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Case Report

Mechanical thrombectomy of venous in-stent thrombosis with the novel RevCore thrombectomy system: A report of 2 cases [☆]

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ABSTRACT

In-stent thrombosis (IST) is a common venous stent complication. Acute IST warranting intervention can generally be treated with catheter-directed thrombolysis or aspiration thrombectomy. However, thrombosed stents often have chronic-appearing components that pose a significant treatment challenge as the thrombus firmly adheres to the stent and vessel wall and becomes resistant to thrombolytics and aspiration thrombectomy. Alternate treatment options such as venoplasty, stent relining, and medical management do not remove existing IST but rather remodel the lumen with limited long-term efficacy. This report details 2 cases of chronic-appearing IST successfully debulked with the novel RevCore Thrombectomy System. RevCore, designed to mechanically liberate acute to chronic IST via an expandable nitinol coring element, achieved substantial luminal gain and sustained patency in both patients.

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Introduction

In-stent thrombosis (IST) is a common venous stent complication occurring in up to 44% of stented patients [1]. Microscopy analysis of IST biopsies taken from newly placed and long-standing stents (0 to >208 weeks old) identified 57% of stents with chronic-appearing thrombus [2]. In cases of IST with chronic-appearing thrombotic material, treatments are limited. Thrombolytics and aspiration thrombectomy cannot remove sub-acute and chronic thrombus [3,4]. Conservative medical therapy, venoplasty, and stent relining do not remove

existing thrombus, limiting their long-term efficacy, as incomplete thrombus removal is a predictor of rethrombosis [5]. In native veins, mechanical thrombectomy can effectively remove thrombus of all chronicity [6,7]; however, no mechanical thrombectomy options exist for IST.

This report details 2 cases of chronic-appearing IST treated with the novel RevCore Thrombectomy System (Inari Medical, Irvine, CA). RevCore is the first mechanical thrombectomy device designed to remove acute to chronic IST. RevCore features a coring element that is manually expandable and can be manipulated within the stent via manual torquing of the catheter, liberating thrombotic material that

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RevCore Thrombectomy System

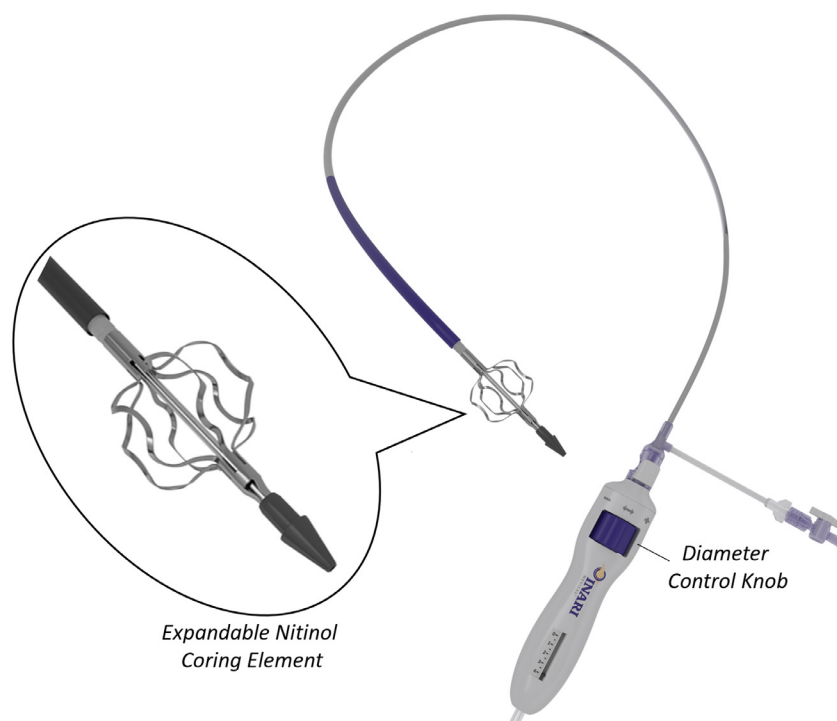


Fig. 1 – Image of the RevCore Thrombectomy System. Image courtesy of Inari Medical.

is subsequently extracted using compatible aspiration devices (Fig. 1). Consent for publication was obtained from all patients.

