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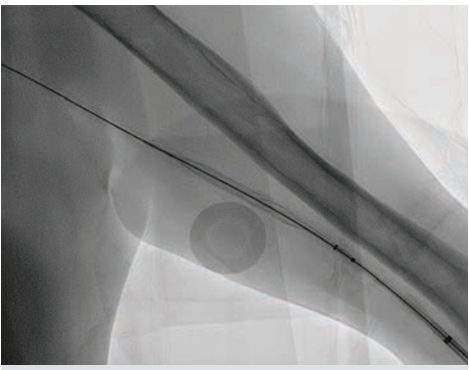

THROMBECTOMY

Early Experience and Key Learnings of the InThrill Thrombectomy System for Treating Arteriovenous Access Thrombosis in Hemodialysis Patients

Alexander Misono, MD, MBA, RPVI

Patients with end-stage renal disease (ESRD) depend on hemodialysis treatment that often utilizes an arteriovenous fistula (AVF) or arteriovenous graft (AVG) for vascular access (Figure 1). Maintaining AV access patency remains a challenge that can require frequent interventions. AV access thrombosis is the most common cause of dialysis failure, occurring up to 2 times per year for each patient and accounting for 65-85% of permanent access loss.[1] Thrombosed AV access has short- and long-term consequences that include delayed or missed hemodialysis treatment, the need for central venous catheter placement,

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(*continued from cover*) inpatient admissions, permanent access loss, and increased mortality, with a hazard ratio of 2.70 associated with early all-cause mortality.[1,2]

Existing treatment options for AV access thrombosis are limited by safety risks, procedural inefficiencies, and poor efficacy, especially in more chronic cases. While effective, surgical thrombectomy procedures are invasive and, in practice, rarely performed. Endovascular thrombectomy treatment options are safer and can be performed as an outpatient procedure; however, many rely on thrombolytics, which carry high risks for bleeding complications and are not effective against chronic thrombus.[3,4] Thromboaspiration devices utilizing aspiration to remove thrombus endovascularly also have limited efficacy on more organized thrombus and can result in high procedural blood loss. Other interventions such as balloon angioplasty and existing thrombectomy devices macerate thrombus but lack a clear mechanism of action to efficiently remove it. As a result, these declot procedures put the patient at risk of pulmonary embolism caused by displaced thrombus fragments that end up in the central venous system.[5] Furthermore, existing techniques often leave behind wall-adherent subacute-to-chronic thrombus, likely increasing the risk of access failure.

We present our early experience with the novel InThrill Thrombectomy System (Inari Medical), an 8 French (Fr) mechanical thrombectomy system that provides a minimally invasive treatment option that does not require thrombolytics. The sheath with a self-expanding funnel and aspiration port, and the catheter with a nitinol coring element are designed to collect and extract acute to chronic thombi and emboli (Figure 2). We describe the procedural workflow along with tips and tricks, and highlight three cases in which InThrill efficiently treated both thrombosed AVF and AVG to achieve and maintain full patency.

