RevCore thrombectomy device effectively restores venous stent patency by treating iliofemoral caval in-stent restenosis

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ABSTRACT

Experience with the RevCore mechanical thrombectomy device in a series of 40 patients is described. The device was employed in the treatment of symptomatic in-stent restenosis (ISR) in iliofemoral caval venous stents in these patients. Computed tomography venography was performed preoperatively to differentiate ISR from stent compression in all patients who underwent intervention. All patients were treated in a single session with a mean estimated blood loss of <10 mL with an average operative time of <30 minutes. Alteplase was not used in any patient. All patients were discharged home the same day. Resolution of ≥50% ISR at the end of the procedure on intravascular ultrasound examination was noted in all patients. Symptom resolution was noted in all patients after the use of the RevCore device. No clinical perioperative pulmonary embolism was observed. Only one patient (2.5%) required reintervention during the follow-up period (range, 2-24 months). (J Vasc Surg Cases Innov Tech 2025;11:101893.)

Keywords: IVUS; Intravascular ultrasound; Chronic thrombus; Venography; RevCore mechanical thrombectomy device

Percutaneous thrombectomy for acute iliofemoral caval venous thrombosis has been well-described in the literature.[1] In contrast, treatment for in-stent restenosis (ISR) in iliofemoral caval venous stents is less well-described. It is a more chronic process whereby chronic thrombus and other connective tissue components layer the lumen of the venous stents over time. ISR is an almost universal phenomenon seen in venous stents.[2] In a series of 578 limbs, the prevalence of ISR was 74% by 3 months after stent implantation and plateaued thereafter.[3] In another series, the prevalence of ISR in venous stents was as high as 80% at 42 months.[4] However, not all ISR in venous stents requires intervention.[2] Generally, patients who have significant ISR on imaging and persistence of lifestyle-limiting symptoms despite conservative therapy should undergo reintervention for ISR.[2] In some earlier reports, ≥20% patients were noted to require reintervention for symptomatic ISR.[2,5,6] In a more recent series, this rate of reintervention for ISR was noted to be approximately 5% to 15%.[7,8]

Experience with several different modalities for the treatment of symptomatic ISR in venous stents has been well-described in the literature. These include angioplasty/balloon dilatation alone or in combination with excimer laser ablation, atherectomy, and Z-stent placement.[1,2,9] More recently, the introduction of the novel RevCore thrombectomy device (Inari Medical, Irvine, CA) has expanded the armamentarium available for the treatment of ISR in venous stents. This modality eliminated the need for alteplase. The aim of this report was to summarize an initial experience with the RevCore thrombectomy device in a large series of 40 patients with symptomatic chronic ISR in iliofemoral caval venous stents.

METHODS

Type of research study. From September 2023 to May 2025, records of all symptomatic patients with significant ISR (per imaging, ≥50%) who had undergone a RevCore thrombectomy procedure were retrospectively analyzed. Informed consent was obtained from the patients for the procedures performed. Institutional review board permission was not needed for this retrospective analysis of deidentified data.

Patient selection and inclusion and exclusion criteria. Symptomatic patients with chronic thrombus (ISR) in stented venous segments (iliofemoral caval venous stents) who underwent single-session mechanical thrombectomy without the use of alteplase using the INARI RevCore device were included in this series. All patients had a previous history of venous stent placement. Initially, the patients reported that their symptoms had improved after stent placement. However, their symptoms then recurred over time. Conservative therapy was attempted in all patients first for ≥6 months before reintervention was considered. Ultrasound examinations were obtained in these patients as a first screening tool because they can detect stent malfunction. However, the degree to which ultrasound examination differentiates