Case reports

Case 1

A 28-year-old female presented with right leg swelling, discoloration, and difficulty ambulating. The patient had Villalta and CEAP scores of 6 and 3, respectively. Medical history included extensive postpartum deep vein thrombosis (DVT) of the right leg 3 months prior, which was treated via mechanical thrombectomy and stenting of the common iliac vein (CIV) and external iliac vein (EIV).

Venography and intravascular ultrasound (IVUS) revealed >25% EIV stent stenosis and mild narrowing in the superficial femoral vein (SFV). Due to the lack of options to remove the stenotic material and anticipating the availability of RevCore, no further interventions were attempted.

One month later, as part of the patient's ongoing work up, reflux ultrasound showed significant reflux throughout the right common femoral vein (CFV), SFV, and popliteal vein. A 13F sheath was placed in the CFV. A 20F Protrieve sheath (Inari Medical) was placed via the right internal jugular (IJ), providing full inferior vena cava (IVC) wall apposition with a self-expanding funnel to trap and aspirate thromboemboli. Venography and IVUS showed significant IST (Fig. 2A and C). RevCore mechanical thrombectomy was performed within

the EIV stent by torquing the element 360° with a revolving motion while incrementally increasing the element diameter followed by a back-and-forth scrubbing motion. Intermittent aspiration was performed through the Protrieve sheath. Thrombectomy was followed by venoplasty.

IVUS showed a 205% increase in luminal area of the treated stent (Fig. 2C and D). Procedure time was 1 hour, with a thrombectomy time of 15 minutes. The patient was prescribed an anticoagulation regimen of enoxaparin and clopidogrel at discharge. At 3-month follow-up, CT imaging showed sustained stent patency. Due to preexisting deep venous reflux, there was no change in Villalta and CEAP scores. Patient was referred for surgical options regarding deep venous valves.

Case 2

A 64-year-old male presented with worsening of chronic left leg swelling (Fig. 3G). The patient had a Villalta score of 7 and a CEAP score of 4. Medical history included DVT and pulmonary embolism, with the placement of an IVC filter 16 years prior and a CIV stent 10 years prior.

A CT venogram identified thrombus from the IVC filter through the left CIV stent, into the CFV. Calcification was identified within the left SFV, suggesting significant chronicity.

The left popliteal vein was accessed, and venography and IVUS showed complete occlusion (Fig. 3A and C). After exhaustive attempts, the femoropopliteal system was unable to be crossed, and access was abandoned. The right IJ was accessed and venoplasty was performed in the stent. A Protrieve sheath was placed with the funnel deployed superior to the IVC filter.

