Clearing the Clot

This case study illustrates the endovascular management of venous thrombosis extending from the popliteal vein to the external iliac vein utilizing a two-part ambulatory venous pharmacomechanical thrombectomy technique with the newest AngioJet™ catheter on the market, the 8-F ZelanteDVT™ catheter (Boston Scientific Corporation).

AMBULATORY VENOUS THROMBECTOMY TECHNIQUE

Two-part ambulatory venous thrombectomy is a technique that I developed 7 years ago that involves bringing the patient into the procedure room to obtain access through a distal vein—typically the popliteal for lower extremity deep vein thrombosis (DVT). I deliver the lytic agent (usually 10 mg tPA mixed in 50 mL for a single limb) using the AngioJet Thrombectomy System in Power Pulse™ mode. Afterward, the patient is taken to the holding area, and a lytic catheter is placed (at 1 mg of lytic infusion per hour) for a minimum of 1.5 hours, possibly more depending on the day’s workflow, to allow the Power-Pulsed tPA to work. After allowing the tPA to exert its effect on the thrombus, the patient is brought back to the procedure room, where mechanical thrombectomy is performed on the residual clot.

From my experience, it is important to use Power Pulse to deliver the tPA prior to performing any thrombectomy, because I believe the delivered tPA has the best chance of penetrating and distributing into the clot when the AngioJet catheter is within the thrombus without any blood flowing around the catheter. This prevents the blood flowing around the catheter from taking the tPA systemically before it has a chance to penetrate the clot.

After mechanical thrombectomy and reimaging, secondary interventions such as ballooning and stenting are performed to correct any underlying lesions within the venous system. After this is performed, the patient is taken back to the recovery area to recover for 2 hours while receiving aggressive hydration. Patients receive postoperative education on potential signs and symptoms of internal bleeding, hemoglobinuria, and the importance of hydration. The patient is then discharged to home and receives follow-up calls the next morning and afternoon.

I primarily choose to use this technique for three reasons. First, it has proven to be effective for me, with 90% to 100% thrombus clearance of the acute clot within the vessel lumen. This does not include intermediate or chronic age thrombus, which is addressed with secondary intervention. Second, it has proven to be safe in my experience. Although every patient will develop hemoglobinuria for 24 to 48 hours after the procedure, no patient has needed periprocedure hospitalization or transfusion for bleeding. Third, it allows for the procedure to be performed within a 6-hour period, including the 2-hour postprocedure recovery, meaning the procedure can be performed in an ambulatory fashion both in the hospital or office-based lab.

CASE PRESENTATION

A 73-year-old man presented with a 1-week history of right leg swelling. He was initially admitted to the hospital for pain and swelling of his right lower extremity. He was started on anticoagulation and discharged after 3 days in the hospital. One day after his discharge from the hospital, he followed up with his primary care doctor, who continued him on anticoagulation and called for a consultation. After the initial phone call, the patient was scheduled to see me in the office 2 days later. During the office visit, he brought an outside ultrasound that showed that the DVT had extended into the external iliac vein on the right side. I performed an additional ultrasound approximately 1 week after his previous ultrasound, which showed that he still had occlusive thrombus in his external iliac and common femoral veins. The patient’s past medical history included hypertension and high cholesterol. He did have an inciting factor of a prolonged car ride approximately 4 to 5 hours.
the week prior to his admission. The patient was scheduled on an elective basis for two-part ambulatory venous thrombectomy in our office-based lab.

**TREATMENT TECHNIQUE**

The preoperative reassessment in our office-based lab confirmed that the patient was still having significant symptoms. He was brought into the procedure room, placed in the prone position, and given sedation and local anesthesia. Aggressive hydration was started, and ondansetron was given. The patient’s right popliteal vein was cannulated under ultrasound guidance with a micropuncture needle. Using the Seldinger technique, an 8-F sheath was placed into the right popliteal vein. Initial venography showed that he had extensive thrombus from his popliteal vein (Figure 1) extending into his external iliac vein (Figure 2). The 8-F ZelanteDVT catheter was then used to Power Pulse the entire 10 mg of tPA along the course of the thrombus (Figures 3 and 4). This was performed by passing the ZelanteDVT catheter to the central-most portion of the thrombus in the common iliac vein and starting Power Pulse from central vein to distal vein. After this was performed, a lytic catheter was secured in place, and the patient was taken to the holding area for lytic infusion of 1 mg per hour.

