A 76-year-old woman was referred by her gynecologist for suspected left deep vein thrombosis (DVT). For 3 days, she suffered from severe left leg swelling and pain. On physical examination, the patient was obese (body mass index, 40.4 kg/m²) and had a painful and swollen left leg with no ulcerations.

DIAGNOSTIC EVALUATION

CT venography was performed, confirming the patient’s swollen left leg (Figure 1A) with an enlarged unenhanced femoral vein (Figure 1B). In order to secure the diagnosis of DVT, an ultrasound was performed, which showed hyperechoic acute thrombus in the left common femoral vein (Figure 1C). A multidisciplinary group decided to treat with pharmacomechanical thrombolysis for fast symptomatic relief and prevention of sequelae. Because only a small amount of thrombus extended into the inferior vena cava, no filter was implanted.

TREATMENT APPROACH

The procedure was performed under conscious sedation, and 5,000 units of heparin were administered intravenously at the beginning of the intervention. The patient was placed in a prone position on the angiographic table. Ultrasound-guided access into the popliteal vein was performed, and an 8-F sheath was inserted. The AngioJet™ ZelanteDVT™ thrombectomy catheter (Boston Scientific Corporation) was advanced into the thrombus, and 200,000 units of urokinase were injected into the thrombus using the Power Pulse™ spray technique. Because of the large vein diameter, the steerable option of the ZelanteDVT catheter was used to deliver the urokinase into the entire thrombus. After a dwell time of 20 minutes, the ZelanteDVT catheter was switched into thrombectomy mode, and the thrombus was aspirated for a total of 180 seconds. The rotation option of the ZelanteDVT catheter tip was used to direct the

Figure 1. Preinterventional workup with CT venography showing substantial left leg swelling (A) and an enlarged iliofemoral vein (B). Ultrasound confirmed the diagnosis of acute DVT (C).
thrombus removal power and clean the vein as completely as possible. A follow-up venogram showed successful thrombus removal within the left common femoral and left external iliac vein (Figure 2A); however, at that time, there was no flow because of the obstruction in the left common iliac vein due to May-Thurner syndrome. After stenting the left common iliac vein with a self-expandable nitinol stent and expanded to 14 mm, good venous outflow was observed (Figure 2B).

After the procedure, the leg was wrapped with compression bandages, and rivaroxaban was started the next morning. A control duplex examination the next day showed a widely patent common femoral vein with no residual thrombus and good venous flow with respiratory modulation (Figure 3). Clinically, the pain improved within 24 hours after the procedure, and the leg swelling resolved over the following week.

CONCLUSION

The removal of thrombus in a large vein was successful using the ZelanteDVT catheter with the Power Pulse spray technique followed by the thrombectomy mode using the Venturi-Bernoulli effect. AngioJet offers a variety of catheters for different venous and arterial thrombus applications. The newest addition, the ZelanteDVT catheter, offers the opportunity to remove thrombus from large venous vessels with a directional tip. It will be interesting to see if this new directional catheter will allow for consistent removal of thrombus from large vessels.

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INDICATIONS AND USAGE

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

- Iliofemoral and lower extremity veins
- Upper and lower extremity peripheral arteries
- Specified fluids, including thrombolytic agents, into the peripheral vascular system.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet 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).

INDICATIONS AND USAGE

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 other thrombectomy catheters were used without treatment of pulmonary embolism.

- 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 AngioJet IFU.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary or cerebral vasculature.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature unless accompanied by a separate coronary IFU.

- The ZelanteDVT Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can cause injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.

- Do not use the Power Pulse to deliver contrast medium through the catheter or via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.

- If the catheter is retracted inside the ZelanteDVT 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)

- Use of a tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a vessel perforation. Guide wire retraction over the catheter as a unit to prevent possible tip separation.

- If retraction 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.

- Careful attention must be paid to peripheral venous thrombectomy to ensure the catheter is not in the vessel wall.

- 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 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
- Hemorrhage
- Hemolysis
- Hypotension
- Hypothermia
- Perforation
- Pseudoaneurysm
- Thrombosis/occlusion
- Total occlusion of treated vessel
- 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 USAGE

The AngioJet SOLENT prox & 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
- Iliofemoral veins ≥ 3.0mm in diameter,
- Upper extremity peripheral veins ≥ 3.0mm in diameter,
- Ileofemoral and lower extremity peripheral veins ≥ 4.0mm in diameter,
- A-V access conduits ≥ 3.0mm in diameter.

- Upper extremity peripheral veins
- Iliofemoral and lower extremity peripheral veins
- A-V access conduits
- Peripheral veins

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
- Iliofemoral veins ≥ 3.0mm in diameter,
- Upper extremity peripheral veins ≥ 3.0mm in diameter,
- Ileofemoral and lower extremity peripheral veins ≥ 4.0mm 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 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.

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

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature unless accompanied by a separate coronary IFU.

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

- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, or if the catheter is not retracted as the catheter is advanced, re-check the lesion site to ensure blood flow is not being obstructed. 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.

- The Thrombectomy Set has not been evaluated for use in the coronary vasculature (unless accompanied by a separate coronary IFU).

- 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 other thrombectomy catheters were used without treatment of pulmonary embolism.

- 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 AngioJet IFU.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature unless accompanied by a separate coronary IFU.

- The ZelanteDVT Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can cause injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.

- Do not use the Power Pulse to deliver contrast medium through the catheter or via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.

- If the catheter is retracted inside the ZelanteDVT 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)

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- If retraction 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.

- Careful attention must be paid to peripheral venous thrombectomy to ensure the catheter is not in the vessel wall.

- 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 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
- Hemorrhage
- Hemolysis
- Hypotension
- Hypothermia
- Perforation
- Pseudoaneurysm
- Reactions to contrast medium
- Thrombosis/occlusion
- Total occlusion of treated vessel
- Vessel wall or valve damage

AMPLATZ SUPER STIFF GUIDewire

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INTENDED USE/INDICATIONS FOR USE


CONTRAINDICATIONS

None known.

WARNINGs:

- The Thrombectomy Set 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
- Thrombomicroembolism, Allergic Reaction, Amyloidosis, Arteriovenous (AV) Fistula, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Septis/Infarction, Myocardial ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transmural Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation/ Dissection/Throma, Vessel Spasm, Wire Entrapment/Entrapment, Foreign body/Wire

- Use of the stated potential adverse events may require additional surgical intervention.

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