From the American Venous Forum

RevCore thrombectomy system for treatment of chronic left external and common iliac vein stent occlusion

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ABSTRACT

In recent years, deep venous stenting has increasingly become a treatment strategy for post-thrombotic syndrome. Stent thrombosis can occur, resulting in symptom recurrence despite medical therapy, and there are few options available for durable stent patency restoration. We present a case of a 50-year-old male with prior iliocaval reconstruction that experienced recurrent left lower extremity swelling secondary to occlusion of left external iliac and common iliac vein stents during follow-up. Mechanical thrombectomy with the RevCore System and angioplasty was performed. One month later, the patient demonstrated widely patent bilateral iliac vein stents and complete symptomatic resolution. The RevCore System is a feasible alternative for treatment of chronic in-stent thrombosis. (J Vasc Surg Cases Innov Tech 2024;10:101482.)

Keywords: Deep venous stenting; Deep venous thrombosis; Iliocaval reconstruction; Inferior vena cava; Inferior vena cava atresia; In-stent thrombosis; Mechanical thrombectomy; Venous stenting

Venous stenting procedures have significantly increased in recent years for treatment of post thrombotic syndrome (PTS) secondary to iliocaval and common femoral venous obstruction, non-thrombotic iliac vein lesions, and acute deep venous thrombosis (DVT).[1,2] Excellent clinical success has been demonstrated, with patency rates of 90% to 100% for non-thrombotic iliac vein lesions and 74% to 89% for PTS at 3 to 5 years.[3] Despite antiplatelet and anticoagulation regimens, in-stent thrombosis (IST) is a phenomenon that occurs in 19% to 30% and 16.6% of acute and chronic stages, respectively.[4-6] We present a case of chronic IST managed with a novel mechanical thrombectomy device. The patient presented here provided written informed consent for the report of his case details and imaging studies.

CASE REPORT

A 50-year-old male with past medical history significant for iliocaval reconstruction for inferior vena cava (IVC) atresia in 2022. The intervention was performed with three Wallstents (Boston Scientific), three Abre (Medtronic) stents, and two Zilver stents (Cook Medical) (Fig 1, *A*), and he was discharged with lifelong apixaban 5 mg twice daily and clopidogrel 75 mg once daily. Seven months after the procedure, he presented with a 1-month history of disabling left lower extremity swelling at a follow-up visit. He had been intermittently compliant with his antiplatelet and anticoagulation regimen. Additionally, he complained of increasing left lower extremity edema and pain. During assessment, he was categorized with CEAP 3 venous disease and severe PTS (Villalta score 15). Venous duplex ultrasound revealed occlusion of left external iliac vein (EIV) and common iliac vein (CIV) stents. Computed tomography (CT) venography confirmed occlusion of the left EIV and CIV stents (Fig 1, *B*). Given persistence of disabling symptoms, the patient underwent venography and in-stent mechanical thrombectomy with the RevCore System (Inari Medical).

Percutaneous access was obtained for the right internal jugular (IJ) vein and right common femoral vein (CFV) with 9F sheaths, followed by venography through the right CFV access (Fig 2, *A*). A short 16F sheath was introduced through the left CFV access, and the stent occlusions were crossed using a stiff Glidewire and Glidecath catheter. The Glidewire was snared through the right IJ access, and through-and-through access was obtained. Following this, intravascular ultrasound (IVUS) was used along the length of the wire and used to confirm intra-stent wire position through the left FV access. A Protrieve sheath was introduced and advanced to the intrahepatic IVC via the right IJ access. The RevCore was introduced through the Protrieve sheath and

