

**and documented VTs. PredischARGE electrophysiologic testing may be useful in patients with prior VF who had no electrophysiologic testing before implantation. Repeat induction of VF does not result in additional information and does not appear to be necessary at predischARGE. Most of the observed problems can be detected by noninvasive predischARGE control.**

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## **Successful Percutaneous Extraction of Pacemaker Leads With a Novel (VascoExtor) Pacing Lead Removal System**

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**P**acemaker lead removal has been done by way of newer percutaneous techniques with use of locking stylets, sheaths, and countertraction, which have supplanted older methods such as manual or weighted traction, and obviated the use of cardiac surgery with its attendant cost and risks.<sup>1-7</sup> Infection has been the standard indication for lead extraction, but in recent years newer indications have emerged.<sup>5,8,9</sup> The locking stylet has been the main extraction tool of any system used.<sup>1,5</sup> In the most widely used extraction system—the Cook locking stylet system (Cook Vascular, Inc., Leechburg, Pennsylvania)—the locking mechanism is traditionally effected through a tedious process of exact size matching. In the present study, a novel lead extraction system, the VascoExtor system (VascoMed GmbH, Weil am Rhein, Germany), utilizing only 3 standard types of universally applied stylets, was tested during procedures of percutaneous extraction of 25 leads in 16 patients.

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Over 12 months, pacing lead extraction with use of

the VascoExtor system was attempted in 16 consecutive patients (11 men and 5 women, aged  $70 \pm 9$  years) who were referred to our institutions for percutaneous lead removal. These patients had an indication for pacing lead removal, including pacemaker infection ( $n = 13$ ) or lead dysfunction ( $n = 2$ ), or had an automatic defibrillator implanted ( $n = 1$ ). Infections involved both pocket and lead(s) and were due to *S. epidermidis* ( $n = 7$ ), *S. aureus* ( $n = 5$ ), or *S. aureus* plus *E. coli* ( $n = 1$ ). Skin erosion was present in 9 patients. Positive blood cultures were detected in 5 patients. Echocardiography revealed small vegetations on the right ventricular pacing leads in 2 patients. No patient had evidence of pulmonary embolism. The indication for pacemaker implantation had been sinus node dysfunction in 4 patients and second-degree Mobitz type II or complete heart block in 12 patients.

Single leads had been implanted in 7 patients, whereas 2 ( $n = 8$ ) or 3 leads ( $n = 1$ ) were in place in 9 patients. Leads had been in place for a mean of  $3.9 \pm 3.8$  years (range 0.3 to 12.3). The lead fixation mechanism was passive in 23 and active in 2 leads. Of the 25 leads, 9 were unipolar ventricular, 6 bipolar ventricular, 2 unipolar VDD, 3 unipolar atrial, 3 bipolar atrial (all tined), and 2 bipolar screw-in atrial leads.

The VascoExtor locking stylet system included 3

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standard types of locking stylets (S, K, L), a noose catheter, outer sheaths, and a motor drive unit. The K stylet is used with conductor coil construction of <4 strands and an inside lumen of <0.7 mm. This stylet has a minimum diameter (anchors folded) of 0.44 mm and a maximum diameter (anchors extended) of 0.8 mm. For leads with a conductor of quadrifilar construction and an inner diameter <0.9 mm, the S (small) stylet is used, which has a minimum outer diameter of 0.44 mm and a maximum anchoring diameter of 0.9 mm. For leads with a larger inner coil diameter (>0.9 mm) the L (large) stylet is used. This stylet has a minimum diameter of 0.75 mm and a maximum diameter of 1.3 mm. The locking mechanism for stylets S and L consists of anchor flanges which, when spread, fix the stylet directly in the coil in the area of the lead tip. After the closed stylet has been advanced through the coil to the tip of the lead, the anchors open by retraction of the inner tip against the outer tube. Locking for stylet K is effected by lateral parallel displacement of the split flanges at the tip of the wire. This is accomplished, after the stylet has been advanced to the tip of the lead, by turning the fixation screw on the handle clockwise. For removal of the locking stylet, a motor driving unit is available. For removal of leads or intravenous fragments using the transfemoral approach, a noose (VascoExtor) catheter is available.

