were removed. If present, the active-fixation mechanism was retracted, and manual traction was attempted. After unsuccessful manual traction with a locking stylet (Liberator Universal Locking Stylet, Cook Vascular Inc.) the new Evolution RL rotational sheath (Cook Medical, USA) was used for all of the patients. Three major principles were followed during the procedure: dissection of fibrotic adhesions when needed, control of the entire lead body and counter-traction at the tip of the lead.

The Evolution mechanical dilator sheath (Cook Medical) is composed of a flexible substance (Teflon) and a metal (steel) sheath, and is available at a French size of 9, 11 or 13 (inner diameter of the sheath) to suit the diameter of the lead. Its threaded metal distal tip allows the system to pass through adhesions. In addition, a new tool, a shorter mechanical dilator sheath known as the Evolution Shortie RL, has been designed to overcome the difficulties of venous access in cases of extensive scarred or calcified tissue around the target cardiac lead. The proprietary decagonal tip and shorter handle of the Evolution Shortie RL allow the device to easily enter the vessel, increasing the physician's control (*Figure 1*). In the current study, the Evolution Shortie RL was used at the discretion of the physician, based on lead characteristics such as dwell time, the use of a dual coil implantable cardioverter defibrillator (ICD) lead, passive fixation and the presence of extensive scarred or calcified tissue under the clavicle.

The operator pulls the handle of the dilator sheath, which causes the cutting tip to rotate either unidirectionally or bidirectionally. The rotational mechanism of the sheath permits movement along the lead body by cutting fibrous attachments using the distal metal tip, and the outer telescoping polymer sheath protects the venous wall from the metal cutting tip while advancing over the lead in tracts free from adherence (*Figure 2*). When fibrous attachments are encountered, the cutting tip is uncovered from the outer sheath. Once the fibrous attachments have been cut, the outer sheath is advanced until another area of attachment is encountered. After the lead has been released from the fibrous tissue, it is pulled back into the sheath and removed.

Free-floating leads and remnants after extraction were snared via either a right-jugular or a femoral approach, depending on how the leads were positioned, using an AndraSnare (Andramed GmbH) or a Needle's Eye Snare (Cook Vascular). None of the patients underwent an open thoracotomy to remove residual hardware due to procedural failure. In patients who required a lead to be replaced after LE, the decision either to use a guidewire placed down the Evolution sheath through the same vein or to use a new vein was at the discretion of the physician.

In all PM-dependent patients with cardiac-device infection, a temporary right ventricular (RV) bipolar active fixation lead was implanted through the contralateral jugular vein or the ipsilateral side. The lead was sutured to the patient's skin with non-resorbable sutures, and the external section of the lead was then connected to a permanent PM pulse generator. Finally, the pulse generator and lead were securely taped to the patient's neck with a Tegaderm™ dressing.

All of the patients were monitored for complications related to the procedure at the time of extraction, during their hospital stay and at a scheduled follow-up with their electrophysiologist 1 month after LE.

Definitions

A completely successful procedure was defined as the removal of all targeted leads and all lead material from the vascular space without the occurrence of any permanently disabling complication or procedure-related death.[18,19] Clinical success was defined as the removal of all targeted leads and lead material from the vascular space or the retention of

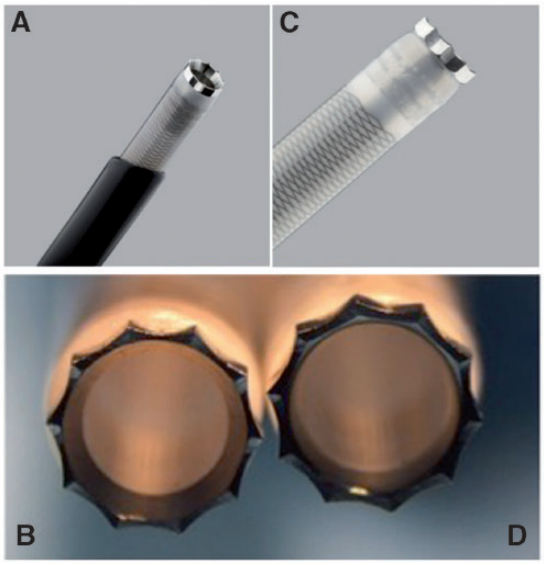

Figure 1 Tips of Evolution Shortie RL (*A* and *B*) and Evolution RL (*C* and *D*) sheaths. The Evolution RL helps physician extract leads by separating binding adhesions along the entire length of the targeted cardiac lead. Designed specifically for vessel entry, the Evolution Shortie RL dilates scarred or calcified tissue bidirectionally around the targeted cardiac lead. The proprietary decagonal tip and shorter handle of the Evolution Shortie RL allow the device to easily enter the vessel, increasing the physician's control.