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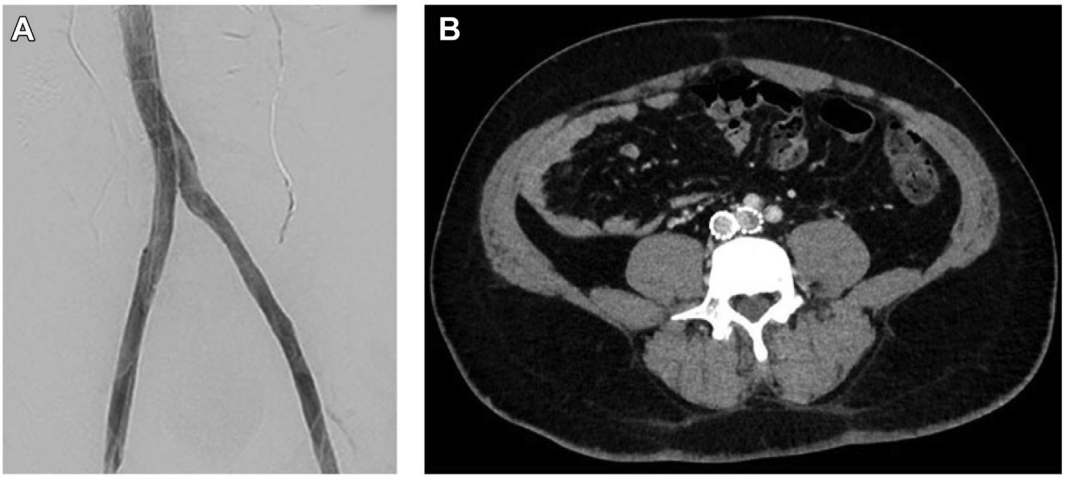

Fig 1. Iliocaval reconstruction completion venogram for index procedure (**A**). Follow-up computed tomography (CT) venogram with presence of left external iliac vein (EIV) stenosis (**B**).