All procedures were performed after the patient gave informed written consent. For pacemaker-dependent patients (n = 5), a temporary pacing wire was introduced via the contralateral internal jugular or subclavian vein. Subsequently, with use of a sterile and aseptic technique under local anesthesia, the pacemaker pocket was opened and the pulse generator was retrieved and disconnected from the lead(s). The lead connector was then severed. A test stylet was advanced under fluoroscopy to the tip of the lead to free the lumen of any material and facilitate the passage of the locking stylet through the inner coil. The test stylet was then exchanged for the locking stylet, which was advanced to the tip of the lead, where it was fixed as described above. Positioning and fixation of the locking stylet was confirmed by gently pulling under fluoroscopy. Then lead extraction was attempted by slowly pulling on the traction cord of the extractor under x-ray visualization. If the lead could not be detached from the myocardium after several minutes, a telescoping sheath was threaded over the lead and carefully pushed and advanced into the heart to provide countertraction to the myocardium.

For leads that could not be extracted from the subclavian route, or for any lead fragments that were not removable from above, the transfemoral approach was used. After lead extraction was completed, the wound was debrided if infected, the pocket was plicated, and wound closure was effected in layers with use of absorbable sutures allowing healing by primary intention. Postoperatively, patients were monitored overnight in the cardiac care unit. For those afflicted by infection, a course of intravenous antibiotic therapy was completed before a new pacing system was im-

**TABLE I** Tools Used for Percutaneous Extraction of 25 Pacemaker Leads in 16 Patients

VascoExtor stylet S	8 patients (11 leads)
Simple traction	2 patients (2 leads)
VascoExtor stylet K	5 patients (5 leads)
Simple traction	2 patients (2 leads)
VascoExtor stylet S plus pigtail catheter	1 patient (2 leads)
VascoExtor noose catheter plus biopptome	1 patient (2 leads)
VascoExtor stylets S/K plus motor drive unit	1 patient (1 lead)*
*Extraction failed.	

planted, usually on the contralateral side. After hospital discharge all patients were followed up at the pacemaker clinic. All data are reported as mean  $\pm$  SD.

Pacing lead extraction was attempted in 16 patients for a total of 25 leads. Removal was successful in 15 patients (93%) for 24 leads (96%). The VascoExtor stylet type S was used in 9 patients, the K stylet in 5 patients, both types (S and K) of stylets in 1 patient, and the VascoExtor noose catheter in 1 patient. Successful removal was effected from a right (n = 11) or left (n = 1) or right plus left (n = 1) subclavian or right subclavian plus right femoral (n = 2) approach. Lead extraction was accomplished by simple traction for 4 atrial leads (only test stylet inserted), sole use of the VascoExtor locking stylets for 17 leads, and through a right femoral approach for 2 atrial and 1 ventricular lead (Table I).

The transfemoral approach was used in 2 patients. In 1 patient with a dual chamber pacemaker and 2 unipolar leads, the K stylet was used to aid the removal of the ventricular lead, but during attempts to remove the atrial lead, the distal part was broken off after the lead was detached from the myocardium and migrated to the right ventricular outflow tract. This fragment was then captured and removed successfully with use of a pigtail catheter passed through the right femoral vein, since the noose catheter was not available at that time. In another patient with a dual chamber device and 2 bipolar leads, locking of either the S or K stylet could not be effected in either the atrial or the ventricular lead. Both leads were then removed during the same time and at a subsequent session with use of an array of ancillary tools, including the VascoExtor noose catheter, a pigtail and an Amplatz catheter, and a biopptome, all introduced via the right femoral vein.

Attempts failed to extract a dysfunctional unipolar ventricular lead (with insulation fracture) that had been implanted 12 years earlier. To facilitate the exchange of locking stylets (types S and K) in this patient, the VascoExtor motor drive unit was employed. Finally, the old lead was capped and left in place, and a new pacing system was implanted. In this and the other 2 patients in whom extraction was difficult and a transfemoral approach was finally required, use of the VascoExtor telescoping sheaths to effect countertraction was attempted, but sheath threading over the leads through the subclavicular space was not possible.

No complications occurred in this series. Two ap-

parently procedure-unrelated deaths occurred. A 70-year-old man with pacemaker infection and bacteremia due to *S. aureus* died of a myocardial infarction at 5 weeks after the extraction procedure. Before his death, his hospital course had been complicated by hepatic failure, possibly related to a suspected antibiotic drug idiosyncrasy. Another patient, an 87-year-old woman, also died a few days after her initial discharge from the hospital due to a recurrence of cholangitis. She had an infected VVI pacemaker system removed 6 weeks earlier, but her hospital course was complicated by recurrent bouts of gallbladder infection and an episode of paralytic ileus, through which she had initially survived and had been discharged from the hospital.