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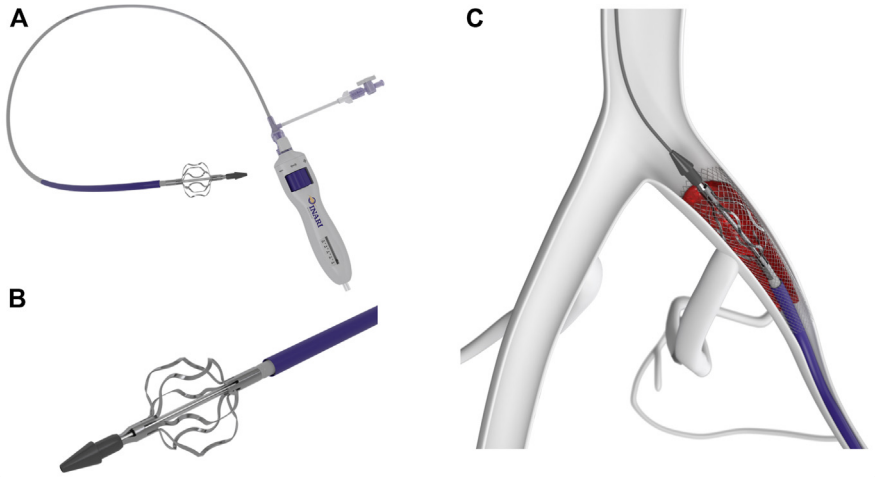

Fig 1. The RevCore device (with permission from INARI Medical). **(A)** Control knob and a coring element. **(B)** Magnified view of the nitinol coring element. **(C)** The device can treat in-stent restenosis (ISR) in venous stents ranging from 10 to 20 mm.

stent compression from ISR is unclear. Also, iliac segments cannot be visualized adequately with ultrasound examination in 15% to 20% of patients for various reasons, such as body habitus, bowel gas, and depth or tortuosity of vessels. Computed tomography (CT) venography was performed preoperatively to differentiate ISR from stent compression to aid in appropriate patient selection. Patients who were treated with modalities other than the RevCore device were excluded from this analysis. Anticoagulation was instituted in all patients at the time of detection of chronic venous thrombosis. Generally, anticoagulation is instituted after venous stenting in patients with acute thrombus/acute on chronic thrombus, significant chronic thrombus or ISR, severe post-thrombotic nature of lesion encountered or in patients with severely compromised inflow.

Strategies to protect the inferior vena cava. Because of the very particulate nature of the debris arising from the venous stent column owing to the thrombectomy maneuvers, it is imperative to deploy a temporary form of embolic protection in the inferior vena cava (IVC). This can be in the form of a Protrieve device, XL discs, or, theoretically, an IVC filter. The Protrieve sheath (Inari Medical, Irvine, CA) consists of a 26F outer diameter, a 20F inner diameter, and a 32-cm working length sheath. XL discs (ClotTriever XL Catheter, Inari Medical) are a series of three discs that can be deployed in the IVC. Their function is to capture embolic material that can later on be removed with an aspiration thrombectomy catheter.

Technical success. In addition to venography, intravascular ultrasound (IVUS) examination was performed before and after the use of the RevCore thrombectomy device in all patients. IVUS examination is a better diagnostic tool than venography alone.[10,11] Technical success of the procedure was defined as the resolution of ISR by ≥50% on IVUS examination after the RevCore thrombectomy device was used.[2]

The RevCore device. General components of the RevCore catheter include an external diameter control knob and a manually expandable coring element (Fig 1, *A-C*). The coring element is expandable and made of nitinol. It is indicated to treat native vessels ≥6 mm or venous stents ranging from 10 to 20 mm. The hand-piece has a dial that controls the expansion of the nitinol element. The user-controlled expansion of the nitinol element allows for the individualized treatment of ISR in every patient because the device can be retracted, torqued, and advanced longitudinally and circumferentially. There is 1:1 torque transfer with the device in all directions. With these torquing and scrubbing type maneuvers, the chronic thrombotic material is macerated into smaller pieces. These thrombus pieces are then captured by the embolic protection devices that have been placed before the device is used. A RevCore catheter can be inserted through a sheath with an outer diameter of 12F over a 0.0035-in guidewire. The length of the catheter is 80 cm.