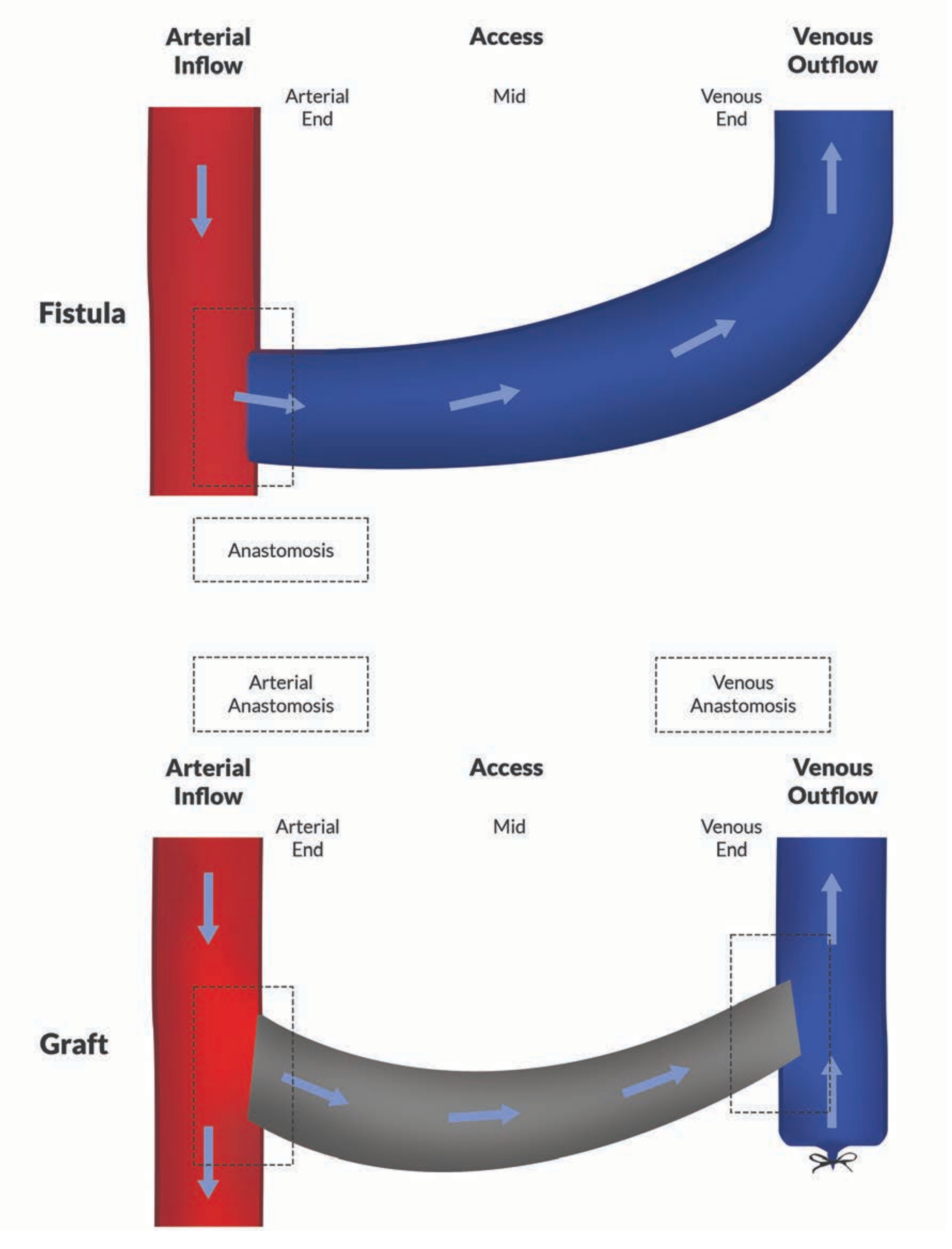

Figure 1. (A) Diagram of AV fistula. Blood flows through the AV fistula from artery to vein. Flow enters the fistula from the arterial inflow via a surgical anastomosis. Thereafter, flow continues through the access vein starting at the arterial end, then mid portion, and then the venous end. From here, flow continues into the venous outflow. Note that fistulas would typically have 1 surgical anastomosis between artery and vein.
(B) Diagram of AV graft. Blood flows through the AV graft from artery to graft and then to the vein. Flow enters the graft from the arterial inflow via a surgical arterial anastomosis. Thereafter, flow continues through the access graft starting at the arterial end, then mid portion, and then the venous end. From here, flow crosses the venous anastomosis and then into the venous outflow. Note that grafts would typically have 2 surgical anastomoses (from artery to graft; from graft to vein).

Technique and Key Learnings

The following procedural guide is recommended for performing mechanical thrombectomy of AV accesses to remove acute to chronic thrombi with the Inthrill Thrombectomy System. The workflow is summarized in Figure 3.

Procedural Planning and Case Supplies

Step 1. Review prior interventions and pre-procedure ultrasound, if available. Knowledge of anatomy and extent of thrombosis can improve case planning and enhance informed consent.

Step 2. Map out artery, access, outflow vein, and anastomosis or anastomoses using ultrasound. Create a plan of procedural steps and expected access sites.

Step 3. Collect the following case supplies:

- InThrill Thrombectomy System
- Micropuncture kit
- .035-inch Exchange Advantage Glidewire (Terumo) or other preferred .035-inch interventional wire
- 11 Fr or 12 Fr dilator (10 Fr dilator is included with InThrill)
- Heparinized saline flush
- Systemic heparin (if desired)
- Activated clotting time (ACT) system (if desired)

InThrill Device Preparation

Step 4. Prepare the InThrill sheath by flushing the sheath without dilator with sterile saline through the flush port stopcock to remove air. Repeat flush for the dilator and insert the dilator through the sheath hub. With the coring element undeployed, flush the InThrill catheter with sterile saline to remove all air from the catheter shafts. Close the stopcock and tighten the rotatable hemostasis valve.

Access

Step 5. Obtain antegrade access using ultrasound guidance. Perform initial catheter maneuvers and venograms per institutional or operator protocol.

Step 6. Insert and advance an .035-inch Exchange Advantage Glidewire (or preferred .035-inch interventional wire) past the thrombus and position it in a patent central vein. We prefer to park the tip of the .035-inch interventional wire in the inferior vena cava (IVC).

Step 7. Pre-dilate the access site up to 11 Fr or 12 Fr by inserting at a 45-degree angle and carefully advancing the pre-dilator over the guidewire to help accommodate the InThrill sheath.

Step 8. Insert sheath with dilator over the guidewire and advance until the dilator tip is proximal to the thrombus. Twist and turn the sheath for smoother insertion. Advance flanges on the sheath in order to deploy the funnel of the InThrill sheath, with care taken to stabilize the sheath from moving retrograde during this maneuver. Stabilize sheath using Tegaderm (3M) or equivalent during intervention.

Step 9. Consider systemic anticoagulation at this time, per operator or institutional preference.

Intervention

Step 10. Insert the InThrill catheter over the guidewire and advance under fluoroscopic visualization until the proximal element marker band is beyond the target thrombus.

