Endovascular mechanical thrombectomy of iliofemoral venous stent occlusion with the novel RevCore thrombectomy system: case reports and literature review

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ABSTRACT

Venous in-stent restenosis is not completely understood, and the currently available treatment is usually unsatisfactory. We describe the cases of two patients treated with the RevCore thrombectomy system (Inari Medical), designed for venous in-stent thrombosis. Case 1 involves a 62-year-old woman with post-thrombotic syndrome from iliac vein stent placement 15 years earlier. Case 2 describes a 30-year-old woman with post-thrombotic syndrome from recurrent iliac vein stent occlusion, despite therapeutic anticoagulation. Both patients had previous recanalization attempts at outside facilities that were unsuccessful. The RevCore system was safe and feasible in these initial cases, and more studies are warranted. (J Vasc Surg Cases Innov Tech 2024;10:101432.)

Keywords: Case report; In-stent restenosis; In-stent thrombosis; Mechanical thrombectomy; RevCore

Venous in-stent restenosis (ISR) is defined as narrowing of the vein lumen after placement of a stent. Pathophysiologically, two mechanisms have been proposed to explain ISR.[1] The first relates to mesenchymal ingrowth through the stent mesh, leading to formation of an extracellular matrix enriched with proteoglycans and collagen and causing narrowing of the vessel.[1] The second pathway is associated with the formation of thrombus, leading to diffuse intimal thickening.[1] The prevalence of ISR has been reported to be 74% at 3 months after stent placement and 78% at 12 months[2]; however, most of these lesions can be managed without reintervention.

The aim of our report is to present two cases of iliac vein stent occlusion that were successfully treated with a novel endovascular mechanical thrombectomy device, the RevCore thrombectomy system (Inari Medical). This system is specifically designed for acute to chronic venous ISR and consists of a catheter with an expandable coring element and a reinforced catheter shaft.[3] This design allows the operator to retract, advance, torque, and scrub circumferentially within a venous stent. The coring element dilates ≤20 mm, is compatible with an outer sheath of 12 F and a 0.0035-in. guidewire, and has an effective length of 80 mm.[3] The patients provided written informed consent for the report of their case details and imaging studies.

CASE REPORT

Patient 1. A 62-year-old woman presented with post-thrombotic syndrome. She had a history of a left iliac vein stenting procedure (two overlapped nitinol stents of unknown size) in 2009 for deep vein thrombosis, which occluded shortly thereafter. She underwent unsuccessful stent revision that same year in her home country, and she presented to our facility 15 years later. Duplex ultrasound showed an occluded stent with excellent inflow from the common femoral, femoral, and profunda femoris veins. She complained of worsening post-thrombotic syndrome with a CEAP (clinical, etiologic, anatomic, pathophysiologic) clinical class of C4 and venous clinical severity score of 12.

With the patient in a frog-legged supine position, left femoral vein access was obtained, and venography showed complete left iliac vein stent occlusion (Fig 1, *A*). Sharp recanalization with the Liverty device (BD) was required to cross the occlusion. Via right internal jugular access, a snare device was used to capture the wire. A Protrieve sheath (Inari Medical) was advanced from the neck, and the integrated self-expanding funnel was deployed in the infrarenal vena cava to provide filtration (Fig 1, *B*). From the femoral access, predilatation with an 8-mm balloon created a tract within the left common iliac stent in preparation for the RevCore system, followed by placement of a 16F sheath. The RevCore coring element was upsized incrementally as it was passed up and down the existing stent (Fig 1, *C*). A visual representation of the device is shown in Fig 1, *D*. Chronic material was extracted, and a satisfactory channel was seen on intravascular ultrasound (IVUS; Fig 1, *E*). The left common iliac, external iliac, and common femoral veins were then relined with a 14-mm × 160-mm Venovo stent (BD) with later postdilatation. On completion, the new stent was well-apposed to the old stent, confirming that most of the chronic material lining the old stent was successfully removed with the RevCore system. Completion IVUS and venography showed no residual stenosis and brisk