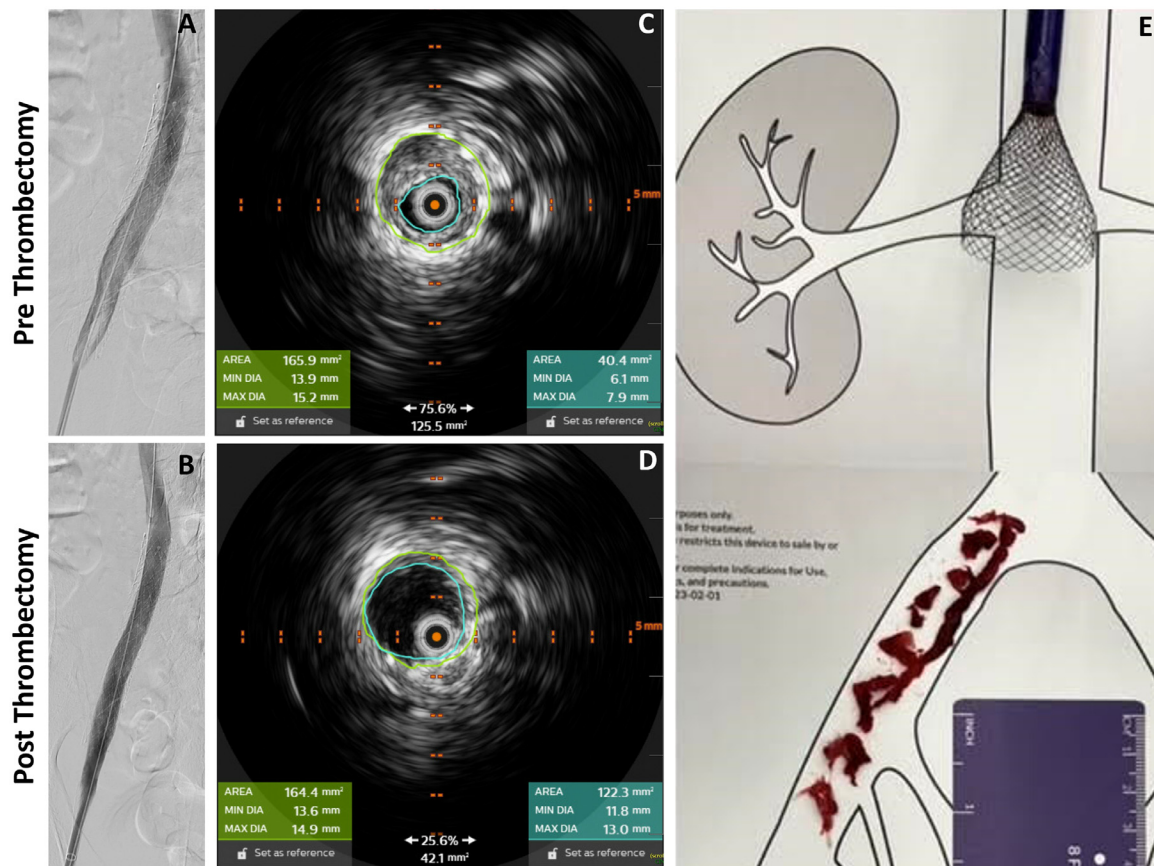


Fig. 2 – Case 1 pre and post-RevCore thrombectomy imaging and removed thrombus. (A) Prethrombectomy venography of EIV. (B) Prethrombectomy IVUS of EIV. (C) Post-thrombectomy venography of EIV. (D) Post-thrombectomy IVUS of EIV. (E) Photograph of removed thrombus with estimated original anatomical positioning. EIV, external iliac vein; IVUS, intravascular ultrasound.

RevCore thrombectomy was performed in the CIV stent as described in Case 1. Aspiration thrombectomy was performed with a Trierer20 catheter (Inari Medical) to remove material liberated by RevCore. Intermittent IVUS and subsequent venoplasty were performed (Fig. 3). Final aspiration was performed from the Protrieve sheath.

Thrombectomy time was <30 minutes and resulted in 70% luminal gain within the stent (Fig. 3C and D). The patient was prescribed an anticoagulation regimen of apixaban at discharge. At 3-month follow-up, the patient showed significant improvement in leg edema (Fig. 3H), a reduction in Villalta score from 7 to 3, and CT imaging showed sustained stent patency. Initially, IVC reconstruction and filter removal were planned if the patency remained, but given the marked improvement, the patient opted for a more conservative plan with imaging surveillance.

Discussion

This report illustrates the ability of an in-stent mechanical thrombectomy device to clear chronic-appearing material from 3-month-old and 10-year-old venous stents.

The endovascular removal of thrombus from native veins can provide immediate symptom relief and sustained clinical improvements [8]. However, when thrombosis occurs within a stent, endovascular options for removing chronic-appearing material are limited. Catheter-directed thrombolysis can dispel acute IST, but is ineffective on sub-acute to chronic thrombus, only recanalizing 61% of ISTs while failing to recanalize any stents with thrombus >21 days old [3]. Other options include venoplasty and stent relining, which do not remove thrombus but rather remodel the lumen. Venoplasty yields median luminal gains of only 31%-42% in stenosed stents [9]. Inadequate thrombus clearance increases the risk of rethrombosis and leads to patients having to endure repeated reinterventions to restore stent patency and treat symptom recurrence [5].

In both cases described here, treatment options were severely limited by the presence of chronic-appearing IST. In case 1, given the patient's young age, it was essential to treat proactively, while avoiding relining with an additional stent that would inevitably reocclude. RevCore removed 90% of the occlusive material, resulting in over 200% luminal gain. In case 2, we achieved more than 70% luminal gain through the removal of acute to chronic and calcified material resulting in significant clinical improvement. Both patients demonstrated