Step 11. Perform mechanical thrombectomy to clear the outflow and access veins by first deploying and then retracting the InThrill coring element in a measured fashion. Consider retracting the at 1-2 cm per second. "Marinating" the element within thrombus for up to 30 seconds can also increase yield. Manual sheath aspiration while removing the coring element can substantially augment removal of thrombus. On rare occasion — when there is a large thrombus burden — it may be valuable to remove the catheter AND sheath as a unit over the wire. Aspirate any residual thrombus from the sheath after each pass to prevent sheath clogging. Clean the coring element over the wire for rapid passes by flicking the towel-wrapped element to

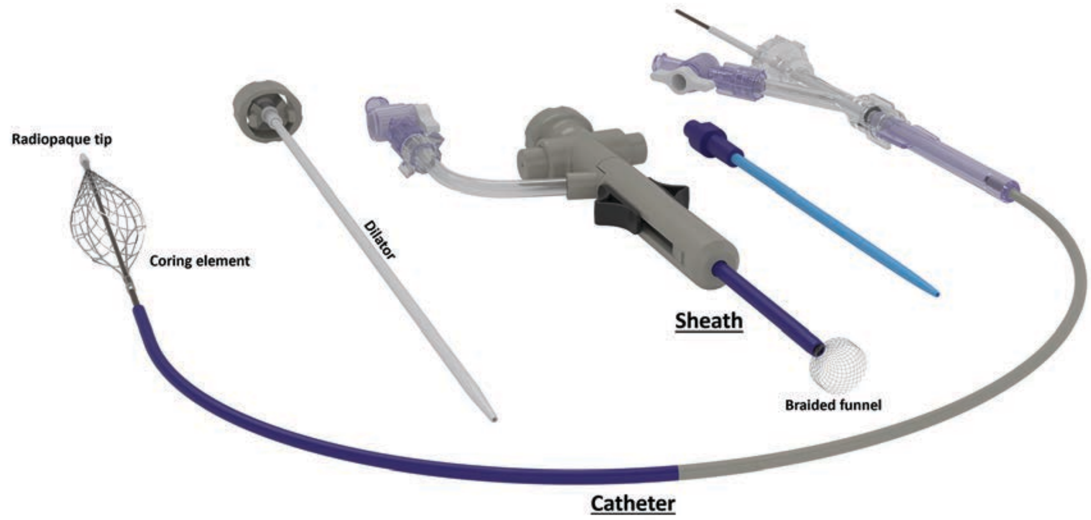

Figure 2. InThrill Thrombectomy System (Inari Medical).

Procedural Planning	• Review prior procedure, surgical notes and ultrasound • Map out artery, access, outflow vein, anastomoses prior to access • Create a plan of procedural steps and expected access sites
Case Supplies	• InThrill Thrombectomy System • Micropuncture kit • 0.035-inch Exchange Advantage Glidewire (Terumo) or preferred wire • 11Fr or 12Fr dilator • Heparinized saline flush • Systemic heparin if desired • Activated Clotting Time (ACT) system if desired
Access	• Ultrasound guided antegrade access with pre-dilation up to 11Fr or 12Fr. Do not typically obtain "dueling access" with this approach • Twist and turn InThrill Sheath for smoother insertion • Stabilize sheath using Tegaderm (3M) or equivalent during intervention

Intervention	• Clear venous outflow and access vein before obtaining retrograde access
	  ◦ Forcefully aspirate during and after each pass to augment thrombectomy and maintain sheath patency
	  ◦ Clean InThrill coring element over-the-wire for rapid passes
	  ◦ After thrombectomy, frequent or continuous heparinized saline flushes maintains access patency
	• Once access is patent, obtain retrograde access and pull the arterial plug
	  ◦ Consider re-deploying InThrill braided funnel when pulling the plug

Closure	• Close with 2-0 Vicryl suture (Johnson & Johnson), or similar, over-the-wire • Pull wire after hemostasis achieved, add manual compression as needed
Follow-up	• Follow patients yourself or in close partnership with referring providers • If necessary, consider repeat procedure to assess for residual disease requiring intervention (e.g., angioplasty, stent)

Figure 3. Workflow for treating thrombosed AV access with the InThrill Thrombectomy System.

remove the thrombus, similar to the Turboflick maneuver.[6] Note that attempting to dry the coring element after each pass tends to slow down efficiency of removing thrombus from the element.

After access patency is achieved and proven by angiography, flush periodically with heparinized saline to maintain patency of the cleared segment. Balloon angioplasty, if needed, is performed.