Procedural steps. Preoperative enoxaparin (Lovenox) or intraoperative IV heparin was administered to all patients. The patient was positioned supine. Ultrasound-guided access of bilateral femoral veins was obtained followed by the placement of 11F sheaths bilaterally. Venography and IVUS examination were then performed on the side of interest (ipsilateral side) with the stent column. On the contralateral side, a ClotTriever XL catheter (Inari Medical) was advanced, and three XL discs were deployed in the IVC to capture any embolic material that may arise from the stent column during the scrubbing/revving maneuvers. Alternatively, a Protrieve sheath or IVC filter can be deployed for embolic

Table. Demographic details of patients undergoing thrombectomy of in-stent restenosis (*ISR*) using the novel RevCore thrombectomy device (n = 40)

Demographic	No. (%)
Male sex	24 (60)
Comorbidities	
Hypertension	10 (25)
Diabetes	12 (30)
History of cancer	10 (25)
Personal history of thrombophilia condition	10 (25)
Prior history of deep venous thrombosis or pulmonary embolism	24 (60)
Chronic complete occlusion of stent column	10 (25)
Stented segments involved with significant ISR	
CFV	12 (30)
EIV	28 (70)
CIV	12 (30)
IVC	6 (15)
Mean ISR percent in patients undergoing intervention	68 (range, 50-100)

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein; *IVC,* inferior vena cava.

protection in the IVC. Mechanical thrombectomy was then performed to treat the ISR in the stent column using scrubbing or revving movements.

Typically, three or four device passes were considered adequate. Device dwell time was ≤2 minutes typically. After this step, the 11F sheath on the ipsilateral side was switched to a 16F sheath. Extirpation of material, including debris and chronic thrombus, was performed via aspiration or suction thrombectomy device such as Triever 16 (Inari Medical). Once the discs were deemed to be free of any embolic material, they were collapsed and retrieved. A venogram or IVUS examination can be performed to ensure that the embolic protection device is free of any debris before retrieval as well. All the blood removed during the aspiration thrombectomy maneuvers was filtered through the FLOWSAVER Blood Return System (Inari Medical) and returned to the patient. Therefore, overall blood loss was minimal in this procedure (≤10 mL in all patients). A completion venogram and IVUS examination were then performed.

In highly selected cases, angioplasty or stent extension (caudal or cranial) was required rarely if additional venous stenosis was identified. Generally, stent relining or extension was not required in 90% patients. Some scenarios where relining may be required include stent foreshortening after ballooning, stent fracture, or stent deformation secondary to aggressive angioplasty. The average case time was ≤30 minutes in this series.

Statistical analysis. Statistical analysis was performed using a commercially available statistics program (Prism software, Irvine, CA). Means and standard deviations were reported. Where appropriate, Fisher's exact test or *t* test was used. A *P* value of <.05 was considered significant.

RESULTS

Demographics. Forty patients underwent RevCore mechanical thrombectomy as the primary thrombectomy modality for ISR in a single session without the use of alteplase. Twenty-four of the patients (60%) were male. The mean age was 60 ± 12 years (range, 20-82 years). Major comorbidities and other patient characteristics are presented in the Table.

Clinical and procedural parameters. At least 50% clearance of the ISR was achieved in all patients (Figs 2 and 3). Thus, procedural technical success was 100% in this series. Venous patency was restored immediately in 100% of the treated patients. The mean estimated blood loss with the device was ≤10 mL. The FLOWSAVER was instrumental in minimizing blood loss and returning all the filtered blood back to the patient. The mean number of passes for the device was four. The mean device dwell-time in the patient was only 2 minutes. Mean case time was ≤30 minutes.

The following clinical events did not occur in any patient: renal failure, perioperative clinical pulmonary embolism, or device-related complications. A routine CT scan of the chest was not performed in all patients who underwent thrombectomy with the RevCore device; only patients who exhibited signs and symptoms of pulmonary embolism in the appropriate clinical context were investigated further with CT of the chest with the pulmonary embolism protocol. Alteplase was not used in any patient in this study. All patients were treated in a single session. No patient was sent to the intensive care unit for postoperative monitoring. All patients were discharged within 12 to 24 hours of the procedure. No perioperative hematomas were observed despite the initiation of anticoagulation within 12 hours of the procedure and the use of large-profile sheaths.

