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The Benefits of Removing Thrombus Right From the Start

Leading experts present case reports and discuss the versatility of using the AngioJet™ Thrombectomy System.

Peripheral vascular thrombosis is a global problem, with one in four patients dying from conditions caused by thrombosis. In the United States, up to 900,000 patients with deep vein thrombosis (DVT) are affected by blood clots annually. Over 1.2 million patients in the United States have peripheral artery disease, and oftentimes thrombosis can lead to acute limb ischemia in these patients.[1] There are many forms of thrombosis; this article focuses on both arterial and venous thrombosis. Arterial thrombosis can lead to acute limb ischemia, a limb-threatening condition that may present as cold foot or ischemia. With arterial thrombosis, it is critical to quickly remove the thrombus, exposing the underlying cause or lesion to enable subsequent treatment. In these cases, aggressive thrombus removal can be accomplished via an endovascular procedure using thrombolysis, mechanical thrombectomy, or combination therapy. DVT is a serious condition if not addressed in a timely manner. Patients with DVT are at risk for long-term complications and can develop recurrent venous thromboembolism (ie, postthrombotic syndrome). Endovascular specialists have the opportunity to treat thrombosis using many techniques, such as dissolving the thrombus via thrombolysis or by physically removing the thrombus with mechanical thrombectomy, which quickly restores blood flow. A combination of these approaches to treatment (pharmacomechanical therapy) is quickly gaining popularity in the treatment of DVT. A recent DVT guidance statement suggests that there may be a benefit to utilizing a pharmacomechanical for thrombus removal, which can reduce the total treatment time and the amount of lytic used during the procedure.[2,3]

The AngioJet™ Thrombectomy System (Boston Scientific Corporation) was introduced by Possis Medical in 1997 under FDA 510(k) clearance for the selective infusion of physician-specified fluids and thrombus removal. The AngioJet System is designed for the treatment of arterial thrombosis, DVT, and arteriovenous (AV) fistula and graft thrombosis and is the only technology on the market that can deliver both infusion of lytics via its patented Power Pulse™ feature and mechanical thrombectomy in one device. The AngioJet System offers a broad portfolio of catheters within a range of indications. The Solent™ Omni and Proxi (6-F) catheters are designed for the treatment of both arterial and venous thrombosis in vessels ≥ 3 mm, the Solent™ Dista offers a 4-F catheter option for small (1.5-mm minimum) distal arterial vessels, the AVX™ catheter (6-F) is for use in AV fistula and grafts, and the newest and largest catheter, ZelanteDVT™, is an 8-F purpose-built device for the treatment of DVT. ■

1. Acute limb ischemia. J Vasc Surg. 2000;31(suppl 1):S135-S166.
2. Vedantham S, Piazza G, Sista AK, Goldenberg NA. Guidance for the use of thrombolytic therapy for the treatment of venous thromboembolism. J Thromb Thrombolysis. 2016;41:68-80.
3. Garcia MJ, Lookstein R, Malhotra R, et al. Endovascular management of deep vein thrombosis with rheolytic thrombectomy: final report of the prospective multicenter PEARL (Peripheral Use of AngioJet Rheolytic Thrombectomy with a Variety of Catheter Lengths) registry. J Vasc Interv Radiol. 2015;26:777-785.

Management of Acute DVT Extending From the Tibial Veins to the Common Iliac Vein Using the AngioJet Thrombectomy System

BY CHRISTOPHER GRILLI, DO; GEORGE KIMBIRIS, MD; AND DANIEL LEUNG, MD

CASE PRESENTATION

A 30-year-old woman with Down syndrome presented to the emergency department with a 4-day history of right lower extremity swelling and pain, which worsened with ambulation. Evaluation in the emergency department revealed severe edema of the right calf and thigh with moderate inflammation and redness. The calf was painful to passive dorsiflexion of the foot.