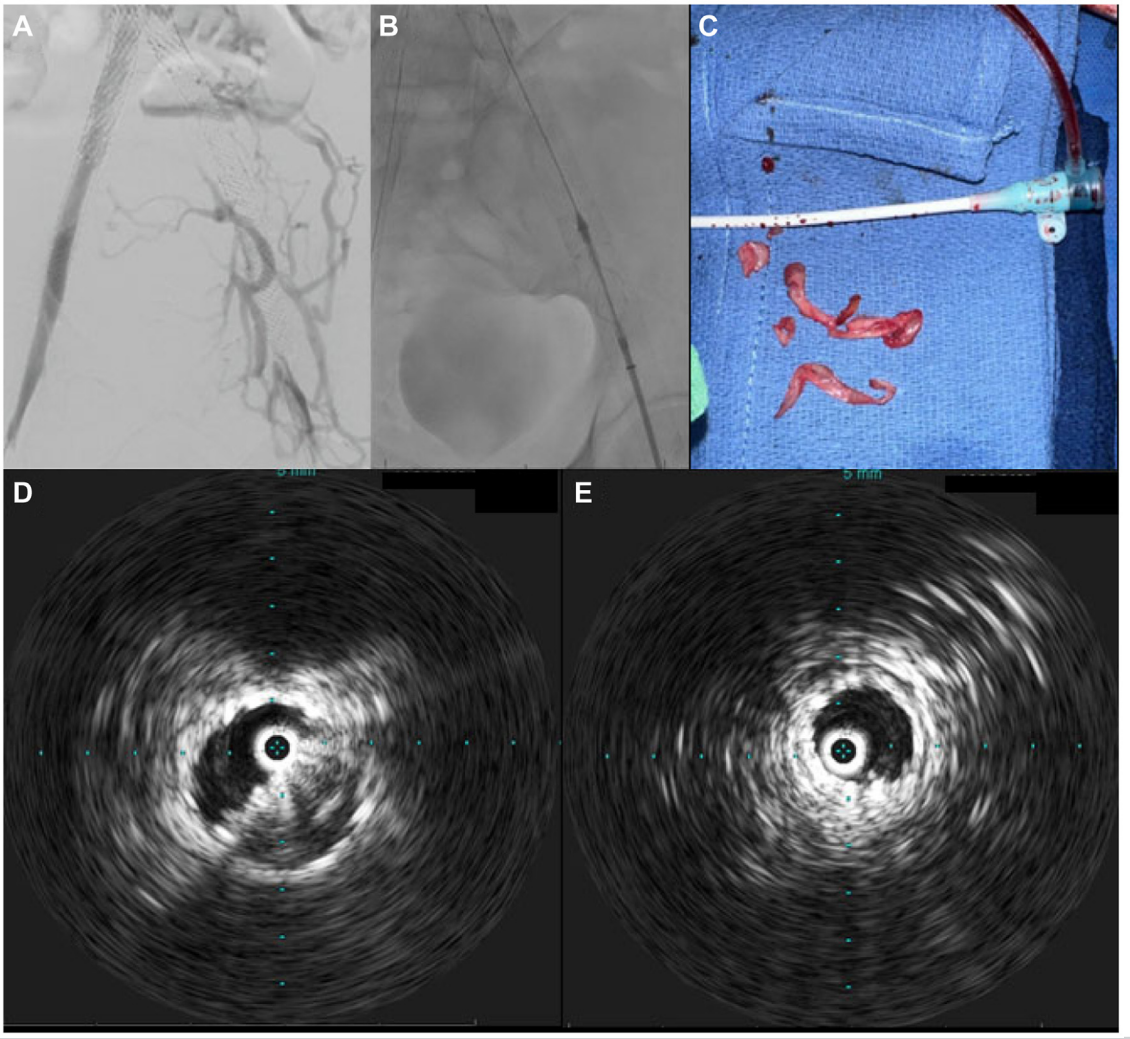

Fig 2. Operative venogram sequence showing left external iliac vein (EIV) and common iliac vein (CIV) stent occlusion (**A**). RevCore system positioned in the left EIV stent (**B**). Extraction of thrombotic material inside the stent (**C**). Intravascular ultrasound (IVUS) images of luminal gain after thrombectomy with for the left CIV stent at the inferior vena caba (IVC) confluence (**D**) and left EIV stent (**E**).

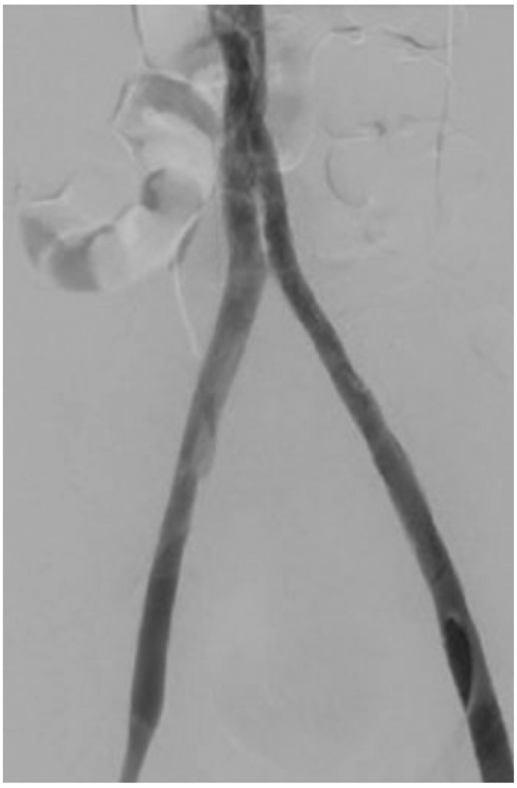

Fig 3. Completion venogram following thrombectomy with excellent stent patency and iliocaval outflow.