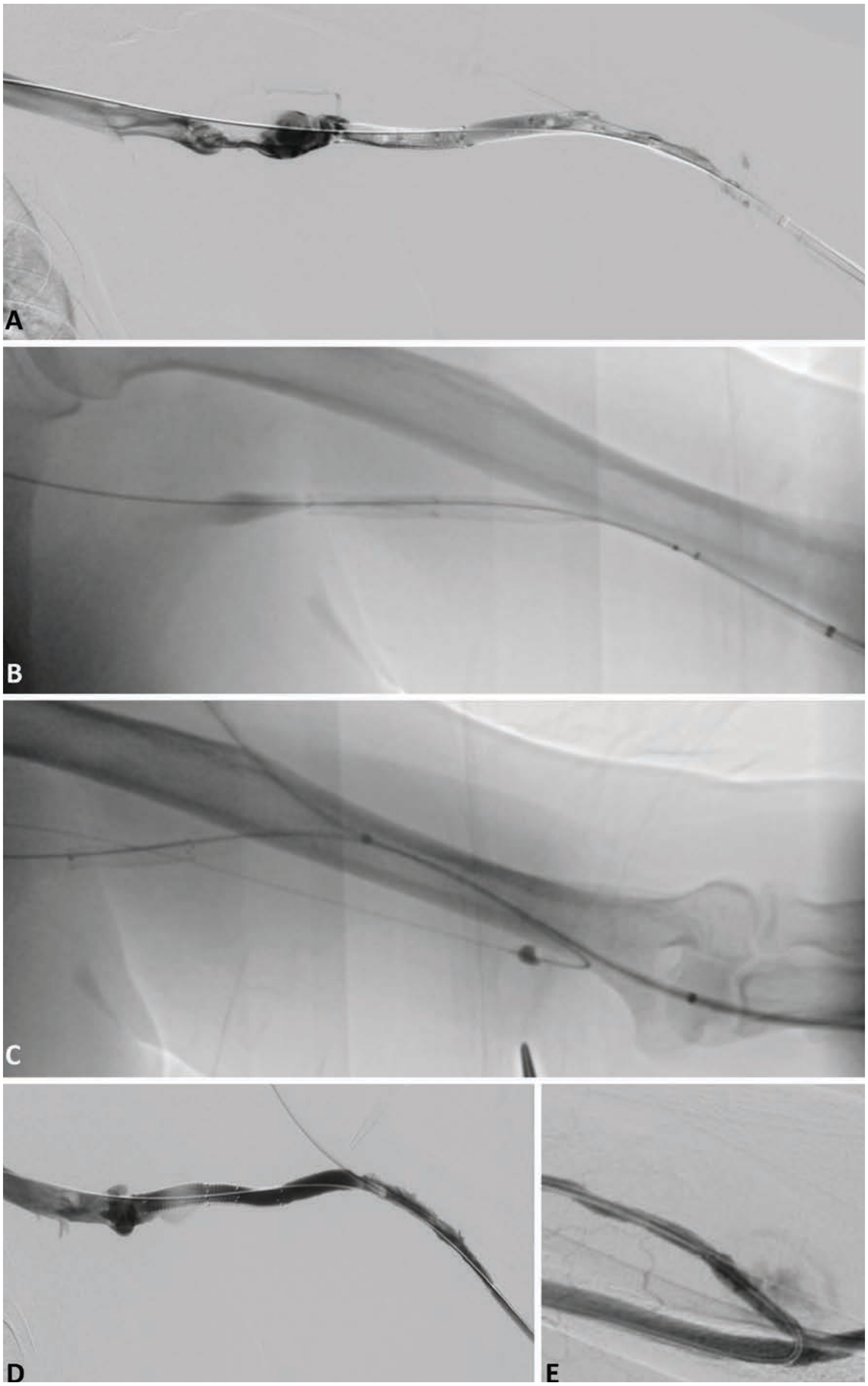

Figure 4. Case 1. (A) Thrombosis of the dialysis access, previously placed Viabahn stent graft (Gore Medical) at the venous anastomosis, and venous outflow is demonstrated prior to intervention with InThrill. (B) InThrill Thrombectomy Catheter deployed in the venous outflow. (C) Fogarty maneuver following retrograde access. (D,E) Completion angiogram demonstrating restored patency of the access.

Step 12. Obtain retrograde access and pull the arterial plug as per usual protocol. Remember to recapture the InThrill sheath funnel to prevent inadvertent wire access through the funnel. In contrast with typical declot procedures, delaying placement of the retrograde sheath allows for maximal thrombectomy yield. Depending on access size, the InThrill sheath can be backed out of the access during Step 12 by replacing the dilator over the wire, recapturing its funnel, and then pulling the entire system back until it is barely plugging the access to the fistula/graft (one can also consider replacing the sheath and re-deploying the coring element when pulling the arterial plug). Additional balloon angioplasty, if needed, is performed. Stent placement, if needed, is typically performed at this time as well, to decrease or eliminate the chances of needing to pass the thrombectomy element through a freshly deployed stent.

Closure

Step 13. Perform a completion angiogram from the arterial end or arterial inflow. Before closure, perform manual palpation of the fistula to assess for patency and flow dynamics.

Step 14. Closure of the InThrill access is efficiently performed with 2-0 Vicryl suture around the sheath, with wire in place. After suture is placed, sheath is removed. The wire is pulled after hemostasis is demonstrated. Manual compression is often added to ensure excellent hemostasis.

Follow-Up

Step 15. Follow up with patients yourself or closely in partnership with the referring provider to ensure access patency and, if needed, develop a plan for short-term repeat intervention.

Case Vignettes (3 Cases)

Case 1. A 67-year-old male with history of hypertension, type 2 diabetes, obstructive sleep apnea, dementia, and ESRD on hemodialysis via a left upper extremity arteriovenous graft presented with a clotted access. His left upper arm 7 mm-4 mm tapered Gore-Tex graft (Gore Medical) was surgically placed in October 2021 with anastomoses to the brachial artery and the brachial vein/axillary vein confluence. Thereafter, he underwent repeated conventional declot procedures in December 2021, June 2022, and October 2022. During his second intervention, a 6 mm Viabahn stent graft (Gore Medical) had been deployed across a venous anastomotic stricture. Previous studies had demonstrated chronic filling defects within the access. He was also noted to have increasingly poor sessions in dialysis with decreased flows.

