Case Report: The ZelanteDVT™ Thrombectomy Catheter for Venous Thrombosis Extending From the Popliteal to External Iliac Vein

BY JEFFREY Y. WANG, MD, FACS

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 ago.
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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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Voltage mechanical thrombectomy ability of the ZelanteDVT catheter. After directing the removal window toward the area of residual thrombus for about 10 seconds, repeat venography showed complete resolution of the residual thrombus (Figure 13).

All catheters, wires, and sheaths were removed, and manual compression was held. The patient’s leg was wrapped in an elastic bandage from foot to mid-thigh. The patient was taken to the holding area and placed on bed rest for 2 hours. He received 1 L of additional normal saline intravenous fluids during that 2 hours. The patient was also encouraged to increase oral intake of fluids. The patient was continued on his anticoagulation and started on aspirin and clopidogrel. He received his postprocedural education and was discharged around 3:00 pm. The patient was contacted in the morning, and he reported that his hemoglobinuria had greatly improved, and his urine was almost normal in color.

He returned to the office approximately 2 weeks after his procedure and was essentially pain free, and his thigh and calf had returned to normal size. He will be continued on anticoagulation for at least 6 months, aspirin for life, and clopidogrel for another 2 weeks. The patient was also referred to a hematologist/oncologist for hypercoagulable testing and further workup.

CONCLUSION

I found that the ZelanteDVT catheter offered more powerful thrombectomy over the previous AngioJet catheters, allowing for faster extraction of the DVT with shorter run times. The ability to control the directional window can facilitate the removal of more persistent subacute thrombus as it did in this case. I believe that the ZelanteDVT catheter is a more purpose-built device that allows for greater ease in extraction of large vein thrombus.

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
The Zelante®DVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:

- Femoropelvic and lower extremity veins ≥ 6.0 mm in diameter
- Upper extremity peripheral veins

The Zelante®DVT Thrombectomy Set is also intended 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.

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.

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

Operative medical conditions may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vascular 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.

- 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 Zelante®DVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the AngioJet IFU.
- Systemic heparinization is advisable to avoid peripherocatheterization thrombus and acute thrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, allow the catheter to flex and release the arterial occlusion by 30 seconds before reintroduction to the patient or guide catheter as a unit to prevent rupture.
- Procedure guidelines recommend use of standard contrast medium can be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter while delivering fluid through the catheter stopcock.
- If the catheter is pushed past any of the electrodes, it may result in 10 to 20 seconds before reintroduction to the patient or guide catheter as a unit to prevent rupture.
- Please refer to the individual AngioJet Ultra Thrombectomy Set Information 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 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 or at the catheter tip. Ensure adequate patient anticoagulation to prevent thrombus formation in the outflow lumen.

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 - bleeding from access site
- Cerebrovascular accident - death - dissection - embolization, proximal or distal - hematoma - hemolysis - hemorrhage - hypoperfusion - infection - ischemia - myocardial infarction - occlusion - perforation - pseudoaneurysm - reactions to contrast medium - thrombosis/oclusion - total occlusion of treated vessel - vascular aneurysm - vascular spasm - vessel wall or valve damage

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 “Instructions for Use” for more information on Indications, Contraindications, WARNINGS, Precautions, Adverse Events, and Operator’s Instructions.

INDICATIONS AND USE
The AngioJet® solpro & omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- Upper and lower extremity peripheral veins 3.0mm in diameter,
- Upper extremity peripheral veins ≥ 3.0mm in diameter,
- Femoropelvic and lower extremity veins ≥ 6.0 mm 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® soldata Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:
- Upper and lower extremity peripheral arteries
- 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 IFU).

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 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 (unless accompanied by a heart catheterization).

OPERATIONAL CONSIDERATIONS
Operation of the AngioJet Ultra System may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vascular 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 IFU).

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 - bleeding from access site
- Cerebrovascular accident - death - dissection - embolization, proximal or distal - hematoma - hemolysis - hemorrhage - hypoperfusion - infection - ischemia - myocardial infarction - occlusion - perforation - pseudoaneurysm - reactions to contrast medium - thrombosis/oclusion - total occlusion of treated vessel - vascular aneurysm - vascular spasm - vessel wall or valve damage

AMPLATZ SUPER STIFF GUIDEWIRE
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 “Instructions for Use” for more information on Indications, Contraindications, WARNINGS, Precautions, Adverse Events, and Operator’s Instructions.

INTENDED USE/INDICATIONS FOR USE
The Amplatzer Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. The guidewire is not intended for use in concomitant angioplasty or stenting procedures. The tip of the guidewire is not designed to be employed in the coronary circulation. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.

- Do not use the guidewire if the tip is bent or kinked.
- Do not use the guidewire if the tip is not aligned with the vessel axis.
- Do not use the guidewire if there is a significant side branch or vessel spasm.

CONTRAINDICATIONS
None known.

WARNINGS:
None.

DO NOT use the device by physicians with a thorough understanding of angiography and percutaneous interventional procedures. Use extreme caution and careful judgment in patients for whom angiography 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, Arteriovenous (AV) Fistula, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, Infarction or Sepsis/Infarction, Myocardial ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Trauma, Vessel Spasm, Wire Entrapment/Entrapment, Foreign body/Wire

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

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