After approximately 2 hours, the patient was taken back into the procedure room, placed in the prone position, and an Amplatz wire was placed up into the inferior vena cava through his preexisting lytic catheter. Mechanical thrombectomy was performed through the length of the thrombus, starting central to distal for approximately 90 seconds. The ZelanteDVT catheter’s additional power and ability to control the direction of the thrombectomy within the vessel facilitated the ease of removing this extensive thrombus (Figures 5–7). After mechanical thrombectomy with AngioJet, repeat angiography revealed that there was what looked to be a narrowing (vs compression) of the right external iliac vein (Figure 8). Angioplasty was then performed on the lesion with a 12-mm angioplasty balloon (Figure 9). The angioplasty did not significantly change the appearance of the lesion, so we decided to place a stent. This was then postdilated with an angioplasty balloon. After placement and angioplasty, the stent looked well positioned and expanded (Figure 10). After the stent placement, repeat venography showed resolution in the narrowed area of the right external iliac vein (Figure 11).

Once the iliac and common femoral veins on the right leg were free of thrombus and the narrowing in the right iliac vein had been corrected, attention was turned to the popliteal and superficial femoral vein on the right side. Repeat venography showed that there was still some residual thrombus in the right popliteal and superficial femoral vein (Figure 12). This thrombus had a subacute appearance. In the past, after performing mechanical thrombectomy with the AngioJet and balloon angioplasty, I would normally have left this alone. This time, I decided to utilize the direc-
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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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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 review complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS AND USAGE

The Zelante® DVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including venous thrombus (DVT), from:

- Femoral and lower extremity veins ≥ 6.0 mm in diameter
- Upper extremity veins

The Zelante® DVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse™ technique for the selective 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
- Who cannot tolerate contrast media
- In whom the lesion cannot be accessed with the guide wire

WARNINGS and PRECAUTIONS

The Zelante® DVT 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.

- Do not use the catheter if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

- Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

- Do not use the catheter in patients with 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 in the carotid or cerebral vasculature.

- The Zelante® DVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.

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- Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

- The Zelante® DVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.

- Upper extremity peripheral veins were used during treatment of pulmonary embolism.

WARNINGs and PRECAUTIONS

Do not use the catheter in patients:

- peripher al vascular system.

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

- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute thrombosis. This is in addition to the heparin added to the saline supply bag.

- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) lists maximum recommended run times in a flowing blood field and total operating time for each vessel treatment setting. The expected hemoglobinuria should be monitored to manage possible renal, pancreatic, or other adverse events.

- 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 catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.

- The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra 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 - bleeding from access site
- Cerebrovascular accident - death - dissection - embolization, proximal or distal - hematoma - hemolysis - hemorrhage - intra-cranial hemorrhage - hypotension - hypertension - myocardial infarction
- Perforation - pseudoaneurysm - reactions to contrast medium - thrombosis/occlusion - total occlusion of treated vessel - vascular aneurysm - vessel wall or valve damage

SOLENT CATHETERS COMBINED W/CONSOLE

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INDICATIONS AND USAGE

The AngioJet® Solent™ Pro & 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
- Intracranial and lower extremity peripheral veins ≥ 4.0mm in diameter
- A-V access conduits

The AngioJet® Solent™ Data Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- Upper and lower extremity peripheral arteries
- Upper extremity peripheral veins ≥ 3.0mm in diameter

The Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

CONTRAINDICATIONS

Do not use the catheter in patients:

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

The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.

ADVERSE EVENTS

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

- Accessory veins and other vessels other than those specified, with the exception of accessories and cables
- Healthcare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra Console.
- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC). Equipment needs to be installed and put into service according to the EMC information provided in the IFU.

AMPLATZ SUPER STIFF GUIDEWIRE

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INTENDED USE/INDICATIONS FOR USE

The Amplatz® Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Use of the guidewire helps facilitate catheter exchange and manipulation in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.

- The guidewire is not designed to be used as a rapid exchange guidewire which meets resistance. Resistance may be felt tactually or noted by tip buckling during fluoroscopy. When used as a guidewire, the guidewire may not pass freely within the lumen (i.e. not against the vessel wall). Contents supplied STERILE using an ethylene oxide (EO) process.

- Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.

CONTRAINDICATIONS
None known.

WARNINGs:

- The device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures. Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

ADVERSE EVENTS

Potential adverse events which may result from the use of the device include but are not limited to:

- Air Embolism/Thromboembolism, Allergic Reaction, Amputation, Arterovenous (AV) Fistula, Death, Embolus, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Sepsis/Endocarditis, Myocardial ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transmural Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Trauma, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire

- Do not use if the stated potential adverse events may require additional surgical intervention.

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