The patient returned in November 2022 with rethrombosis, less than one month after his last declot procedure. Given the history of repeated thrombosis as well as increasing frequency of thrombosis, Interventional Radiology and Nephrology planned for one final attempt at declot.

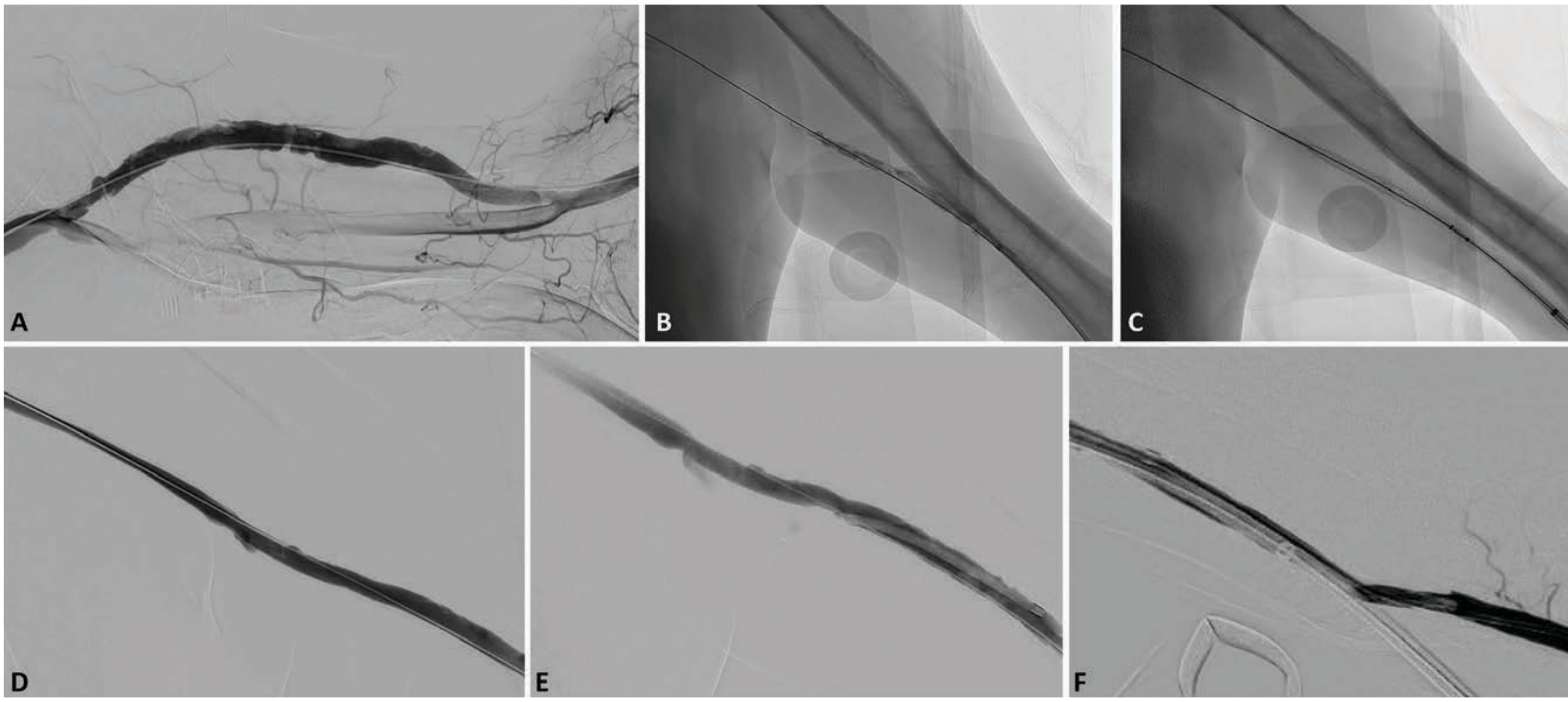

Figure 5. **Case 2. (A) Completion angiogram from previous intervention shows residual filling defects within the access. (B) Initial angiogram prior to intervention with InThrill shows rethrombosis of the graft. (C) InThrill Catheter is deployed and thrombectomy is performed. (D, E, F) Completion angiogram of arterial anastomosis, access vein, venous anastomosis, and venous outflow demonstrate patency.**

A tunneled dialysis catheter was to be placed if the intervention were to fail.

With sonographic guidance, access was obtained near the arterial anastomosis directed towards the venous outflow. Using Seldinger technique, a short 6 Fr vascular sheath was placed into the access. A Glide hockey catheter was advanced into the central veins over an 0.035-inch angled Glidewire. Pullback venography was performed revealing thrombosis of the outflow vein, previously placed Viabahn stent graft at the venous anastomosis, and dialysis access (Figure 4A). Catheter and wire were then advanced into the inferior vena cava. The wire was exchanged for an .035-inch Advantage Glidewire. After removing the catheter and sheath, the percutaneous access site was dilated to 12 Fr.