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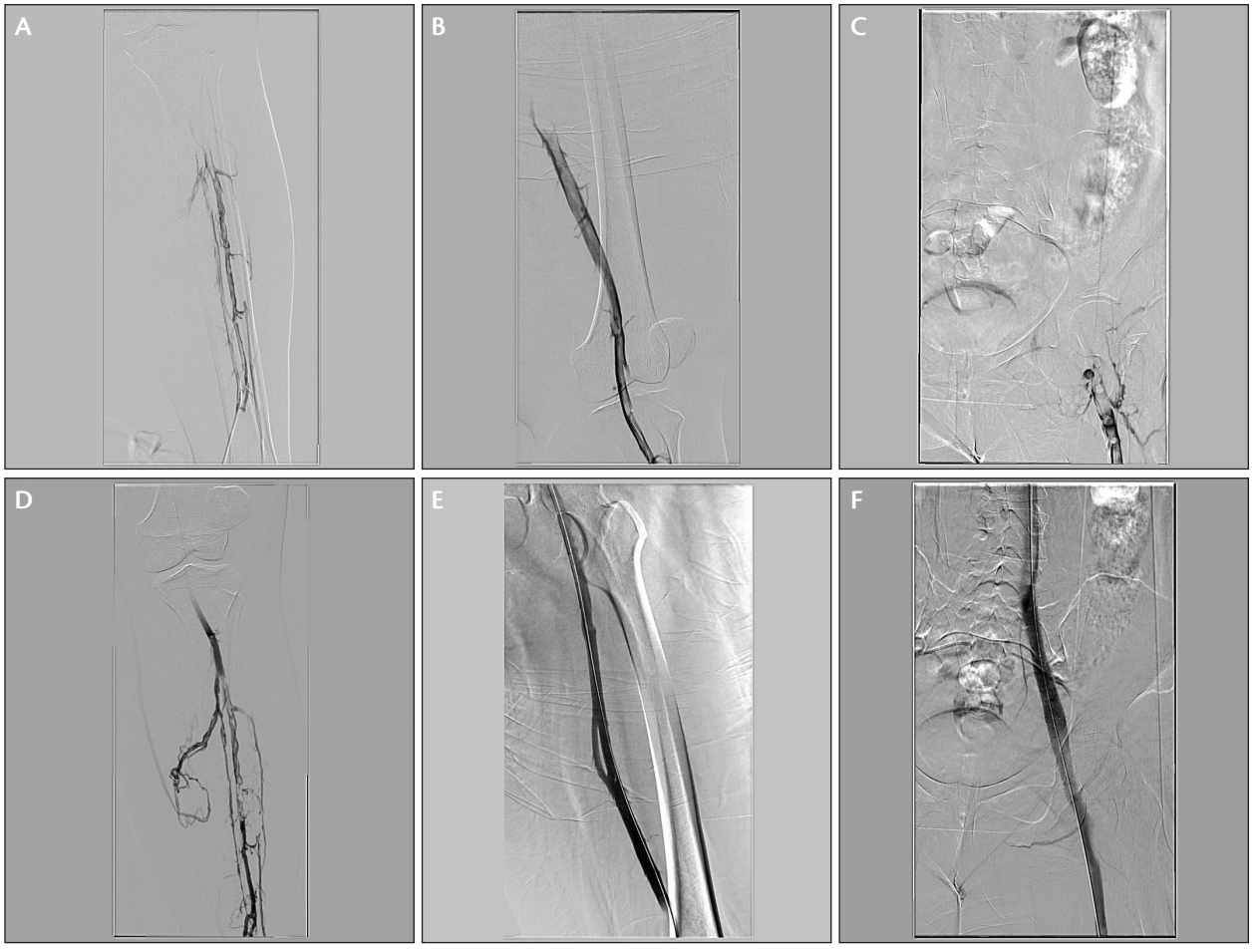

Figure 1. Initial venogram via right posterior tibial vein access demonstrates acute nonocclusive thrombus in the posterior tibial veins and occlusive thrombus at the level of the popliteal vein (A). After initial PMT via posterior tibial vein access, there is complete resolution of thrombus within the popliteal vein. A degree of spasm can be seen in the treated posterior tibial vein (B). Acute thrombus can be seen extending throughout the femoral vein (C) into the external and common iliac veins (D). The completion venogram after femoral and iliac PMT demonstrates an excellent result with complete resolution of thrombus throughout the femoral (E) and iliac veins (F). A patent right common iliac vein stent is also noted (F).

DIAGNOSTIC EVALUATION

Venous duplex ultrasound of the bilateral lower extremities demonstrated acute nonocclusive deep vein thrombosis (DVT) in the right common and external iliac veins. Acute occlusive DVT extended from the right common femoral vein to the peripheral posterior tibial and peroneal veins. The left lower extremity was unremarkable with no evidence of DVT.