advanced to the left EIV and CIV stents. The RevCore element was unsheathed and was utilized to perform mechanical thrombectomy of the occluded stents. Multiple passes were performed from the right IJ access and the left CFV access (Fig 2, *B*), with substantial collagenous thrombus removal from the stents (Fig 2, *C*). Given the patient's height, we were concerned that the length of the device would be appropriate for treating the patient's CFV disease if therapy was exclusively performed from the right IJ access. Aspiration thrombectomy was performed through the Protrieve sheath with a Triever16 catheter, and filtered blood was returned to the patient through the FlowSaver System. IVUS confirmed minimal residual material within the stent lumen (Fig 2, *D* and *E*). Next, venoplasty was performed with a 14- × 60-mm Atlas noncompliant percutaneous transluminal angioplasty balloon (BD Interventional). Completion venogram confirmed full patency and brisk flow through the previously occluded stents (Fig 3). The patient was discharged on postoperative day 1. At 1-month follow-up, the patient referred complete swelling resolution, and CT venography revealed widely patent bilateral iliac vein stents (Fig 4). The patient will continue to have 3-month and 6-month follow-up with duplex ultrasound and 1-year monitoring with CT venography, with yearly monitoring with CT imaging thereafter.

DISCUSSION

PTS is a common complication of DVT due to thrombosis-induced inflammation, occurring in up to 50% of patients after a prior episode of proximal DVT.[7] This process produces fibrotic injury, which results in vein wall thickening, decreased compliance, valvular reflux and mechanical obstruction, ultimately leading to chronic venous hypertension.[8-10] Significant quality of life disruption occurs given clinical manifestations such as leg swelling, pain, venous ulcers, and skin induration of the affected limb.[11] In addition to medical treatment and interventions such as catheter-directed thrombolysis, treatment options have aimed to restore venous patency in the acute setting to reduce PTS onset and burden; however, these strategies may have limited utility in chronic stent thrombosis.[11]

Diverse endovascular approaches for stent stenosis and compression have been described, which include balloon angioplasty (isodilation and hyperdilation), laser ablation, directional atherectomy, Z-stents, drug-eluting balloons and stents, and bilateral stenting.[12] The most common method used for these cases is balloon angioplasty with high-pressure balloons. However, this approach may provide suboptimal outcomes, especially for cases in patients with severe PTS changes with recalcitrant restenosis.[13] The overall reintervention rate of stent restenosis and compression ascends to 16% after interventions for chronic iliofemoral venous obstructions.[14] The RevCore mechanical thrombectomy system is the first to be designed for removal of acute to chronic IST. This device includes a manually expandable coring element, which allows enhanced manipulation inside the stent through manual torquing of the catheter. With this configuration, thrombotic material is disrupted and removed, with residual material capable of being removed with aspiration thrombectomy devices (Fig 5). Shaikh et al reported a case series with two patients with 3-month-old and 10-year-old venous stents, respectively, who presented chronic venous occlusion that underwent mechanical thrombectomy with RevCore.[15] Both cases demonstrated successful debulking of chronic-appearing IST, with achievement of substantial luminal gain and sustained patency. Given these findings, RevCore represents a significant advancement for chronic IST management. The use of this device should be considered for any patient who has undergone stenting with recurrence of symptoms in the setting of in-stent restenosis (ISR), stent compression, a combination of ISR and stent compression, or an occluded stent. Currently, it is challenging to observe how ISR predicts clinical symptoms. Patient selection should be determined according to clinical manifestations and radiographic findings. Further studies and long-term follow-up may help to provide evidence on safety and effectiveness of the device in this scenario.

Standardized anticoagulation therapy has not been established. A systematic review reported warfarin as the most common alternative for venous stenting.[16] Direct oral anticoagulants and low-molecular weight