The patient was systemically heparinized. The InThrill sheath was placed and deployed, with care taken to stabilize the sheath while exposing its funnel. InThrill thrombectomy catheter was introduced over the wire and deployed with the pin-and-pull technique. A total of 8 separate passes were made in rapid succession, leaving the element on the wire and "flicking" off any extracted thrombus (Figure 4B).

Once the dialysis access, Viabahn stent, and venous outflow were documented to be patent, attention was turned to the arterial end of the dialysis access. During this brief period, the InThrill sheath was flushed periodically with heparinized saline to maintain a column of stagnant saline (as opposed to blood). Using Seldinger technique, retrograde access was obtained using palpation. A Kumpe catheter (Cook Medical) and .035-inch angled Glidewire were used to cross into the brachial artery. Then, the Fogarty maneuver was repeated 3 times over an .018-inch wire (Figure 4C).

After performing the Fogarty maneuver, the graft was immediately noted to be patent, as evidenced by a restored mildly pulsatile thrill throughout the access. As repeat angiography showed a stenosis at the end of the previously placed Viabahn stent graft, an additional 7 mm x 4 cm Viabahn stent graft was placed across the stenosis and into the outflow vein.

To obtain a completion venogram, the dilator was replaced into the InThrill sheath, and the entire system was pulled back over the wire. Venogram performed from the retrograde access showed a patent access with rapid antegrade flow, residual but significantly improved peripheral filling defects within the access vein, and excellent washout of contrast (Figure 4D-E). After closure using an over-the-wire suture technique, the graft was examined. There was minimal pulsatility and an excellent thrill.

The patient has had problem-free dialysis sessions three times a week since the intervention. He has not presented with rethrombosis.

Case 2. A 52-year-old male with history of cirrhosis, hypertension, type 2 diabetes, and ESRD on hemodialysis via a left upper extremity arteriovenous graft presented with a clotted access. A left upper arm brachial artery to axillary vein graft was surgically placed in July 2022 using a 7 mm-4 mm tapered Gore-Tex graft.

The patient initially presented in October 2022 with thrombosed access. Declot with angioplasty and rheolytic thrombectomy was performed through a left transradial arterial access via a 6 Fr slender sheath. At procedural completion, the graft was noted to be grossly patent but with residual filling defects within the access (Figure 5A).

Unfortunately, the patient returned to interventional care when the graft clotted less than a month later in November 2022. Using Seldinger technique and sonographic guidance, the graft was accessed with needle and wire pointed towards the venous outflow. After upsizing to a short 6 Fr vascular sheath, a Kumpe catheter and angled Glidewire were used to navigate into the central veins. Pullback venogram revealed thrombosis only of the access itself which was full of irregular filling defects (Figure 5B).

Subsequently, after obtaining access to the IVC, an .035-inch Advantage Glidewire was placed into the IVC. Serial dilatation was performed to 10 Fr and subsequently 12 Fr. Then, an InThrill sheath was placed into the access and the funnel was deployed.

The patient was systemically heparinized. Thereafter, multiple rounds of thrombectomy were performed of the access using the Inthrill thrombectomy catheter (Figure 5C). These maneuvers yielded small amounts of subacute and chronic appearing thrombus. Repeat angiogram was performed revealing a stenosis at the venous anastomosis, which was treated with balloon angioplasty up to 7 mm.

Only after establishing patency of the access, a retrograde access was obtained using Seldinger technique. A Kumpe catheter and .035-inch angled Glidewire were used to cross into the brachial artery. Then, the Fogarty maneuver was repeated three times over an .035-inch wire.