TREATMENT APPROACH

The options of conservative therapy with compression and anticoagulation versus endovascular management were discussed in consultation with the patient and her family. Given the severity of the patient's symptoms, the decision was made to proceed with endovascular intervention. The patient was transported to the endovascular suite and placed in the prone position. A therapeutic dose of Lovenox (Sanofi US) and moderate sedation was administered. The patient's right leg was prepped from the popliteal fossa to the ankle. Under ultrasound guidance, the right posterior tibial vein was accessed with a micropuncture set, and a 4-F introducer sheath was placed. Initial venography demonstrated acute, partially occlusive thrombus within the paired posterior tibial veins with occlusive thrombus in the popliteal vein (Figure 1A). Over a 0.014-inch guidewire, a 4-F Solent™ Dista AngioJet catheter (Boston Scientific Corporation) was employed for pharmacomechanical thrombectomy (PMT) of the posterior tibial and popliteal veins using an eluent consisting of 10 mg tissue plasminogen activator (tPA) in 500 mL normal saline solution; 145 mL of the lytic solution was used for rheolytic

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PMT in thrombectomy mode. Completion venography demonstrated resolution of thrombus within the posterior tibial and popliteal veins (Figure 1B). Subsequently, under ultrasound guidance, the right popliteal vein was accessed with a micropuncture set, and an 8-F sheath was placed. Venography via the sheath demonstrated acute thrombus extending from the femoral vein to the common iliac vein (Figure 1C and 1D). A guidewire and catheter were negotiated into the inferior vena cava (IVC), where contrast was injected to exclude IVC involvement. Subsequently, an 8-F ZelanteDVT™ AngioJet catheter (Boston Scientific Corporation) was advanced for PMT of the femoral through common iliac veins using the same eluent in thrombectomy mode. After 470 mL of 10 mg tPA in 500 mL normal saline solution with the ZelanteDVT catheter, completion venography demonstrated complete resolution of acute thrombus (Figure 1E and 1F). Moderate chronic stenosis of the common iliac was noted and treated with a single 14-mm nitinol self-expanding stent (Figure 1F). Total fluoroscopy time for the procedure was 17 minutes.

The patient was discharged the same day on a therapeutic dose of Lovenox. At 1-month follow-up, she reported complete resolution of symptoms. A duplex ultrasound was obtained, demonstrating a widely patent deep venous system with excellent flow. The patient has remained symptom-free since the procedure. Repeat duplex ultrasound obtained at 3 and 6 months postprocedure showed no recurrent thrombosis. On examination, there was no evidence of postthrombotic syndrome (PTS) or chronic venous insufficiency. Villalta scores at the 1-, 3-, and 6-month follow-up remained at 0.

DISCUSSION

This case study describes the endovascular management of acute DVT extending from the tibial veins to the common iliac vein utilizing the AngioJet Thrombectomy System and a dual-access approach via the posterior tibial and popliteal veins. As patients and the medical community have learned more about DVT and PTS, there has been an increasing need for treatment beyond that of standard anticoagulation and compression. The AngioJet catheter is a powerful tool for reliable thrombus removal. The new ZelanteDVT 8-F catheter has the benefit of a larger inflow window as well as rotational directionality, increasing the likelihood of complete thrombus removal without the need for prolonged catheter-directed thrombolysis. Another feature seen in this case study is the value of the ankle access site, which, combined with the 4-F Solent Dista AngioJet catheter, allows for small-bore thrombus removal from the popliteal vein prior to popliteal access and ensures good inflow after subsequent iliofemoral PMT, thus minimizing the chance of future PTS. ■

Christopher Grilli, DO
Christiana Care Health Services
Wilmington, Delaware
christopher.grilli@me.com
Disclosures: Paid consultant for Boston Scientific Corporation.

George Kimbiris, MD
Christiana Care Health Services
Newark, Delaware
Disclosures: None.

Daniel Leung, MD
Christiana Care Health Services
Newark, Delaware
Disclosures: Paid consultant for Boston Scientific Corporation.

Pharmacomechanical Thrombectomy With the AngioJet Thrombectomy System for the Treatment of an Iliofemoral Arterial Occlusion

BY WM. BRITTON EAVES, MD

CASE PRESENTATION

An 84-year-old man presented to the emergency department with a painful, cool left lower extremity. He reported a history of oral squamous cell carcinoma treated with the commando procedure, coronary artery disease, hypertension, and hyperlipidemia. He complained of increasing claudication over 2 days, with a sudden onset of severe leg pain approximately 3 hours prior to presentation to the emergency department. The patient admitted to continued tobacco use and noncompliance with medication therapy. The patient was known to have a chronic total occlusion of the

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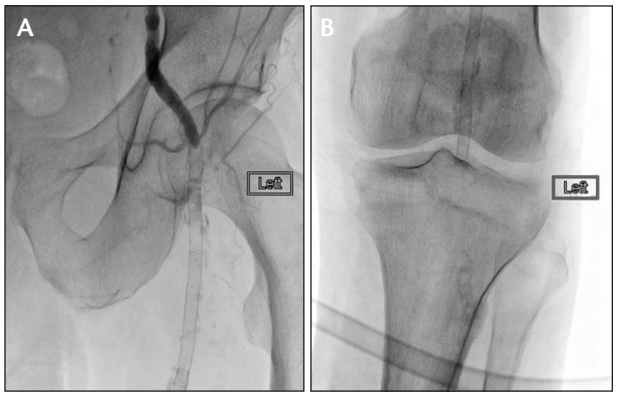