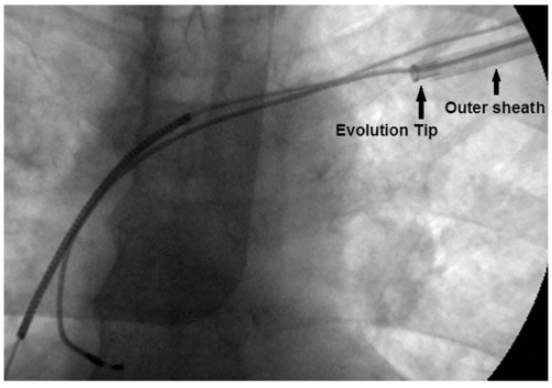

Figure 2 Atrial LE procedure with Evolution RL sheath (9 F).

a small portion of the lead (< 4 cm) that did not increase the risk of perforation, embolic events or the perpetuation of infection in the absence of complications. A failed procedure was defined as the inability to achieve either complete procedural or clinical success, the occurrence of any permanently disabling complication or procedure-related death. Major complications were defined as outcomes that were life-threatening, resulted in significant or permanent disability or death or required surgical intervention. Minor complications were defined as events related to the procedure that required medical intervention or minor procedural intervention.[18,19]

Statistical analysis

Continuous variables are expressed as mean ± standard deviation (SD) or median values and 25th and 75th percentiles (25/75 percentile). Categorical variables are presented as actual numbers and frequencies. The analysis was performed using the SPSS statistical software package (version 21.0; SPSS Inc., Chicago, IL, USA).

Results

The study population comprised 124 consecutive patients (105 [84.7%] male; mean age 65 ± 14) who underwent LE. The patient and lead characteristics for the whole study population are reported in *Table 1*. The indications for LE were cardiac-device infection in 63 cases (50.8%), lead malfunction in 41 cases (33.1%), upgrade in one case (0.8%) and other reasons in the remaining 19 cases (15.3%) (*Figure 3*). Overall, 295 leads were extracted (mean number 2.38 ± 0.96 per patient; median 2 [25/75 percentile 2/3]; range 1–5], 238 of which required the use of the Evolution RL power sheath. In 46% of the cases (109 of 238 leads), both the Evolution Shortie RL sheath and the Evolution RL sheath were used.

The characteristics of the leads extracted using the new device are reported in detail in *Table 2*. All of the leads were extracted via the subclavian approach. Of the extracted leads, 91 (38.2%) were ICD leads (81 dual-coil vs. 10 single-coil leads); 38 (16%) were RV pacing leads; 86 (36.1%) were right atrial leads; and 23 (9.7%) were left ventricular leads. The mean implant duration was 92.2 ± 52.9 months (median 79.5 [25/75 percentile 64/124], range 12–336). Of 41 malfunctioning leads, two were Riata leads (St Jude Medical) and two were Sprint Fidelis leads (Medtronic). These were successfully extracted using the Evolution sheath. Eleven patients (8.8%) were PM-dependent with cardiac-device infection, and received implantation of a temporary RV bipolar active fixation lead through the contralateral jugular vein ($n = 5$) or the ipsilateral side ($n = 6$).

The additional use of a snare was required for six patients (seventeen leads; 7%). Complete procedural success without the use of an additional snaring system was achieved with 218 of the 238 leads (91.6%). The success rate rose to 98.7% (235/238 leads) with the additional use of a snare. The overall clinical success rate was 100%. Of the 238 extracted leads, 63 (26.5%) had been implanted >10 years previously (*Table 2*). Of the leads with an implant duration >10 years, 98.9% (173/175) were extracted with complete success, and 98.4% (62/63) of the leads implanted fewer than 10 years earlier were extracted with complete success ($P = 0.78$). No complications related to the Evolution sheath were noted. In average, 1.02 (range 1–2) sheaths were used.