Immediately upon pulling the plug, a palpable

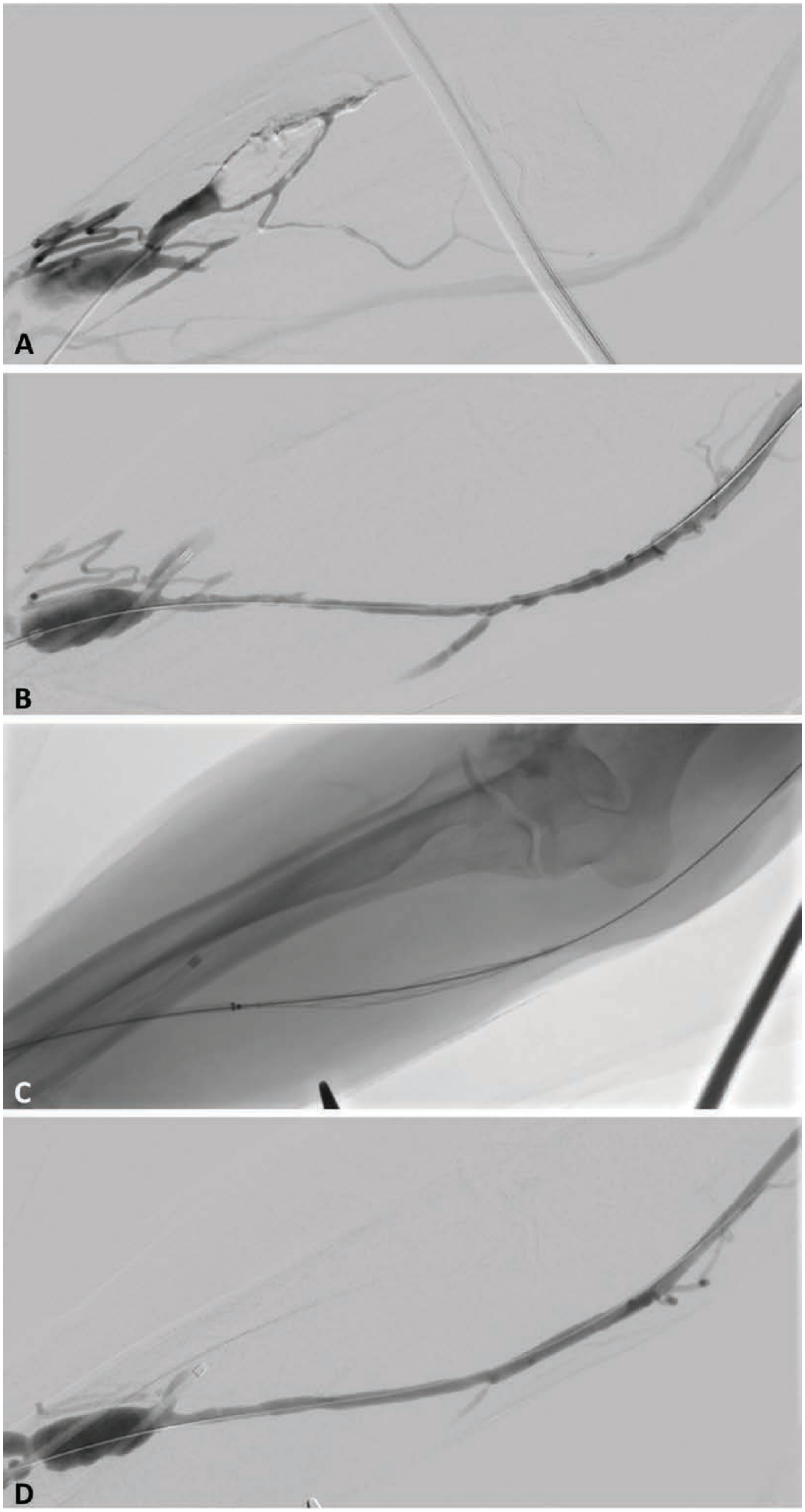

Figure 6. Case 3. (A) Initial fistula venogram shows no appreciable outflow channel or vein. (B) After crossing the occluded venous outflow and performing angioplasty, angiogram shows only partial recanalization of this new venous outflow. (C) InThrill Catheter is deployed and thrombectomy is performed throughout the venous outflow. (D) Angiography following InThrill thrombectomy demonstrates complete recanalization of the venous outflow with wide patency throughout.

thrill was felt in the fistula. An angiogram was again performed, demonstrating a patent arterial anastomosis, patent access, and patent venous anastomosis as well as central veins (Figure 5D-F).

After closure using an over-the-wire suture technique, the graft was examined. There was an excellent thrill with no pulsatility.

The patient was returned to dialysis three times a week without issues. During clinic follow-up at 12 weeks, the patient reported that his graft has a more robust and readily palpable thrill now than it ever has, including after initial surgical placement or after the initial declot procedure. His graft remains open at now over 12 weeks follow-up.

Case 3. A 95-year-old male with history of coronary artery disease, hypertension, hypothyroidism, anemia, and ESRD on dialysis via a right arm Cimino fistula presents with dysfunctional access. In 2019, the patient first had his radiocephalic fistula created in the operating room. He returned for intervention once in 2021 during which he had a routine fistulogram with angioplasty. Since then, he has been undergoing dialysis three times a week via his Cimino fistula. Due to rapidly worsening flows, recirculation, and prolonged bleeding, he was sent back to IR for fistulogram and possible intervention in August 2022.

Physical examination of the fistula showed it to be extremely pulsatile near the arterial anastomosis but lacking a thrill or even a pulse in the mid forearm. Sonographic evaluation showed a mildly aneurysmal segment of what appeared to be fistula full of calcified thrombus. A native outflow vein was not evident by sonography.

Despite lack of architecture that might be suitable to durable dialysis access, intervention was attempted. Using Seldinger technique, the fistula was accessed in an antegrade fashion with the needle pointed towards the thrombosed aneurysmal segment. A short 6 Fr vascular sheath was placed into the aneurysmal segment and multiple attempts were made to cross the thrombosed segment into normal veins. However, likely due to sheer chronicity, no outflow veins were visible or identifiable, with angiogram showing a large ovoid filling defect in the access and no discernable outflow (Figure 6A). Due to this finding, the operator assumed that a different outflow vein must have been present for the patient to have undergone dialysis.

Therefore, a separate 6 Fr access was obtained closer to the arterial anastomosis. The access was probed, and a separate venous outflow channel was identified and able to be crossed. Although this was not felt to be the original fistula, decision was made to attempt recanalization of this segment to salvage the fistula. Over an .035-inch Advantage Glidewire, balloon angioplasty was performed up to 6 mm.