Figure 1. Angiogram showing an occluded profunda and no flow in the tibial vessels (A, B).

left profunda, which was supplied by collaterals from the hypogastric artery. The patient had a previously occluded superficial femoral artery (SFA), which was treated with angioplasty and stenting 1 month prior to presentation. Physical examination of the left lower extremity revealed no palpable pedal pulses in a cool, dusky extremity. Ultrasound revealed no flow in the left SFA or popliteal or pedal vessels.

TREATMENT APPROACH

The patient was taken emergently to the angiography suite. The right groin was prepped for a contralateral approach, which allowed visualization of the entire left lower extremity, including inflow from the iliac and the superficial femoral ostium, and did not limit access for treatment. The initial aortogram demonstrated a total occlusion of the SFA at its ostium, which was previously stented, and no flow in the remainder of the stent. The profunda was occluded and no flow was identified in the tibial vessels (Figure 1A and 1B). A pigtail catheter was used to place a 0.035-inch guidewire into the contralateral common femoral artery, and the sheath was replaced with a 7-F, 45-cm sheath with the distal tip positioned in the left common femoral artery. The lesion was crossed with a 0.035-inch crossing catheter, the 0.035-inch guidewire was removed at the level of the knee joint, and the catheter was aspirated. After blood was aspirated through the length of the catheter, contrast was injected. The tibial runoff was evaluated and documented prior to proceeding. The patient received 7,000 units of heparin. Activated clotting time was 264 seconds. A filter was deployed in the popliteal artery (Figure 2A and 2B). The crossing catheter was removed and a repeat angiogram from the femoral sheath was obtained, which showed no flow in the stented SFA. An AngioJet™ Solent™ Omni catheter (Boston Scientific Corporation) was prepped according to manufacturer's

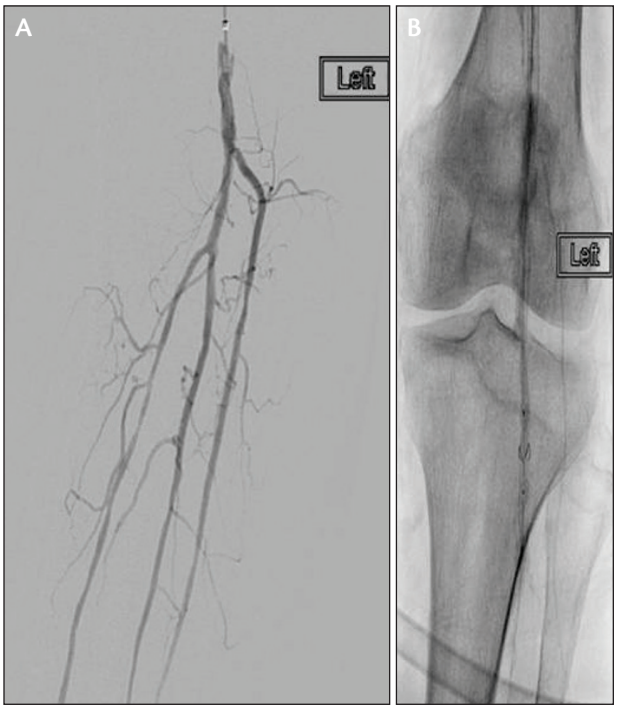

Figure 2. Angiogram showing filter deployment in the popliteal artery (A, B).

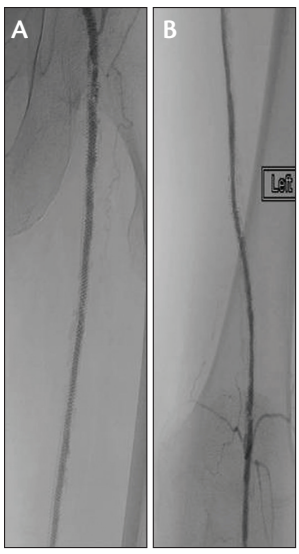

Figure 3. Angiogram showing a proximal inflow lesion and a distal outflow lesion, both within the stent (A, B).