Symptomatic improvement was noted in >90% of patients on follow-up (range, 2-24 months). The mean Venous Clinical Severity Score (VCSS) improved from 6.2 ± 2.4 (before the intervention) to 4.9 ± 2.1 (after the intervention; $P < .001$). Quality-of-life score, as adjudged by the Chronic Venous Insufficiency Quality of Life Questionnaire, improved from 58.0 ± 22.3 before the intervention to 51.0 ± 25.2 after the intervention ($P = .002$). The quality-of-life questionnaire and VCSS are evaluated at every clinical visit.

On postoperative ultrasound examination, all the stents were patent with <50% ISR, and this persisted at follow-up visits in all patients except one. This patient had a relatively poor inflow and she developed recurrent

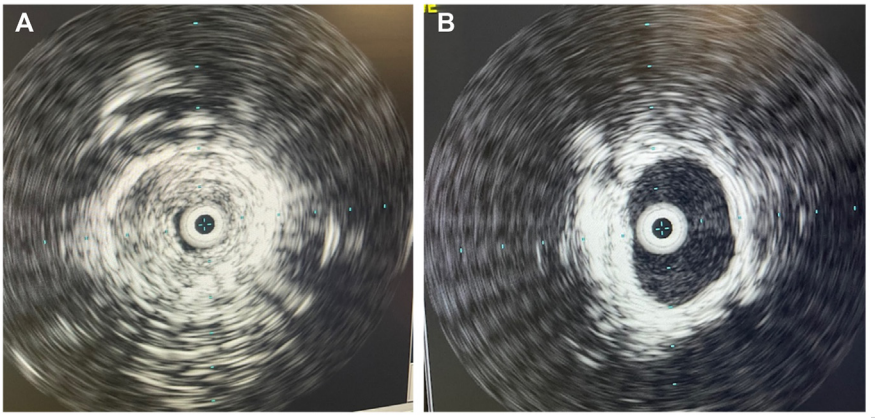

Fig 2. (A) Preintervention intravascular ultrasound (IVUS) showing near complete occlusion of venous stent due to in-stent restenosis (ISR). **(B)** Postintervention IVUS showing resolution of ISR.

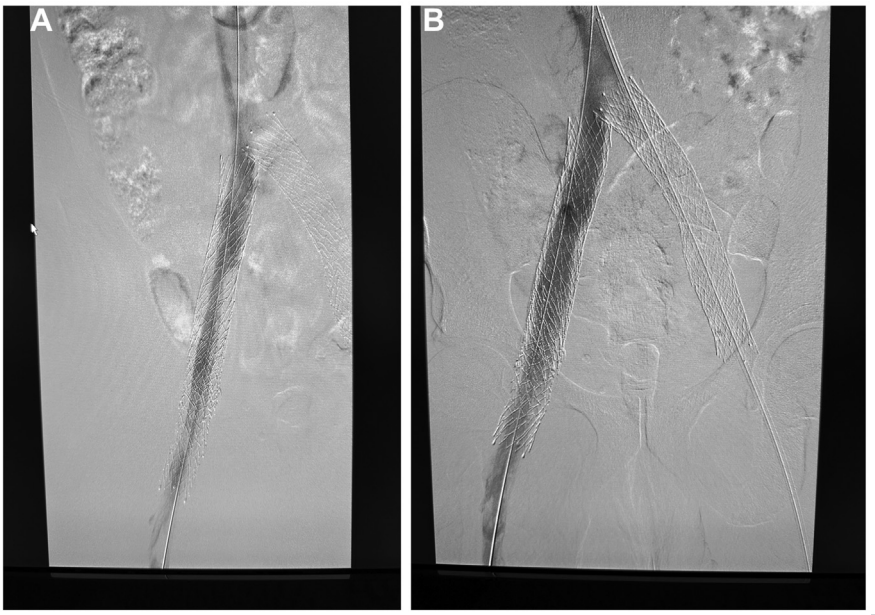

Fig 3. (A) Venography demonstrating severe in-stent restenosis (ISR) in the iliofemoral venous stent. **(B)** Post-intervention venography showing resolution of most of the ISR in the stent column.

significant ISR (72%) with severe symptoms requiring reintervention. Her symptoms were again poorly responsive to conservative therapy alone. Therefore, the reintervention rate in this series was 2.5%.