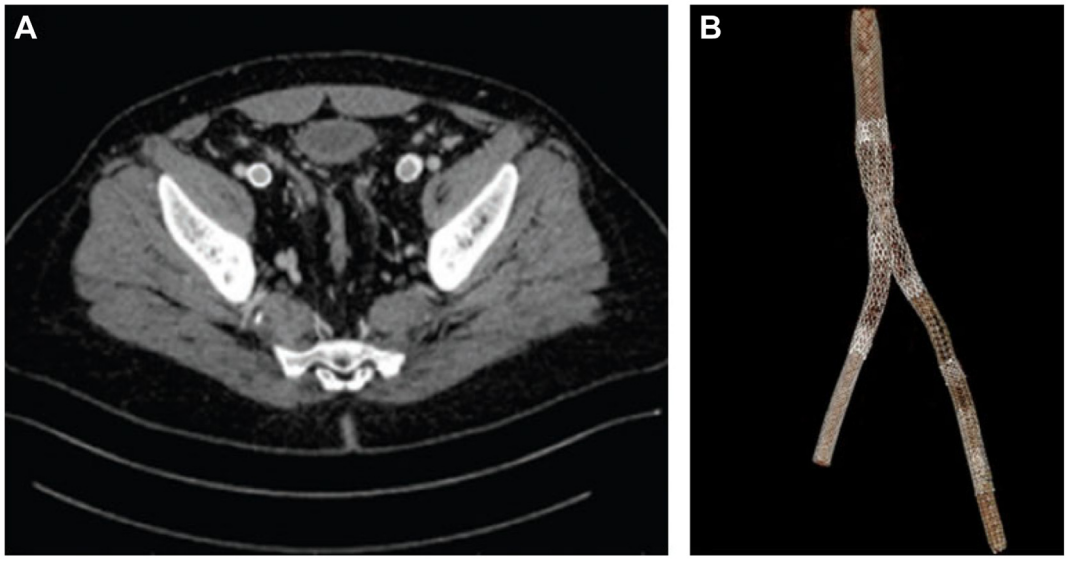

Fig 4. (**A** and **B**) Axial view of 1-month follow-up computed tomography (CT) venogram with confirmation of iliocaval stents patency. Three-dimensional postoperative reconstruction of percutaneous mechanical thrombectomy.