There were no deaths or major complications. Five minor complications (4%) were reported, including pericardial effusion not requiring pericardiocentesis or surgical intervention ($n = 1$), pneumothorax ($n = 1$) and haematoma at the pocket requiring drainage ($n = 3$). Additional events were classified as observations: transient hypotension that responded to fluid infusion or minor pharmacological intervention in six patients and atrial fibrillation not requiring electrical cardioversion in two patients. No changes in the rates of success or

complication were observed over time. When companion leads (functional leads not targeted for removal) were present, no wrapping was detected by fluoroscopy and no clinically significant changes in electrical parameters (impedance, sensing, and threshold) were observed during the extraction procedure.

Discussion

In this prospective multicentre study, we demonstrated that the new hand-powered bidirectional rotational Evolution mechanical LE sheath is an effective tool for extracting chronically implanted leads that require advanced extraction tools without causing fatal peri-procedural complications, wrapping or damage to neighbouring leads.

Table 1 Patient and lead characteristics for the study population ($n = 124$)

Mean age (years) ± SD, range	65 ± 14 (15–92)
Male, *n* (%)	105 (84.7%)
Number of leads	311
Mean number of leads per patient ± SD, range	2.51 ± 0.88 (1–6)
LE indication, *n* (%)	
Infection	63 (50.8%)
Lead malfunction	41 (33.1%)
System upgrade	1 (0.8%)
Other	19 (15.3%)
Number of leads extracted, *n*	295
Mean number of leads extracted per patient ± SD, range	2.38 ± 0.96 (1–5)

SD, standard deviation.

Although manual traction is an effective technique for removing recently implanted leads, chronically implanted leads develop fibrous adherences around surrounding structures and require additional extraction tools. In recent years, the development of advanced techniques such as mechanical dilators and powered (mechanical or laser) sheaths has contributed to the high rates of success and low rates of complication of transvenous LE procedures.[5–9,20] Studies have found that certain patient and lead characteristics, such as age, dwell time, number of extracted leads, use of ICD leads, use of dual-coil ICD leads, and presence of passive-fixation mechanisms, are independent predictors of the presence of fibrous adherences requiring advanced LE techniques.[20,21]

The Evolution mechanical extraction sheath is an effective and safe tool for extracting chronically implanted leads.[10–14] The Evolution system comprises a powered sheath with a rotating tip that can cut through fibrous tissue, which significantly reduces the amount of traction and counter-traction needed to extract the lead. In the first generation of the Evolution mechanical rotational extraction sheath, ablation forces were directed sideways and the tip was assumed to advance in a unidirectional 'screw' motion. Although the outer sheath provided the electrodes with a mechanical barrier, physicians using this tool reported the wrapping of coexisting leads, potentially leading to insulation damage.[12] The second-generation Evolution device has been redesigned to address these problems; it has a bidirectional rotational mechanism, which prevents lead wrapping, and a less aggressive tip, which may reduce the risk of damage to coexisting leads and vascular structures.[15–17] In addition, a shorter mechanical dilator