Clots that were extracted from patients varied from acute to subacute to chronic, as shown in Fig 4.

All patients were maintained on at least a prophylactic dose of anticoagulation after thrombectomy in the hopes of preventing recurrence of severe ISR or acute thrombus, usually in the form of apixaban 2.5 mg twice a day or rivaroxaban 10 mg once daily administered orally. As mentioned, one patient developed recurrent severe ISR despite this anticoagulation regimen. She was maintained on full-dose anticoagulation after the reintervention procedure for 1 year.

Follow-up. The mean follow-up duration was 1 year (range, 2-24 months). The most recent follow-up was used for the purposes of the analysis. At serial follow-up visits, improvements in VCSS, edema grade, and pain persisted in all patients except one who developed recurrent severe ISR (72% ISR) at 10 months, requiring reintervention with the RevCore thrombectomy device.

DISCUSSION

This study showed that the RevCore thrombectomy device is an effective tool to address ISR in a series of 40 patients. This modality also appeared to be durable and restore venous patency effectively. The catheter removes acute, subacute, and chronic clots in a single session without the use of alteplase. The associated blood loss

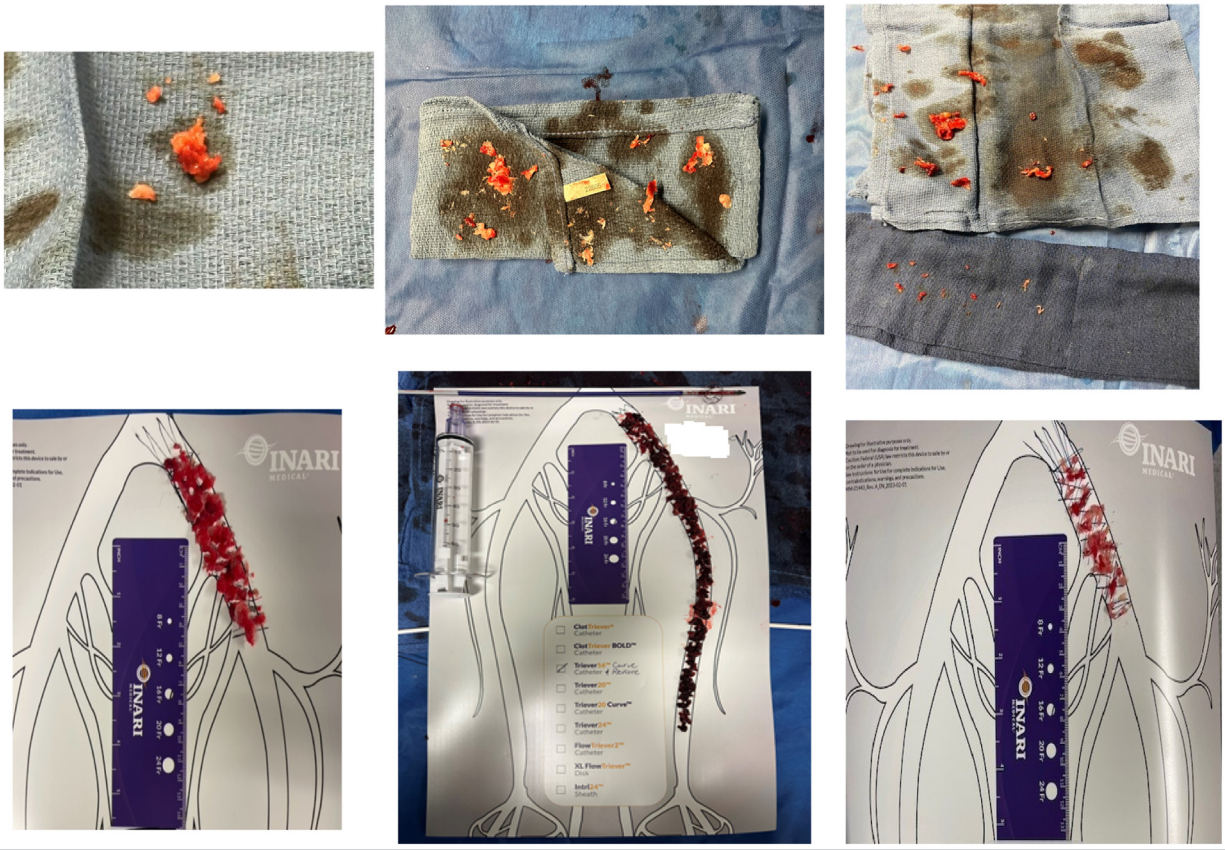

Fig 4. Various samples extirpated ranged from acute to subacute to chronic thrombi.

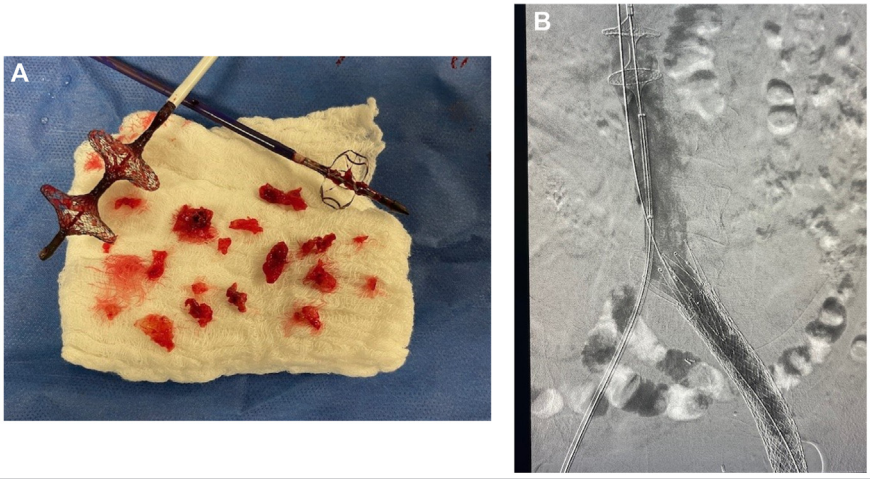

Fig 5. (A) Image showing XL discs, nitinol coring element of RevCore device and specimen extracted. **(B)** Radiographic image showing XL discs in the inferior vena cava (IVC).

is minimal, because all blood is filtered and returned to the patient safely via the Flowsaver Blood Return System (Inari Medical). In this series, there were no device-related complications that necessitated further surgical intervention. Anticoagulation was safely resumed within 12 hours of the procedure despite the use of large-profile sheaths. All patients were discharged within 12 to 24 hours of the procedure on anticoagulation. The benefit of the thrombectomy persisted in most patients at follow-up (>90%). The low number of passes needed, short procedural time, use of IVUS examination, and brief device dwell time practically translated into minimal