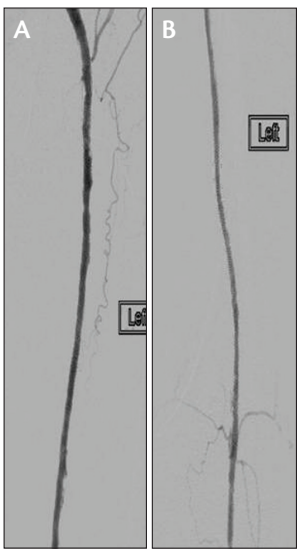

Figure 4. Final angiogram demonstrating a good angiographic result (A, B).

instructions outside the body, and 10 mg of tissue plasminogen activator (tPA) was injected in a 50-mL bag of normal saline. The AngioJet Ultra console was set to Power Pulse™ mode, and using the Solent Omni, the tPA mixture was sprayed throughout the length of the clot. It was allowed to dwell for 35 minutes. Power Pulse

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mode was discontinued, and the Solent Omni catheter was used to aspirate the entire length of the SFA. The device was then withdrawn, and a femoral angiogram was obtained, which demonstrated restoration of flow through the SFA. With visualization of the artery, we identified two lesions: a proximal inflow lesion and a distal outflow lesion, both within the stent (Figure 3A and 3B). The lesions were treated with an adjunctive specialty balloon. The final angiogram demonstrated a good angiographic result (Figure 4A and 4B). The patient was restarted on dual anti-platelet therapy with ticagrelor and low-dose aspirin. The patient's symptoms resolved, and his 1-month ultrasound showed continued patency of the left SFA stent and a preserved ankle-brachial index of 0.9. The patient was claudication-free at 6 months.

DISCUSSION

The case study is a familiar clinical scenario that illustrates the use of pharmacomechanical thrombectomy and thrombolysis in the treatment of an iliofemoral arterial occlusion. This case is a relatively common presentation of acute limb ischemia, and several strategies can restore blood flow and achieve a good clinical outcome. Pharmacomechanical thrombectomy with the AngioJet catheter was chosen in this case because we felt that there was a large acute thrombus burden. We suspected a large thrombus burden due to the acute presentation, the involvement of the entire stent, and the fact that the patient had an excellent angiographic result from treatment within the last month. AngioJet has several advantages over other techniques for the removal of large thrombus burden. High-pressure saline jets are delivered to the tip of the AngioJet catheter, which results in microfragmentation and thromboaspiration of the thrombus via the Venturi effect. The device has no direct contact with the endothelium, minimizing injury. If thrombolysis is desired, low-dose thrombolytic agents can be delivered directly into the thrombus using the incorporated Power Pulse option. This can lower complication rates associated with higher thrombolytic doses and shorten procedure time. We elected to use the Power Pulse technique on the patient, followed by mechanical thrombectomy. If flow had been reestablished after crossing the lesion, we likely would have used thrombectomy alone. With the lack of flow, the low dose of tPA remains within the thrombus rather than travelling systemically where it would have little effect. We chose a dwell time of 30 to 40 minutes for the tPA infusion, which is consistent with the PEARL registry,[1] and given the half-life of tPA, we believe this is an effective interval. The patient presented several hours after the onset of acute limb ischemia, and the addition of thrombolysis allowed for a rapid flow restoration within the time frame for limb salvage. The incorporation of the Power Pulse into the console makes the technique user friendly. In addition to removal of obvious thrombus, we feel the primary use of the AngioJet Thrombectomy System, with or without thrombolysis, is reasonable for any long occlusions.

The use of a filter is not a requirement for the AngioJet System, and decisions on whether to use a filter should be made on a case-by-case basis. We used a filter based on the fact that this patient had acute limb ischemia and the profunda was occluded. Device considerations such as thrombus burden and distal runoff will dictate whether a filter should be deployed. Techniques, such as leaving a "distal cap" of the lesion to act as a barrier and activating the device proximally and moving distally, may decrease the incidence of distal embolization, which is low (< 1%), as seen in the PEARL registry.[1]

Another feature of the AngioJet System is distal injection through the side port of the device, which allows for visualization of the thrombus as well as distal injection of vasoactive medications. In the case patient, the AngioJet System allowed us to remove the thrombus burden so that we could identify the culprit lesions and appropriately target treatment. We believe the use of AngioJet thrombectomy in arterial occlusions is safe, shortens procedural time, and improves clinical outcomes. ■

1. PEARL Registry Update. https://www.bostonscientific.com/content/dam/bostonscientific/pi/portfolio-group/Catheter%20Thrombectomy/AngioJet/Resources/4114-PEARL_Registry.pdf. Accessed October 24, 2016.

Wm. Britton Eaves, MD
Cardiovascular Consultants LLP
Bossier City, Louisiana
brittoneaves@yahoo.com
Disclosures: None.