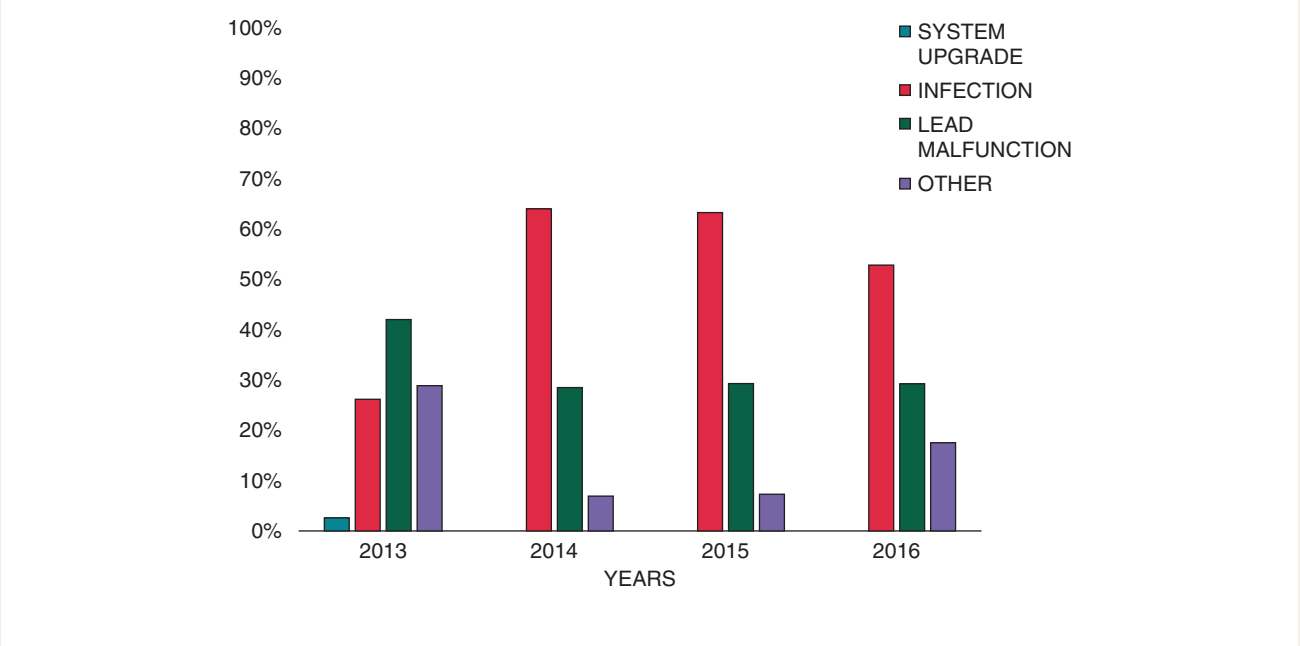

Figure 3 LE indications over study period.

Table 2 Characteristics of leads extracted with the new Evolution RL sheath

Number of leads extracted with Evolution RL sheath, *n*	238
Mean number of leads extracted per patient ± SD, range	1.92 ± 0.44 (1–3)
Mean implant duration ± SD, range (months)	92.2 ± 52.9 (12–336)
Distribution of lead implant duration (months), *n* (%)	
12–24	11/238 (4.6%)
24–48	26/238 (11%)
48–72	60/238 (25.2%)
72–96	49/238 (20.5%)
96–120	29/238 (12.2%)
>120	63/238 (26.5%)
Passive fixation, *n* (%)	135 (56.3%)
Lead type, *n* (%)	
Right atrium	86 (36.1%)
Right ventricle	38 (16%)
Coronary sinus	23 (9.7%)
Defibrillator	91 (38.2%; 81 dual coil vs. 10 single coil)
Clinical success, *n* (%)	100%
Complete procedural success per lead/per patient, *n* (%)	235/238 leads (98.7%)/121/124 (97.6%)
Minor complications, *n* (%)	5 (4%)
Major complication, *n* (%)	0
Dilator sheath diameter, *n* (%)	
9 F	36 (15%)
11 F	191 (80%)
13 F	16 (7%)

F, French size; SD, standard deviation.

sheath known as the Evolution Shortie RL has been designed to facilitate venous access in cases of extensive calcification under the clavicle, where the laser has proved to be ineffective.[13,22]

Recently, initial single-centre experiences with a limited number of patients yielded promising results with the new Evolution mechanical extraction device.[15–17] Our multicentre registry with a larger study population confirmed and extended these observations, demonstrating that the new Evolution device is an effective LE tool with high success rates with long-implanted leads. With a complete procedural success of 91.6% without the use of further extraction tools, the efficacy of this new extraction device is comparable with that of widely used devices and techniques.[5–7,15,17]

Recently, in a single-centre study involving a relatively small number of patients, Witte *et al.* demonstrated a higher complete procedural success rate with the novel Evolution sheath than with the first-generation sheath, although no significant differences were observed in complication rates.[17] Witte *et al.* did not use the Evolution Shortie RL; they found that passage through the proximal subclavicular vein could be successfully achieved with the long Evolution sheath in all cases.[17] In 46% of the cases in our study, both the Evolution Shortie RL and the Evolution RL mechanical dilator sheaths were used. However, the Shortie RL was used at the discretion of the physician. According to Witte *et al.* and our own findings, the use of the Evolution Shortie RL is likely to be restricted to specific cases (e.g. cases with a long dwell time, a dual coil ICD lead or pre-LE venographic results indicating extensive scarred or calcified tissue under the clavicle), making the LE procedure much more cost-effective.