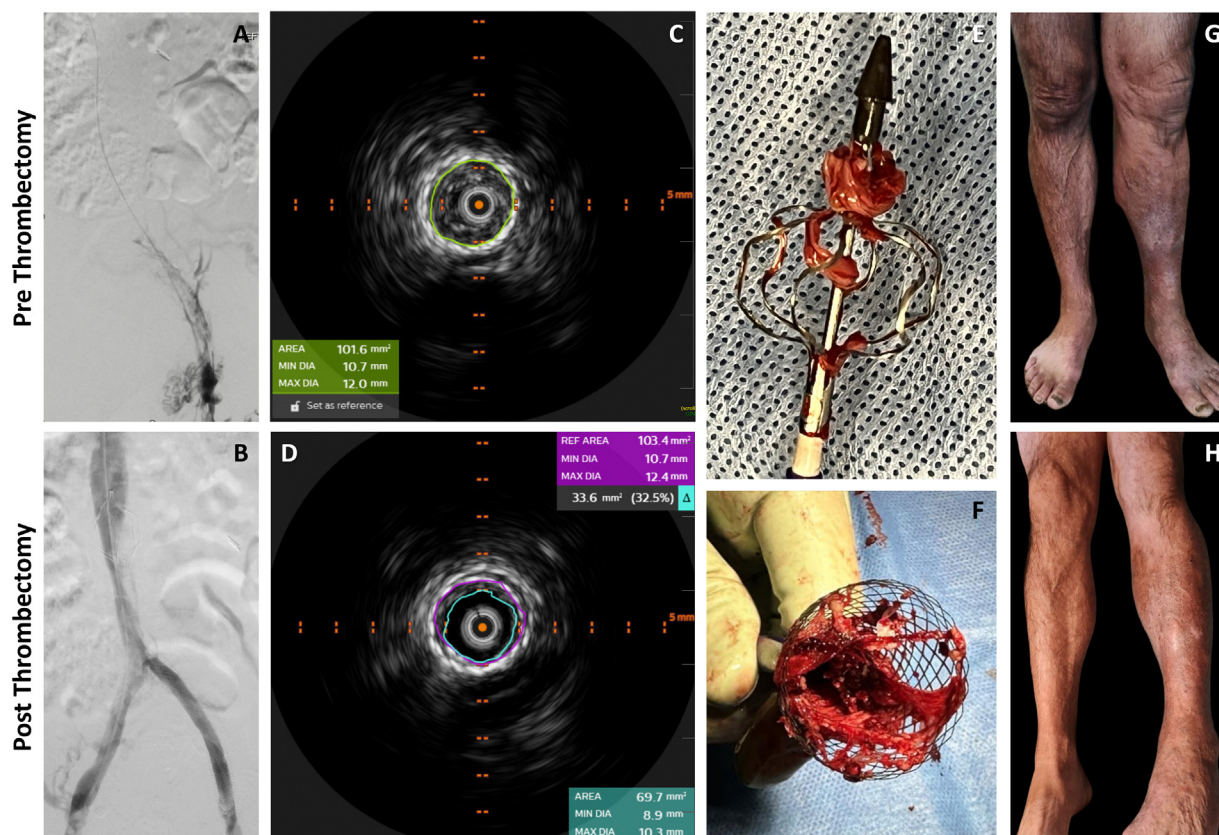


Fig. 3 – Case 2 pre and post-RevCore thrombectomy imaging and removed thrombus. (A) Prethrombectomy venography of CIV. (B) Prethrombectomy IVUS of CIV. (C) Post-thrombectomy venography of CIV. (D) Post-thrombectomy IVUS of CIV. (E) Photograph of removed thrombus on the RevCore catheter. (F) Photograph of thrombus captured in the Protrieve funnel. (G) Prethrombectomy photograph of left leg edema. (H) Three-month follow-up photograph of left leg. CIV, common iliac vein; IVUS, intravascular ultrasound.

sustained stent patency at 3-month follow-up. No stent damage or migration was observed in either case.

These cases are examples of common occurrences in the venous thromboembolism space. Treatment options that can effectively debulk acute-to-chronic IST could extend the secondary patency of stents and improve quality of life.

Conclusion

By successfully debulking chronic-appearing IST in the cases described here, RevCore represents a significant advancement in IST management. Long-term follow-up and dedicated clinical studies will help further examine the safety and effectiveness of RevCore.

Patient consent

Consent for publication was obtained from all patients.

Disclosures

Medical writing assistance was provided by Inari Medical.

Ethics approval

For this type of report, formal review by institutional review board or ethics committee is not required.

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