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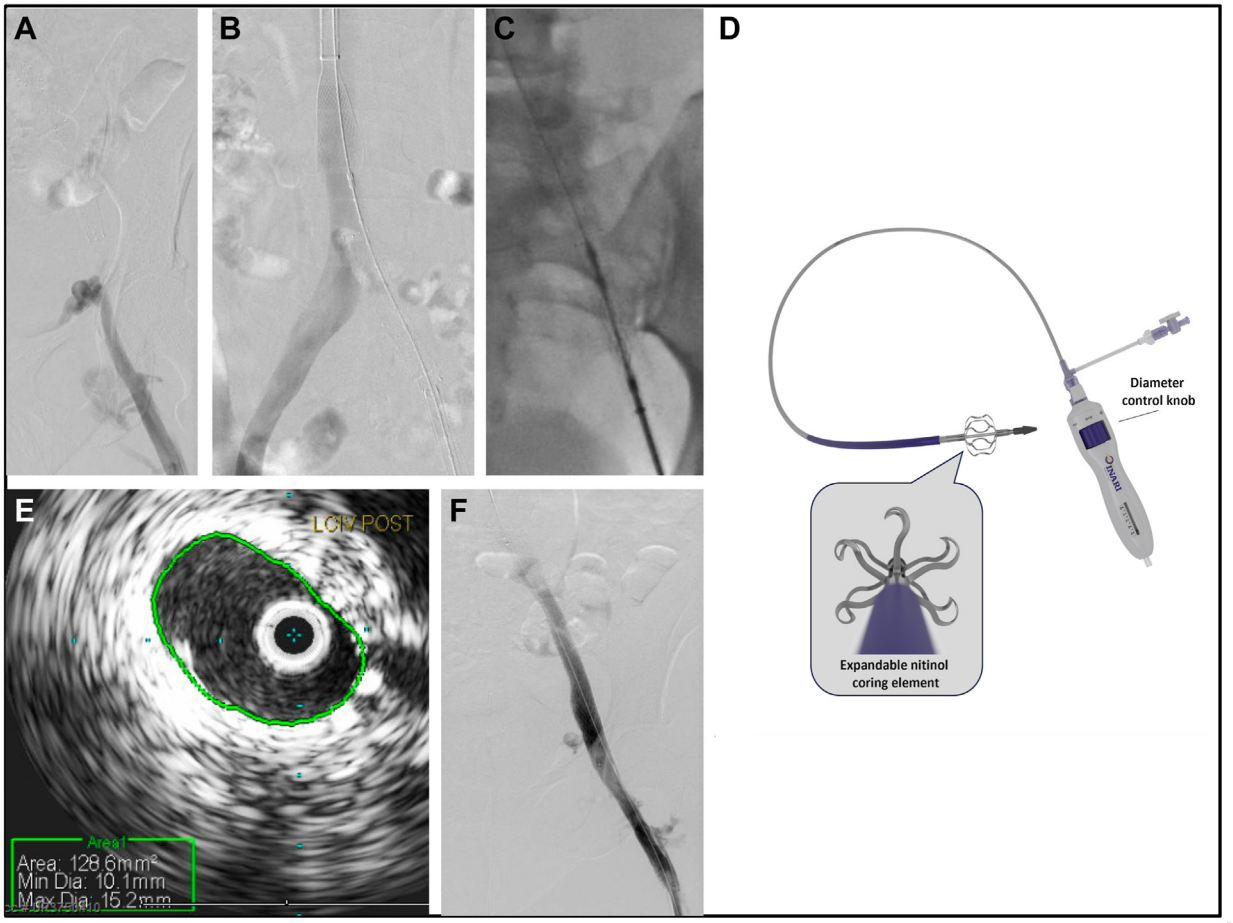

Fig 1. Intraoperative images of patient 1. **A,** Initial venography demonstrating left iliac stent occlusion. **B,** After obtaining right internal jugular and left femoral vein access, a through and through technique was performed and visualized with the Protrieve funnel deployed. **C,** RevCore device deployed in the stent. **D,** Diagram of the RevCore device. **E,** Intravascular ultrasound (IVUS) scan of the left stented vein after RevCore deployment showing an area of 128.6 mm^2, a minimum diameter of 10.1 mm, and a maximum diameter of 15.2 mm, demonstrating increased luminal patency of the stented vein. **F,** Completion venography showing good patency of the stented left iliac vein.

flow of contrast (Fig 1, *F*). Her stent was shown to be widely patent by duplex ultrasound at her 6-month follow-up visit at our facility. She will receive lifelong anticoagulation therapy with apixaban and undergo annual screening with duplex ultrasound.

