CLEARING THE CLOT

MOVING BEYOND STANDARD DVT TREATMENT

Leading experts discuss the evolution of DVT treatment and the latest product advancements.
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The Need to More Efficiently Treat Large Vein Thrombus

BY MARK HILSE, MS

Over the years, physicians using the AngioJet™ Thrombectomy System for deep vein thrombosis (DVT) treatment expressed their need to more efficiently address the large thrombus burden that is often found in the iliofemoral veins. Specifically, physicians treating DVTs in the iliofemoral veins found that a significant number of cases still required an overnight thrombolytic drip to achieve a more complete resolution of thrombus. This resulted in the need for a new AngioJet catheter: the ZelanteDVT™ (Boston Scientific Corporation), with power that could remove the thrombus burden in large venous vessels, aiding in decreased treatment times.

DESIGN CONSIDERATIONS FOR THE NEW ANGIOJET CATHETER

One of the barriers to removing large, organized thrombus is the inflow window size of the current 6-F AngioJet catheters (Solent Omni and Solent Proxi). The unique mechanism of action within the AngioJet catheters is based on the high-speed jets that create a near-perfect vacuum to pull in and break up the thrombus. Because the inflow window size on the 6-F catheters only allows relatively small-sized thrombus to enter, Boston Scientific aimed to specially design a catheter to address large, organized thrombus burden, which meant having a larger inflow window. The resulting design demonstrated that having one large inflow window instead of three or four small windows, as on predicate catheters, enables this catheter to most optimally remove the thrombus burden found in larger iliofemoral and upper extremity peripheral veins. Because the inflow window pulls in thrombus from one side of the catheter, the outflow jet, which liberates the thrombus from the vessel wall, was shifted to the inflow window side of the catheter. Therefore, the design includes only one outflow window located on the same side as the large inflow window. The outflow jet is also more powerful than the 6-F AngioJet models, which aids this catheter in more efficient removal of tough thrombus from the vessel walls.

In addition, the unidirectional design of the windows drove the need for a rotating hub, so the single window could be swept around the vessel in order to clear thrombus on all sides. To facilitate improved visualization of the window orientation, a marker band was added opposite the window and is visible under fluoroscopy. When using the rotating hub, the inflow window directional design allows the user to direct the thrombus removal power where it is needed most. The Power Pulse™ feature remains on the ZelanteDVT catheter but is also directionally controllable, which may aid in more uniform distribution of the physician-specified fluid.

Lastly, from a design standpoint, a dedicated guidewire lumen was created to ensure that the 0.035-inch guidewire could not potentially exit through the now much-larger inflow window. Developing a catheter with a dedicated guidewire lumen also provides the user with easy guidewire exchanges and eliminates the need for a hemostasis valve. As a result, a larger 8-F lumen was required to accommodate these requirements.

THE ZELANTE DVT CATHETER WAS BORN

The AngioJet ZelanteDVT catheter design has a single inflow window with a surface area that is 60% larger than the combined area of four inflow windows on the Solent Omni and Proxi. The larger window combined with a more powerful outflow jet has created a catheter that can remove four times more thrombus* in the same amount of time as the Solent catheters.

With its more powerful action, it is limited to a minimum indicated vessel diameter of 6 mm, whereas the Solent Omni and Proxi are ideal catheters when treating vessels of 3 mm in diameter. Preclinical testing showed that in its vessel size range, the ZelanteDVT’s safety profile is the same as the Solent Omni catheter. Hemolysis with the ZelanteDVT is also similar to the Solent catheters for its respective indicated vasculature. Therefore, the ZelanteDVT catheter allows more efficient treatment of large DVT while maintaining its safety profile.

ZelanteDVT was designed specifically to fill an unmet physician need to address larger, more organized thrombus. This new catheter enables physicians to more efficiently treat large vein DVTs.

Mark Hilse, MS, is an AngioJet R&D Manager for Boston Scientific Corporation. He may be reached at mark.hilse@bsci.com.

Endovascular Management of Deep Vein Thrombosis: An Expert Panel Discussion

Endovascular Today met with a multidisciplinary panel of venous experts to discuss the current status of DVT treatment in the United States and abroad and how the field has evolved in the last 10 years.

EVT: What is the current state of deep vein thrombosis (DVT) treatment for the majority of patients in the United States?