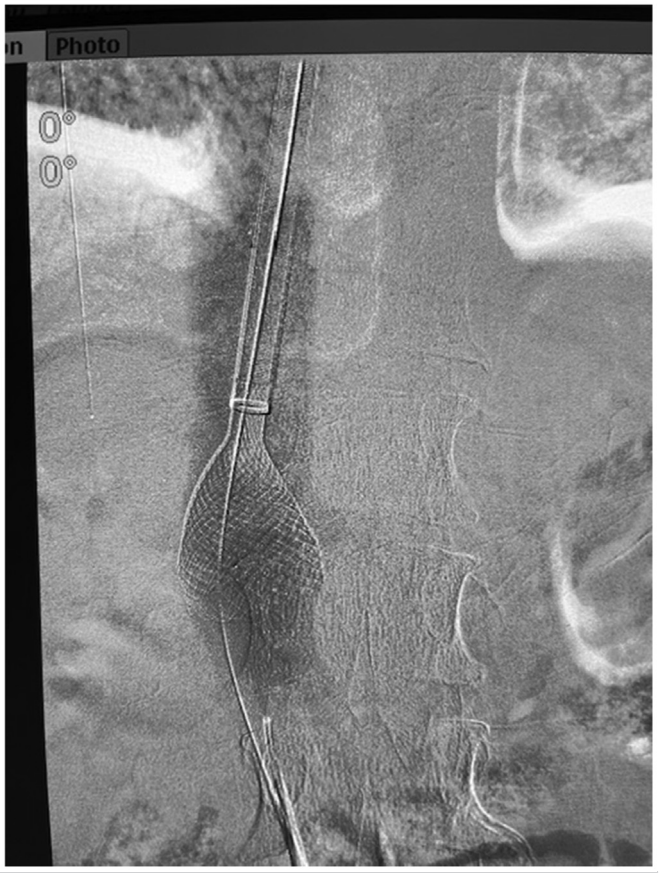

Fig 6. Protrieve deployed in the inferior vena cava (IVC) to provide embolic protection.

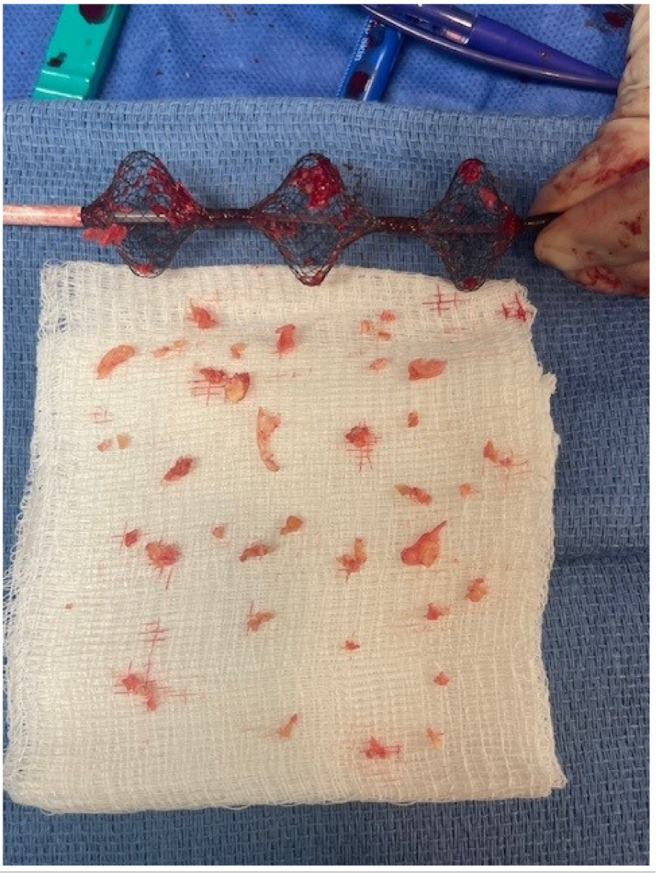

Fig 7. Specimen showing the hard type of in-stent restenosis (ISR) with calcification.

radiation exposure for the vascular surgeon, the team, and the patient.

Open endovenectomy has been described in the literature in the past; a venotomy is created and tissue is extirpated from the lumen of the vein, followed by patch angioplasty with a venous or bovine pericardial patch. The RevCore device is a type of endovenectomy device because it can core out the connective tissue/chronic thrombus from within the lumen of the vein without the need for a separate open venotomy.

Several specimens obtained from the RevCore thrombectomy device were sent for histopathological examination to the laboratory as well. An admixture of thrombus and fibrous tissue was observed in all cases of chronic ISR. This process is consistent with several reports reviewed previously.[2]

The nature of ISR in venous stents is complex and not at all like arterial ISR. There is acute-on-chronic thrombus admixed with connective tissue elements that is encountered most frequently in ISR tissue samples from venous stents. Anticoagulation is believed to prevent the acute-on-chronic thrombus component of the venous stent ISR.