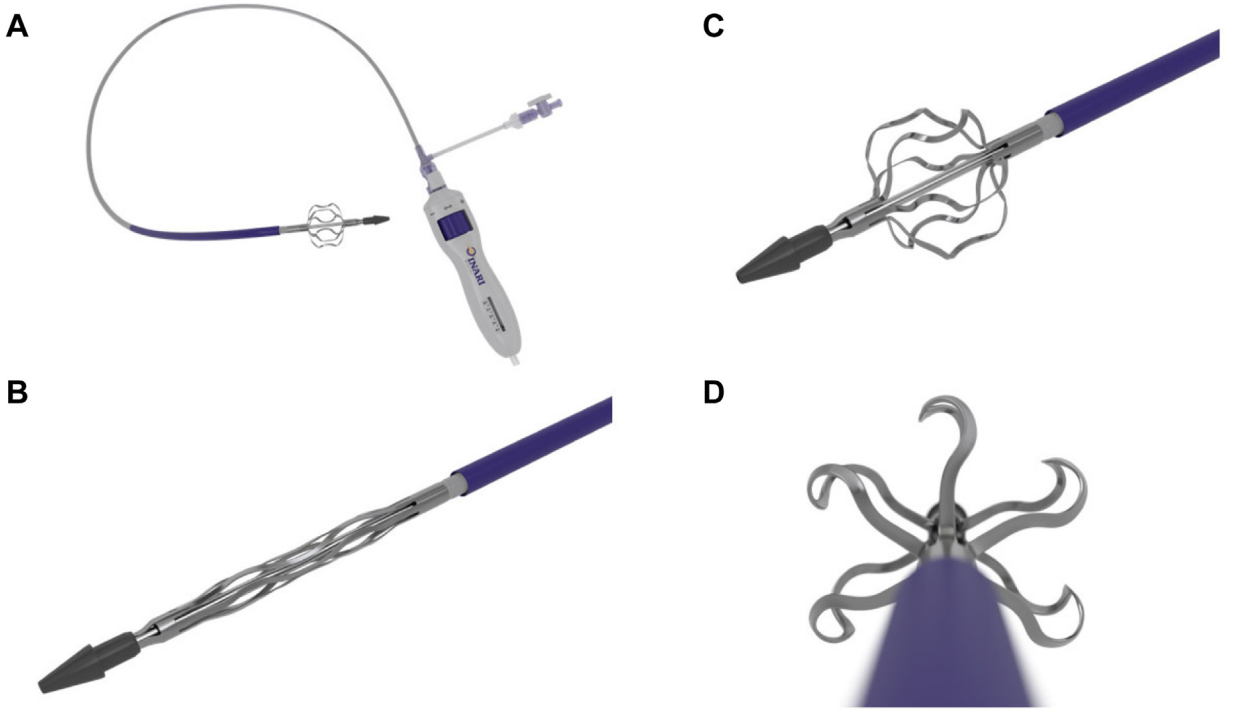

Fig 5. RevCore thrombectomy system device (**A**). Close-up images of expandable nitinol coring element in contracted (**B**) and open (**C**) configuration on anterolateral projection. Posterior view of coring element while open (**D**). Images courtesy and permission obtained from Inari Medical.

heparin have also been described. Overall stent restenosis or occlusion occurs within the first 3 months.[17] Antiplatelets, in addition to anticoagulants, have been proposed to address IST in the first 6 months after stent recanalization and optimize patency.[2] Regarding IST, 6-month incidence rates of 13.7%, with 3% to 4% per year after 6 months, even in presence of anticoagulation treatment, have been reported.[2] In this case, our patient had intermittent compliance with lifelong medical treatment and presented IST 7 months after the index

procedure. We held an extensive discussion with the patient to ensure understanding about the role of pharmacologic treatment to ensure optimal clinical outcomes for the procedure. Patient education plays an important role in ensuring the effectiveness of medical treatment. Thus, adequate compliance with medical treatment is paramount to ensure long-term patency, reduce thrombus and symptom recurrence, and ensure treatment effectiveness.

Jayaraj et al reported stent occlusion rate of 3% in patients who underwent iliocaval stenting, with 77% of patients with PTS. The median time of occlusion was 5.8 months after stenting: acute (≤30 days since stent placement) and chronic (≥30 days since stent placement) occlusion was 31% and 69%, respectively. The most significant risk factor for occlusion was native vein occlusion ($P < .01$).[18] In this case, presence of chronic occlusion was observed for the left EIV and CIV. We consider that intermittent adherence to anticoagulation therapy contributed to IST, as well as the baseline chronic iliocaval venous occlusion. Current evidence has described that ISR develops in a time-dependent course. Williams et al reported the pathologic features of venous in-stent stenosis over time in bare metal stents. Initially, fresh thrombus can occur from 0 to 2 days, organizing thrombus from 5 days to after 2 weeks,[19-21] old thrombus from >2 days to months, diffuse intimal thickening (DIT) after 4 weeks, and calcification. The presence of fresh and organized thrombus decreases over time, whereas DIT and calcification increases over time.[22] DIT could be a possible mechanism attributed to suboptimal response to thrombolytic or anticoagulation therapy in the context of IST. Close monitoring ensures a timely diagnosis.

Duplex ultrasound surveillance is the most common method to monitor stent thrombosis and ISR, which is performed 1 day, 30 days, 3 months and 1 year after the procedure.[23] Chronic stent occlusion can be treated with wire recanalization and angioplasty.[23,24] In this case, the patient had a long-standing history of disabling lower extremity symptoms, which served as the indication to proceed with intervention. The stent occlusion was successfully treated with RevCore Thrombectomy system using IVUS guidance with significant symptomatic relief, demonstrating feasibility in patients with long-standing IST. The objective is to have yearly follow-up with CTV, which can be conducted on a more frequent basis according to clinical manifestations or evidence of stent malfunction. Percutaneous interventions have proven to be a safe and effective treatment strategy for both acute and chronic iliofemoral venous occlusions.[25,26] Increasing evidence and studies with new technologies for this condition may further broaden the spectrum of treatment and enhance outcomes for iliocaval stenting patency and durability.

CONCLUSION

The RevCore system is a feasible alternative for treatment of chronic IST. This device has the potential for improving long-term patency following recanalization of occluded iliofemoral venous stents and can be used as an adjunct when standard angioplasty fails to provide adequate luminal gain to mitigate venous hypertension.

DISCLOSURES

None.

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