Dr. Garcia: I think the current practice in many ways, somewhat disappointingly, is initially still the same [as it was 10 years ago]. Patients who have acute DVT receive standard-of-care medical treatment. I do think, however, we’ve come a long way in recognizing the benefits of techniques like pharmacomechanical thrombolysis as well as catheter-directed thrombolysis in aiding these patients and improving their quality of life at the time, but I still think that we have a long way to go. Thankfully, the ATTRACT trial has completed [enrollment], which hopefully will show the benefit of aggressive management with endovascular techniques for DVT.

Even in our institution, where we’ve developed pretty good algorithms for DVT, there is still a significant...
number of patients who receive standard of care despite extensive clot—it really depends on who happens to see them up front. Across the country, I’d be amazed if it’s more than a third of the DVT population who could benefit from it who actually receives aggressive DVT therapy.

Prof. Kucher: Switzerland has improved a little bit. It’s a conservative country, but we have done a lot of work on increasing awareness for DVT, and now we see more patients being referred for catheter-directed thrombolysis and stenting. When we go back 10 or 15 years ago, we were not really aware of the clinical problems of iliofemoral DVT, and we underestimated the risk for these patients to develop postthrombotic syndrome (PTS). Now, I think our knowledge has improved over the last 10 years, and we know that half of the patients at least have an increased risk of developing PTS if they are not being treated.

Ten or 15 years ago, we went out and told our primary care physicians that we don’t want to have these patients in the hospital because we had low-molecular-weight heparin and compression treatment, and we have not seen these patients in the hospital because they were managed as outpatients. They were diagnosed and managed by vascular specialists in private care. Now, I think it’s our job to go out again and say, “We want patients with iliofemoral DVT back in the hospitals because there is more to do than just anticoagulation and compression therapy.”

Dr. Lookstein: I would echo Dr. Garcia and Prof. Kucher’s points—I think there is, unfortunately, only a minority of patients in the greater New York City area who are being treated with aggressive therapy. I would be surprised if it’s greater than 10% of patients with symptomatic lower extremity DVT who were being treated [endothrombolitically]. One of the major drivers has been a transition to outpatient treatment of DVT. There is not a tremendous public awareness campaign about options that patients can have, and certainly that public awareness campaign hasn’t filtered out to primary care physicians or primary hematologists who might be managing these patients in an outpatient setting. I think it behooves all of us as vascular specialists to take that as a challenge to generate data.

There is still a huge opportunity to educate primary care physicians, internists, and hematologists about the risks to their patients. A significant percentage of patients who I see in my practice are learning about these risks on their own, largely due to social media, which is a sad state for the level of public awareness about the potentially devastating consequences of PTS.

Dr. O’Sullivan: Most of the time, the focus of the internal medicine specialist or hematologist is not about the patient’s leg, it is about the side effects from the medication. [The patients are] asked, “How are the tablets going? Any interactions? Any drug rashes?” Way down the list is, “How’s your leg?” and when the [patients] do tell them about the leg, the [physicians] say, “Oh, well that’s not my area, we’ll have to refer you on.”

Prof. Kucher: I think that’s very much true. I’m often invited to controversy sessions and speak in favor of catheter-directed thrombolysis and stenting, and I’m having difficult discussions with the contrasting speakers because what I often hear from them is that we overestimate PTS. They say it’s probably less than 10%, and that’s the problem—they don’t even check the leg symptoms or look to see if the patient has swelling. There’s an additional point: Patients in the early stages of PTS have difficulties explaining their symptoms. Sometimes, you find that they gain weight, they exercise less, but you don’t see much on the leg. Often, the leg is not even very swollen. Now imagine a physician has on the last of his list of priorities to check for symptoms and signs of PTS—then it’s no surprise to me that it’s underestimated. Our conservative colleagues are convinced that we exaggerate the problem, and this is the main concern I have for the future.

EVT: What is the referral pattern for your practice? Where are the DVT patients coming from?

Dr. Wang: That’s probably been the biggest change over the last half a decade. There [used to be] a lot of referrals for DVT that came through the hospital, where the patients were initially sent. [A vascular surgeon] would potentially capture some of the patients that need intervention at that point because you’d be asked to see them and may even be involved in their anticoagulation regimens.

The referral pattern now typically comes through the outpatient setting. A primary care physician may see the patient and say, “Hmm, this patient has a swollen leg,” so we make ourselves available to do ultrasounds so the patients will find their way to our office.