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According to the U.S. Lead Extraction Database (1994) (using the Cook stylet system<sup>5</sup>) of the attempted extraction procedures for 2,195 pacing leads from 1,299 patients, 86.8% of leads were completely extracted and 7.5% were partially extracted. Success was higher for physicians with greater experience, for shorter implant duration, active fixation, and atrial leads. A femoral approach was used in 18% and increased with implant duration (up to 31% for leads implanted >8 years). Thoracotomy was used in 3.4%, including 1.3% for complications and 2.1% for extraction failures. The complication rate was 3.9%, including hemopericardium and tamponade (1.2%), hemothorax (0.5%), pulmonary embolism (0.2%), migrating lead fragment (0.3%), bacteremia (<0.1%), stroke (0.1%), ventricular tachycardia (<0.1%), and various other complications (1.4%). Procedure-related deaths occurred in 8 patients (0.6%). Potentially life-threatening complications occurred more frequently in women than in men (4.3% vs 1.5%). The average implant duration was longer in patients with than without complications.

The most commonly used lead extraction system, the Cook retrieval system, includes a variety of locking stylets that increase the expense and the effort involved for exact size matching for each pacing lead, a process that is mandatory for successful locking of the stylet at the tip of the lead. A universally applied locking stylet is therefore desirable to simplify this tedious process of stylet selection during the procedure and also to reduce the cost of the extraction system. Working in this direction, a European multicenter study<sup>10</sup> recently reported on the results obtained from the use of a novel locking stylet (VascoExtor, VascoMed) in 105 patients for 150 leads. This type of stylet could fit a large number of different leads with a variety of internal lumen diameters. In addition to its universal applicability, another major advantage of this locking stylet over other existing types of stylets, is that the locking mechanism is reversible with use of a motor drive unit, which renders feasible the removal and exchange of stylets. Using this locking stylet, complete removal was possible for 122 leads (81%) and partial removal for 18 leads (12%) in the multicenter study with no serious complications reported. Since then, this extraction system has been improved

further with new features and tools. Instead of 1 stylet version, 3 types of stylets are now available (S, L, and K) to accommodate a greater number of pacing leads. Two of these have a similar locking mechanism but different sizes (S and L) for conductors with quadrifilar construction, and the other (type K) has a different locking mechanism for conductors with 1 to 3 strands. Furthermore, this newer version now comes with a transfemoral kit, which includes a noose catheter for extraction of pacemaker leads or lead fragments from the femoral vein.

Using the newer version of this novel lead extraction system (VascoExtor), in the present study (independent of the multicenter series), we were able to extract 24 of 25 (96%) pacing leads having a mean implant time of 3.9 years. In 81% of patients, the leads had to be removed because of infection. In most patients, sole use of the locking stylet sufficed for extraction. However, we encountered 3 cases (19%) whereby ancillary tools were required during the procedure, including telescoping sheaths to apply countertraction, the motor drive unit to facilitate exchange of stylets, and the transfemoral kit for removal of leads or lead fragments not extractable from the subclavian approach. All these enhancements, now available with the newer version of the VascoExtor extraction system, were useful, except for the sheaths, which were impractical. Nevertheless, the universally applicable locking stylet greatly simplified the extraction process in most patients, and proved effective in 81% of our patients. Importantly, the use of this system was safe with no complications observed during the procedures. There was only 1 patient in whom the stylets could not be fixed in the distal tip of the electrodes, and the extraction was finally accomplished using entirely transfemoral techniques.

Although there were no complications in our study, percutaneous lead extraction techniques may pose a significant risk with potentially life-threatening complications, as confirmed by data reported by the U.S. Lead Extraction Database.<sup>5</sup> Thus, safer and more efficacious techniques are sought for lead extraction. Recently, laser sheaths have been added to our armamentarium and the preliminary results appear promising. However, cost appears to be a significant drawback of laser technology, and simpler and less expensive mechanical systems, such as the one used in the present study, may offer an important alternative solution. As seen in our study, many leads, even those in place for a mean duration of 4 years, can be removed by simple extraction alone, as long as the leads are not damaged, so that subsequent use of extracting equipment is not made more difficult.

**In conclusion, the new pacing lead extraction system (VascoExtor) with a universally applicable locking stylet appears simple to operate, safe, and highly successful in permanent pacemaker lead extraction. With use of this system, we were able to remove 24 of 25 chronic pacing leads (96%) in 15 of 16 patients (93%). Sole use of the locking stylet**

**was successful in 81%, whereas an array of ancillary tools were required in 19% of cases.**

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