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Thrombus Removal Technique in a Hero Graft

BY JOHN R. ROSS, MD

INTRODUCTION

Dealing with arteriovenous (AV) fistulas and grafts has become a challenging part of the interventional procedures. Oftentimes, the AV conduits are complicated with recurring thrombotic events that prevent patients from receiving necessary dialysis treatments. As a result, urgent thrombectomy is needed to restore flow to allow the patient to return immediately to their dialysis session and avoid potential complications. The Hero graft (Merit Medical), which is recently being utilized to maintain long-term vascular access, can add to the challenges of managing thrombus.

The Hero device has become prominent because total catheter contact time has increased central venous system injuries, requiring endovascular bypass. Figures 1 through 9 demonstrate my technique for thrombus removal in a Hero graft using the AngioJet™ Thrombectomy System (Boston Scientific Corporation) to quickly and efficiently restore flow.

APPROACHES TO THROMBUS REMOVAL IN AV GRAFTS

The techniques for placing the Hero graft in a total superior vena cava occlusion have been nicely delineated. However, I have experienced two types of thrombotic events with the Hero grafts. The first thrombotic event is when the access site for the Hero graft clots. At times, treatment can be very straightforward with a simple thrombectomy declot procedure. In these cases, there is very little clot in the outflow component of the graft and a small volume of thrombus to remove.

Unfortunately, remarkable clot volume can form at the outflow site, extending all the way from the connector to the tip of the graft. Under fluoroscopy, it shows a spiral image similar to what one would see in a spiral dissection of a superficial femoral artery. Generally, this does not respond to thrombolytic therapy. In our experience, we have identified two methods to quickly and efficiently remove the thrombus from the graft, ensuring restoration of flow with complete thrombus removal: (1) do an open declot procedure in the traditional fashion; or (2) use the AngioJet Solent™ Proxi Thrombectomy Catheter.

Using the AngioJet Thrombectomy System

One benefit of the AngioJet Thrombectomy System is its ability to aggressively remove thrombus to provide quick flow restoration. The AngioJet System creates a

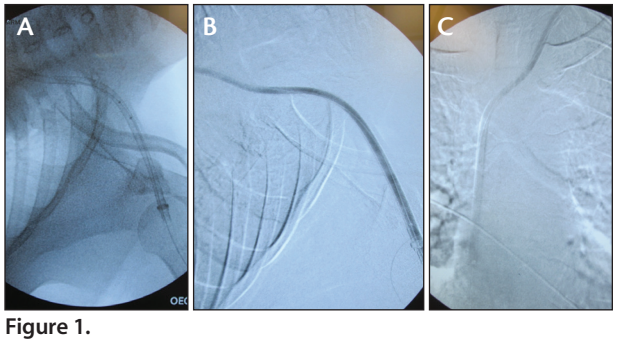
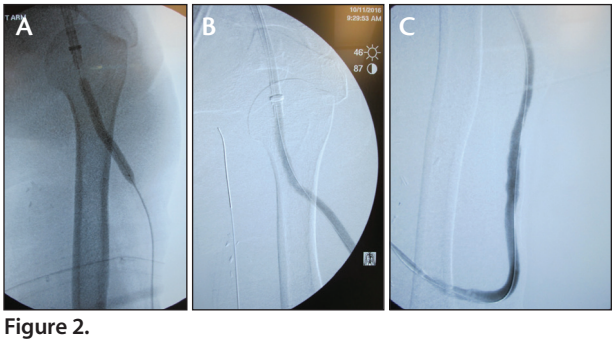


Figure 1.



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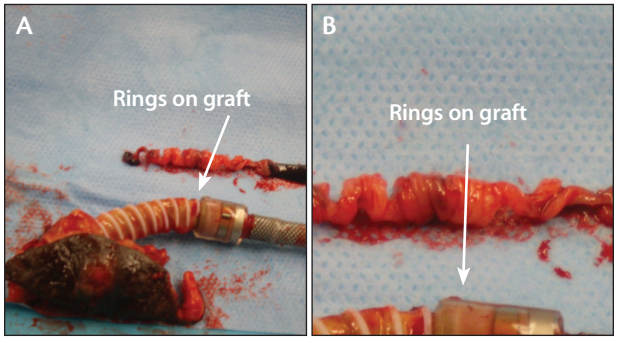

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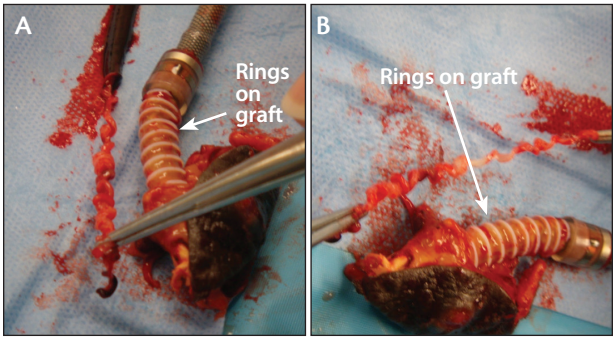

Figure 4.