Repeat angiogram was performed which showed partial recanalization of this "new" outflow vein. However, this channel has multifocal stenoses and irregularities suggestive of chronic thrombus related to chronic occlusion (Figure 6B). At this time, examination of the fistula demonstrated it to be still pulsatile.

To optimize chances of durably recanalizing this segment, after dilatation to 10 Fr, an InThrill sheath was placed into the access over the wire. Multiple rounds of mechanical thrombectomy were then pursued using the Inari InThrill catheter (Figure 6C). This yielded small amounts of chronic-appearing thrombus.

After thrombectomy with Inari InThrill, the fistula instantly became less pulsatile and demonstrated a thrill. Repeat angiography was performed that showed a smooth, albeit small, caliber outflow vein with rapid antegrade flow (Figure 6D). After closure, the access remained patent with a palpable thrill.

One month later, the patient returned for evaluation and was found to have restenosis of the access, which was not surprising, if not expected; follow-up had been closely arranged as a result. This was treated electively without incident with angioplasty and stent placement. At this time, due to the nature of this access — featuring a new outflow vein created by InThrill and a subsequent stent — a plan was formulated to transition to a tunneled dialysis catheter if needed.

However, the patient has since remained on dialysis via his right forearm fistula. He has yet to re-thrombose or require additional intervention.

Discussion

For many years, interventionalists have performed dialysis fistula and graft interventions with a combination of thrombolysis and various techniques of thrombus disruption. Whether balloon angioplasty, spinning mechanical elements, and even various forms of small-bore thrombectomy catheters, a variety of techniques have been applied to assist thrombolytics. Historically, neither thrombolytics alone nor thrombus disruption techniques alone have been adequate to restore flow to damaged dialysis accesses.

Those who have adopted large-bore mechanical thrombectomy for patients with deep venous thrombosis are familiar with the mental paradigm change that is nearly synonymous with modern-day venous thrombectomy. This paradigm change most often occurs immediately after seeing the mixed acuity and sometimes shockingly chronic-appearing thrombus extracted from a patient's leg or pelvic veins. This mental paradigm change is upon us in the world of thrombosed dialysis access intervention as well.

Existing interventions for clotted dialysis accesses center mostly around attempting some degree of thrombolysis of acute components. The remaining acute and subacute thrombus is then macerated and/or mobilized with balloons and other mechanical devices. Vanishing few interventions with small-bore thrombectomy are performed, but when they are, small amounts of acute or subacute thrombus may be mobilized. Unfortunately, with all aforementioned techniques, any subacute-to-chronic or chronic thrombus is unlikely to be removed. In fact, as in the world of deep venous thrombosis, this thrombus is typically wall-adherent and recalcitrant to most interventions. With time, the burden of chronic thrombosis will only grow. For those who have grown accustomed to the technical and clinical successes of large-bore venous thrombectomy, the idea of leaving thrombus behind is certainly unappealing.

Existing techniques — essentially by definition — result in periprocedural pulmonary embolism (PE). Balloon maceration, sweeps, and mechanical disruption will unnecessarily send small emboli into the lungs of patients who are especially susceptible to PE. In fact, dialysis patients are at a higher overall risk of PE compared to the general population. PE was observed in 150/100,000 dialysis patients compared to 25/100,000 in the general population in the same year.[7] While symptomatic PE is reportedly rare following current percutaneous declotting techniques (pharmacological, mechanical, and pharmacomechanical), radiologic evidence of PE via perfusion lung scan is as high as 59% of cases.[5] Furthermore, dialysis patients were reported to have 12.2 times higher mortality rate due to PE than the general population.[8] Given the particular vulnerability of this patient population, intentionally causing PE as part of an intervention will likely be increasingly antiquated as newer-generation tools enter widespread usage.

Thrombectomy of dialysis accesses with the Inari InThrill system can clearly be highly effective, succeeding even in situations where other techniques have previously failed. With Inari InThrill, mechanical disruption as well as removal of thrombus need not be limited to acute and subacute thrombus, but also extend to previously untreated chronic thrombus as well. The ability to perform these interventions without use of thrombolytics or causing intentional PEs should be viewed as groundbreaking.

As with any new technique, treatment techniques and procedural efficiency will take dedication to master and improve. These should be anticipated to rapidly evolve and improve. Given similarity with other Inari thrombectomy tools, there is certainly a learning curve, but it will be short for most operators. Future iterations of the device and novel approaches to dialysis access thrombectomy will surely come as well.

In the past, the operator in various venous thrombectomy devices derived great satisfaction from removing, visualizing, and inspecting thrombus. While this remains an important element, the most exciting part of InThrill thrombectomy is almost predictably the restoration of palpable thrills in the treated dialysis accesses.

Conclusion

Inari InThrill provides a powerful new entry to the armamentarium of interventional tools in dialysis access. Early experience shows that InThrill has great potential for treatment dialysis access thromboses effectively and efficiently. Gone might be the days of clot maceration, intentional PEs in susceptible patients, and inability to remove chronic thrombus from dialysis accesses. With continued device innovation and dedicated use by physicians at the forefront of dialysis care, InThrill is poised to fundamentally change the interventional operator's mental paradigm regarding dialysis access. ■

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Disclosure: Dr. Misono reports he is a consultant to Inari Medical, Microvention/Terumo, and TriSalus Life Sciences.

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