Patient 2. A 32-year-old woman presented with a history of deep vein thrombosis and pulmonary embolism 12 years earlier. In 2018, she underwent left iliac vein stenting at an outside facility, which subsequently required mechanical thrombectomy and stent relining on multiple occasions before presenting to our office in 2023 with post-thrombotic syndrome (CEAP class 3; venous clinical severity score, 8). Her duplex ultrasound revealed an occluded left iliac vein stent, an occluded common femoral vein and femoral vein, and limited inflow from the profunda femoris vein. It was unclear to us whether the previous failures were from inadequate inflow, inadequate anticoagulation, or an inability to adequately reopen the conduit (stent). The patient was emphatic that she wanted another intervention to relieve her symptoms.

With the patient in a frog-legged supine position, we could not access below the common femoral vein confluence; thus, landing the stent in continuity with the profunda vein inflow was a challenge. Venography showed left iliac vein stent occlusion (Fig 2, *A*). The true lumen was confirmed by puff venography, and serial dilatation with a 12F dilator was performed before placing a 12F sheath. A 0.035-in. stiff angled glide wire was used to cross the occlusion. Via right internal jugular access, a snare device was used to capture the wire. A Protrieve sheath was advanced from the neck with the funnel deployed in the infrarenal vena cava (Fig 2, *B*). Predilatation and RevCore thrombectomy within the stent were performed as described for patients 1 (Fig 2, *C*). A satisfactory channel was seen on IVUS (Fig 2, *D*), with chronic material extracted (Fig 2, *E*). The left common iliac, external iliac, and common femoral veins were then relined with a 14-mm × 160-mm Venovo stent, with good

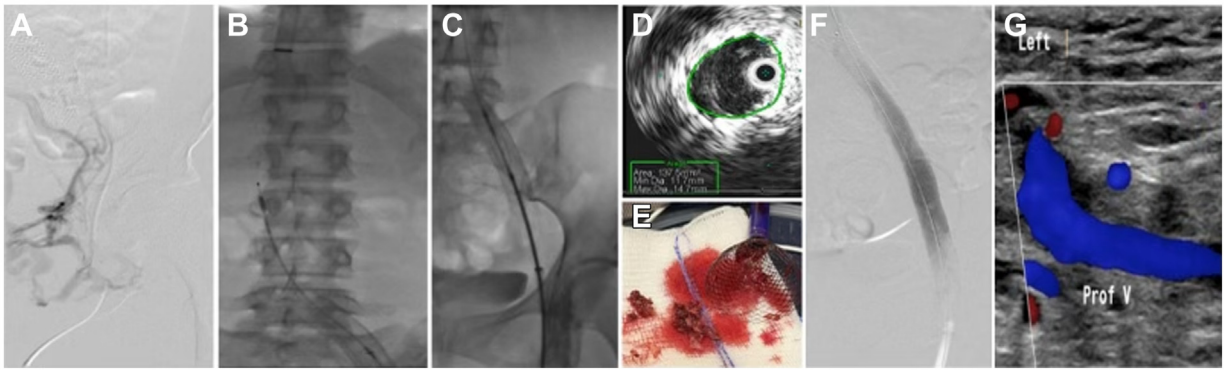

Fig 2. Intraoperative images of patient 2. **A,** Initial venography demonstrating left iliac stent occlusion. **B,** After obtaining right internal jugular and left femoral vein access, a through and through technique was performed and visualized with the Protrieve funnel deployed. **C,** RevCore device deployed in the stent. **D,** Intravascular ultrasound (IVUS) scan of the left stented vein after RevCore deployment showing an area of 137.5 mm^2, a minimum diameter of 11.7 mm, and a maximum diameter of 14.7 mm, demonstrating increased luminal patency of the stented vein. **E,** Left iliac material extracted showing chronic thrombus organization. **F,** Completion venography showing good patency of the stented left iliac vein. **G,** Six-month duplex ultrasound scan showing stent occlusion at profunda vein orifice.