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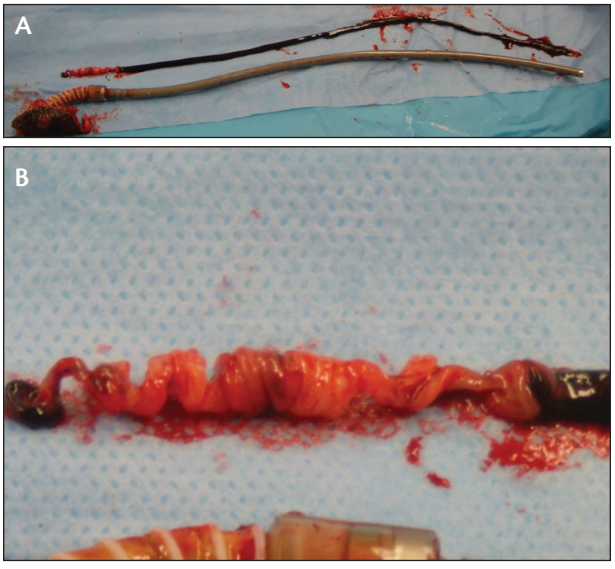

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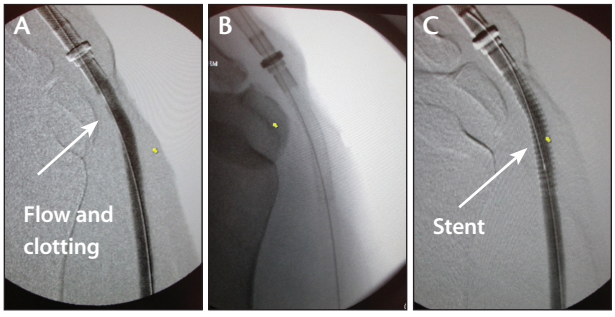

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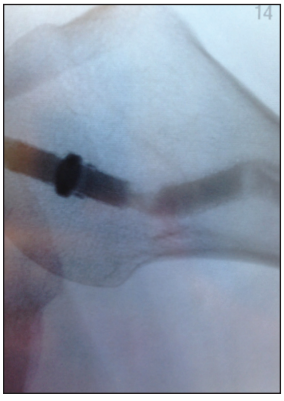

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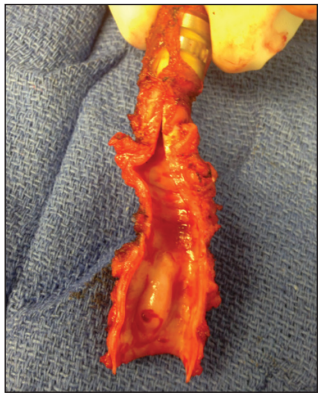

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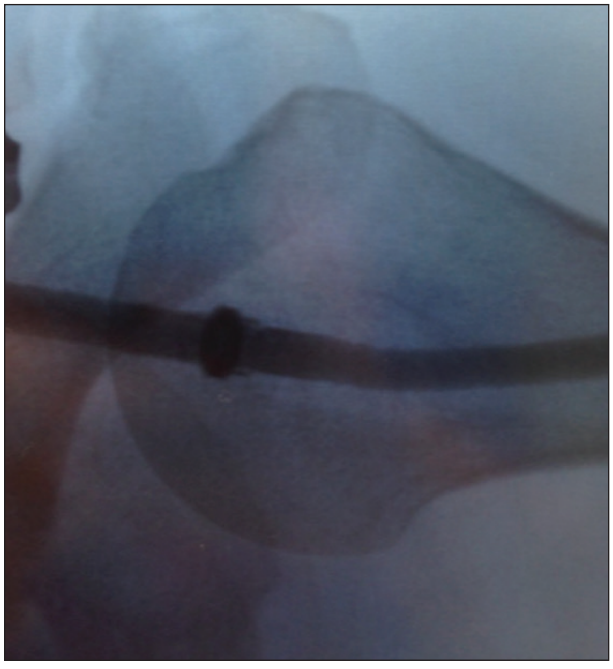

Figure 9.

high negative pressure of -600 mm Hg at the tip of the catheter and acts like a vacuum to remove thrombus from the graft. Another advantage is the ability to visualize the graft and thrombus using the AngioJet side port for contrast injections, delivering contrast to the site of treatment. With this feature, we can actually see the clot being removed and ensure complete thrombus removal.