Our data and the findings of previous studies[15–17] suggest that the LE success rate is higher with the new Evolution device, probably due to its bidirectional rotation, which facilitates the dissection of tight adhesions and advances the sheath without the need for a snare in the majority of cases. Previous single-centre studies have reported similar efficacy rates with the first Evolution sheath, but the additional use of a snare has frequently been required.[10–13]

As previously mentioned, the use of a dual coil ICD lead, the presence of a passive-fixation mechanism and longer dwell time were found to be significant risk factors for fibrous adherences, making leads difficult to remove. In our study group, 34% (81/238) of the leads extracted using the new Evolution sheath were dual coil ICD leads, 56.3% of the leads had a passive-fixation mechanism (*Figure 4*) and the mean implant duration was 92.2 ± 52.9 months.

It is well-known that despite recent improvements, LE procedures may still be associated with life-threatening complications. Therefore, safety is an essential clinical endpoint in the design of every new LE technique.[2,4,9] In this study, no major complications, wrapping or damage to companion leads were observed during the extraction procedure. Our results for the new Evolution sheath confirmed and extended previous observations,[15–17] demonstrating that the new Evolution device is both an effective and safe tool for LE.

From a clinical perspective, the efficacy, safety and relatively low cost of the Evolution RL may be the main factors recommending its use as a first-line approach in centres with experienced operators when advanced LE techniques are needed. However, the extent to which different mechanical LE techniques and laser systems vary in efficacy and safety remains to be established in a future prospective randomized trial.

The findings of a recent single-centre study by Witte *et al.* suggested that the landscape of LE is changing in response to an increase in the proportion of malfunctioning leads.[17] However, device infection was the main LE indication in our multicentre registry. The discrepancy between our findings and those reported by Witte *et al.* may arise from differences in patient population, study characteristics and study period. Prospective multicentre studies designed to evaluate changes in LE indications over time are necessary to resolve this inconsistency.

The current study was limited by a lack of comparison of the first- and second-generation Evolution devices. In addition, although our data were collected from a multicentre registry with the largest study population observed to date, larger-scale randomized prospective studies should be conducted in the future to verify our findings and compare the clinical success, safety and cost effectiveness of different devices.

Conclusions

On the basis of our findings, the new Evolution sheath (Evolution RL Cook Medical, USA), with its bidirectional rotational mechanism and redesigned tip, provides an effective and safe first-line tool for the

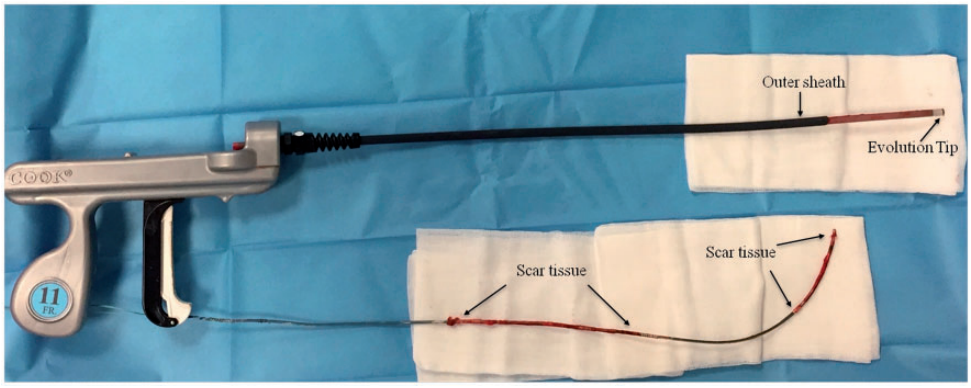

Figure 4 Successful extraction of dual coil defibrillator lead and passive fixation using Evolution RL sheath (11 F). Of note: fibrous material adherent to defibrillator coils at multiple sites.

extraction of chronically implanted leads when advanced techniques are required. In addition, the use of this device was not found to cause lead wrapping or damage to leads in a multiple-lead setting.

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Conflict of interest: F.M. works as a consultant for Boston Scientific; P.M. provides consultancy work for Boston Scientific and St Jude Medical; and E.B. works as a consultant for Boston Scientific.

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