Table I. Technical and medical factors associated with in-stent restenosis in different studies

Risk factor	Patients, no.	HR	95% CI	*P* value	Reference
Shear rate 1 day after procedure	578	6.702	NR	<.001	2
Shear rate 3 months after procedure	578	4.527	NR	<.001	2
Inflow area 1 day after procedure	578	1.877	NR	.017	2
Chronic post-thrombotic lesions	44	7.15	1.32-38.00	.023	4
Distal stent positioning relative to iliocaval junction	44	5.59	1.46-21.38	.012	4
Stent extension to common femoral vein	155	3.13	1.16-8.47	.024	5
Combined stent length	155	1.06	1.02-1.11	.004	5
Number of stents used	155	1.45	1.05-2.00	.022	5
Minimum stent diameter	155	—	—	.013	6
Maximum stent diameter	155	—	—	.049	6
Protective factor					
Postoperative antithrombotic therapy	62	0.28	0.10-0.83	.022	5
Antiplatelet therapy	62	0.23	0.08-0.66	.007	5

CI, Confidence interval; *HR*, hazard ratio.

apposition to the preexisting stent after postdilatation, as seen with patient 1. Completion IVUS and venography showed no residual stenosis and brisk flow of contrast through the stent (Fig 2, *F*). At her 6-month follow-up, the stent was occluded on duplex ultrasound despite aggressive anticoagulation with enoxaparin (Fig 2, *G*). The images clearly demonstrated that we had accessed the common femoral vein too far cranially and had failed to establish continuity between the profunda femoris vein and the stent lumen. We believed that accessing from below at the popliteal vein and entering the profunda orifice at Hunter's canal would be futile because of the severe post-thrombotic popliteal disease; therefore, we decided to leave the stent occluded and work on developing collateral vessels with aggressive exercise and lifelong oral anticoagulation.

DISCUSSION

Reintervention after venous stenting is required in 11% to 20% of cases.[2] It is unclear how ISR progresses to stent occlusion; however, this is likely a result of poor inflow or outflow, stent compression, and/or inadequate anticoagulation. The risk factors associated with ISR are summarized in Table I.[2,4-6] We found that chronic post-thrombotic lesions (hazard ratio [HR], 7.15),[4] shear rate 1 day after the procedure (HR, 6.7),[2] and distal stent positioning relative to the iliocaval junction (HR, 5.59)[4] were the greatest risk factors. Other common factors include thrombophilia, recent surgery, immobilization, use of oral contraceptives, and anomalous prothrombotic factors.[7,8] In a study of 578 limbs, Jayaraj et al[2] found that

Table II. Indications and contraindications for use of the RevCore device

RevCore use
Indication
Nonsurgical removal of thrombi and emboli from blood vessels in peripheral vasculature
Nonsurgical removal of thrombi and emboli within implanted venous stents
Contraindications
Not intended for use without anticoagulation
Not intended for use in cerebral, carotid, or coronary vasculature
Not intended for use in pulmonary arteries
Not intended for use in endarterectomy procedures or vessel dilation
Not indicated for removal of predominantly fibrous, firmly adherent, or calcified material (eg, atherosclerotic plaque)
Not intended for use in vessels <6 mm
Not intended for use with power injectors

the severity of the initial venous stenosis, assessed via IVUS, had no significant impact on patient outcomes, quality of life improvement, or the likelihood of ISR after stent placement and potential reintervention.

ISR can be diagnosis using different modalities including duplex ultrasound, contrast-enhanced ultrasound, IVUS, venography, computed tomography, and magnetic resonance imaging.[9] When a severe stenotic lesion is diagnosed with the presence of symptoms, recanalization could be indicated.[9] The treatment options for organized ISR material, such as balloon angioplasty, rely on lumen remodeling rather than removal of the stenotic material, limiting the luminal gain (≤31%-42% of improvement in the flow channel area).[10] Additionally, incomplete clearance of venous occlusions before stent placement in native veins has been shown to be a predictor of repeat thrombosis, emphasizing the importance of removing thrombotic material.[11] Strijkers et al[12] showed that thrombolysis is ineffective against organized ISR. Ultrasound-assisted catheter-directed thrombolysis was unable to successfully recanalize any stents that had been stenosed for >3 weeks and was associated with major hemorrhages that required transfusion in 2 of 18 patients.[12]

CONCLUSIONS

These two cases introduce the RevCore system into the armamentarium of the venous surgeon, being the first two in our experience. The indications and contraindications for use are included in Table II. Two types of ISR lesions have been described: one soft lesion with more thrombotic origin, which can happen early after stent placement, and a second hard lesion with more fibrotic and chronic occlusion. The main advantage of the RevCore system is the aggressive extraction of organized material from chronic stent occlusion without procedural adverse events. In this first and limited experience, we observed effective material extraction and luminal gain, which improve patency even in cases when relining of stents is necessary. Further extensive studies are required to evaluate the medium- and long-term benefits of this approach.

DISCLOSURES

None.

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