Our technique is fairly simple. We start at the tip of the outflow component that is located in the right atrium and move the AngioJet Thrombectomy Catheter retrograde and back again antegrade. As we go retrograde in the outflow component, serial angiograms are obtained to show that the entire clot has been removed.

After several passes through the thrombosed section with the AngioJet catheter, we confirm the thrombus has been removed. Following thrombectomy, the AngioJet catheter is simply brought back into the graft itself in the usual fashion and the arterial plug is pulled. Particularly with the Hero device, angioplasties are frequently needed at cannulation zones, including the venous cannulation zone, requiring a 7- or 8-mm angioplasty balloon. ■

John R. Ross, MD
Medical Director
Dialysis Access Institute
Orangeburg, South Carolina
jrrsurgery@aol.com
Disclosures: Consultant to Boston Scientific Corporation.

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SOLENT CATHETERS COMBINED W/ CONSOLE

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE

The AngioJet SOLENT Proxi & Omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

• upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,
• upper extremity peripheral veins ≥ 3.0mm in diameter,
• ileofemoral and lower extremity veins ≥ 3.0mm in diameter,
• A-V access conduits ≥ 3.0mm in diameter and
• for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The AngioJet SOLENT Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

• upper and lower extremity peripheral arteries and
• for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the DFU).

CONTRAINDICATIONS

Do not use the catheter/Thrombectomy set in patients:

• Who are contraindicated for endovascular procedures
• In whom the lesion cannot be accessed with the guide wire
• Who cannot tolerate contrast media

WARNINGS

The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.

• The Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
• The Thrombectomy Set has not been evaluated for use in the coronary vasculature.
• Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
• Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
• Use of the catheter may cause a vessel dissection or perforation.
• Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
• Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the DFU); such use may increase risk of vessel injury.
• Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
• Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the DFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
• Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
• Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
• Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
• The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

PRECAUTIONS

• If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
• Do not exchange the guide wire. Do not retract the guide wire into the catheter during operation. The guide wire should extend at least 3 cm past the catheter tip at all times. If retraction of the guide wire into the Thrombectomy Set occurs, it may be necessary to remove both the Thrombectomy Set and the guide wire from the patient in order to re-load the catheter over the guide wire. *(Dista only)*
• Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
. *(Below is Omni, Proxi only)*

• Use of a J-tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a side window on the distal end of the catheter. *(Omni, Proxi only)*
• Hand injection of standard contrast medium may be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.
• Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
• The Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
• Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
• Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

CONSOLE WARNINGS AND PRECAUTIONS:
• Use the AngioJet Ultra 5000A Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter.
• Do not attempt to bypass any of the Console safety features.
• If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient.
• Refer to the individual AngioJet Ultra Thrombectomy Set *Directions for Use* manual for specific warnings and precautions.
• Do not move the collection bag during catheter operation as this may cause a collection bag error.
• Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked.
• Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen.
• Refer to individual Thrombectomy Set *Directions for Use* manual for specific instructions regarding heparinization of the Thrombectomy Set.
• The Console contains no user-serviceable parts. Refer service to qualified personnel.
• Removal of outer covers may result in electrical shock.
• This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating.
• Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
• To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
• Where the *"Trapping Zone Hazard for Fingers"* symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury.
• Do not reposition or push the console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.
• The AngioJet Ultra 5000A Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used.
• Portable and mobile radio frequency (RF) communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
• The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra 5000A Console.
• MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the Operator's Manual.

ADVERSE EVENTS
Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:
• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmia • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

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ZELANTEDVT THROMBECTOMY SET

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE/INDICATIONS FOR USE
The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:
• Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
• Upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

CONTRAINDICATIONS

Do not use the catheter in patients:

- Who are contraindicated for endovascular procedures
- In whom the lesion cannot be accessed with the guidewire
- Who cannot tolerate contrast media

WARNINGS

The ZelanteDVT Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where other thrombectomy catheters were used during treatment of pulmonary embolism.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the ZelanteDVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the DFU; such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus

PRECAUTIONS

- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- If resistance is felt during the advancement of the ZelanteDVT Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath as a unit to prevent possible tip separation.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

• abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmia • bleeding from access site • cerebrovascular accident • death • dissection • embolization, proximal or distal • hematoma • hemolysis • hemorrhage, requiring transfusion • hypotension/hypertension • infection at the access site • pain • pancreatitis • perforation • pseudoaneurysm • reactions to contrast medium • thrombosis/occlusion • total occlusion of treated vessel • vascular aneurysm • vascular spasm • vessel wall or valve damage

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