Sporadic case reports have detailed experiences with the RevCore thrombectomy device so far in literature, with very short follow-ups and long case times.[12-14] Solano et al[12] described a patient with stent occlusion in whom the RevCore device restored venous stent patency with a 1-month follow-up. Shaikh[13] described two cases with very long case times and a follow-up of 3 months. Montoya et al[14] described the use of RevCore device in two patients with a 6-month follow-up; one of these stents completely reoccluded on follow-up. Other investigators have reported procedural times in excess of 110 minutes and with 1-month follow-ups.[15]

Preoperative CT venography and intraoperative IVUS examination are very helpful in differentiating stent compression from ISR. The RevCore device does not have a role in the treatment of stent compression. IVUS examination and CT venography are also helpful in quantifying the total burden of ISR in the stent column and evaluating the result and success of intervention.

With the RevCore thrombectomy device, relining of stents was not required because reasonable luminal gain was achieved in the majority of patients. Angioplasty did not cause significant stent foreshortening. Angioplasty was not required in most patients; in most cases, excellent clearance of the thrombus was achieved with the RevCore device and stent compression did not

coexist with ISR. The RevCore rarely, if ever, became entangled with the tines of the stent or the IVC filter. If that occurred, it was quite easy to disengage it from the entanglement by rotating the dial clockwise or counterclockwise and gentle manipulation of the device.

Deployment of an IVC embolic protective device is an instrumental step while using the RevCore device. This process is different from that used with aspiration thrombectomy of acute thrombus. A variety of options are available for this purpose. XL discs can be deployed in the IVC from either the contralateral iliofemoral venous system or via the right internal jugular vein Fig 5. The Protrieve device can be deployed from the right internal jugular vein or the common femoral vein (Fig 6).[16] Finally, an IVC filter can be placed temporarily for the duration of the case as well. A significant amount of particulate material embolizes after the use of the RevCore device and is captured by these embolic protection devices. A suction/aspiration thrombectomy device can then be used to clear out these embolic protection devices before they are collapsed and retrieved from the patient.

Two types of ISRs have been described previously.[2] The first type is soft, predominantly thrombus, and responds well to angioplasty alone. Techniques of hyperdilation and isodilation have been well-described effectively with this type of ISR.[2] In contrast, the second type of ISR is hard, may have fibrotic tissue, and often has calcification. It responds poorly to angioplasty techniques alone. In the current series, several patients had the calcified, hard type of ISR. The RevCore thrombectomy device was able to debulk easily this type of ISR quite well, in contrast with angioplasty alone (Fig 7). Of note, RevCore is not indicated for the removal of atherosclerotic calcifications.

It is important to be mindful that not all ISRs require treatment. There is absolutely no role for prophylactically treating a failing venous stent in a patient who is asymptomatic. Symptoms (residual or recurrent) should guide the treatment of ISR, not just the numerical value obtained from an imaging study. In the current study, the mean percentage of ISR in symptomatic patients was 68% (range, 50%-100%).

A robust stent surveillance program is key to the detection of ISR in symptomatic patients. A comprehensive stent surveillance program has been described previously in detail in the literature.[2] It usually includes duplex ultrasound examination of the stent on postoperative day 1 and weeks 3 or 4, every 3-6 months, and then annually. Ultrasound examination, being noninvasive and inexpensive, remains the primary modality for surveillance. However, its ability to differentiate stent compression from ISR is limited. As mentioned, CT venography should be obtained in symptomatic patients to differentiate ISR and stent compression before taking a patient to the operating room for further intervention.[2]

Study limitations. The main limitations of the study include its retrospective nature, lack of a comparison arm, and single-center patient selection.

CONCLUSIONS

The RevCore thrombectomy device proved to be an effective and durable treatment modality in the management of ISR in a series of 40 patients. It minimized procedural blood loss while providing excellent thrombus clearance in iliofemoral caval venous stents. Embolic protection of the cardiopulmonary system, available in many forms, from particulate debris is vital with the use of the RevCore device.

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DISCLOSURES

S.R. reports a US Patent for IVUS diagnostics.

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