I started doing thrombectomy procedures for iliofemoral DVTs [in patients in the hospital who were having difficulty walking]. The patients would then go back to their primary care doctors, and I would seize every advantage or opportunity to help with the education process. I would go out and essentially do grassroots educational programs in doctors’ offices, which is ultimately how we were able to build a referral base for these types of procedures.
Dr. Lookstein: One thing I would add is that the major transformation in primary care physicians’ and internists’ willingness to accept this aggressive procedure is a commitment to provide it in the ambulatory setting. Historically, when we all used to treat patients with DVT 15 years ago, that required an inpatient stay of 2 to 3 days on average, sometimes much longer. Because this procedure using pharmacomechanical techniques is an outpatient procedure, there has been a greater acceptance of the procedure’s benefits for the patient population at large and a lower threshold to refer patients. When they know the patient will be home the same day and be safe, referring physicians feel much more comfortable sending the patients to you.

Dr. Garcia: In our institution, I found that by educating the hospitalists (because the hospitalists do the admission and initial patient evaluations), they’re much less resistant to endovascular therapies for people suffering from acute DVT. The amazing thing I find is that the hematologists still resist, despite the fact that every one of them had patients who were dealing with extensive DVT and phlegmasia whom we’ve treated and had great successes. Their field in general, like oncology, is very scientific, and they need tens of thousands of patients to show a benefit in randomized trials to convince them differently.

Many of the referring physicians don’t recognize that by the advancement of our pharmacomechanical and debulking techniques, we’ve limited the amount of tPA. They keep bringing up numbers of giving tPA with astronomical bleeding rates, which we just don’t see. There’s been some ignorance to what we’ve actually been able to obtain across the world with these newer techniques.

EVT: What is your preferred treatment algorithm when a DVT patient comes to your office?

Dr. Garcia: If they’re not suffering from phlegmasia], usually we do serial ultrasounds for several weeks [to see if they are resolving the clot] … but we found that if we get to [these patients] within 4 weeks, we’re almost always successful in completely recanalizing and resolving the clot.

Once we know we’re going to treat, we get every patient on Lovenox starting the day before, and we use a technique called “rapid lysis” that we’ve been doing since 1997. We think that [technique] has completely changed our ability to rapidly restore flow, get wall-to-wall apposition, clean out the vast majority of clot, and preserve the vein function, as well as the valve function. In over half of our population, [we perform a single] session, and those who may undergo additional catheter-directed therapy, it’s for a short period of time because you’ve debulked the clot. That technique, spiraling through the venous system and through the clot, is really our mainstay of treatment and has worked incredibly well.

Prof. Kucher: First of all, we have to say that not all DVT patients are candidates for interventional treatment. We have a flow chart in our hospital emergency department across all walls. When there is a DVT diagnosed in which the upper leg is swollen and at least the common femoral vein or a higher-located vein is thrombosed, those patients are candidates for interventional treatment, which I would say is approximately 20% of all DVTs. Most DVTs are confined to the thigh or the lower leg, and those patients are not candidates for interventional treatment because their risk of PTS is very low. We have learned that the common femoral vein is the most important functional inflow vessel, where three veins of the leg come together. Functionally, if this vein or a higher vein is thrombosed, those patients have the highest risk of PTS. It’s fivefold higher than when any other vein is thrombosed, and those patients should be treated.

We just published our series of 90 patients with iliofemoral DVT. In most cases, we use catheter-directed thrombolysis and a fixed-dose regimen of tPA (20 mg over 15 hours), and then we bring the patient back to the cath lab and do a venogram. Our stenting rate is 80%; I think this is a very critical point because one of the problems from earlier studies was that the stenting rate was very low. For example, in the CAVENT study, it was 17%, and that’s the main reason that one-third of the vessels were closed at 6 months, and their PTS rate was 40% in the treated arm. In our series, the patency rate at 1 year was 96%, and the PTS rate was 6% and only mild PTS forms.

Dr. Lookstein: Most patients who are seeing me in the office have already received medical therapy and don’t feel that it’s giving them enough symptomatic relief. If patients come into my office seeking more aggressive therapy or if they’ve told their primary care provider they want more aggressive therapy, as part of the consent process of reviewing their options, we typically risk stratify them by obtaining cross-sectional imaging of their pelvis and lower abdomen to determine whether or not there is a mechanical cause for their iliofemoral DVT.

In the majority of patients with symptomatic iliofemoral DVT, there is, in fact, a mechanical cause,
and that goes into the risk stratification conversation. Most times, when patients find out that they do have a mechanical cause for their DVT, they’re much more enthusiastic about having that mechanical cause corrected, and they’re willing to undergo the pharmacomechanical thrombectomy procedure.

These procedures are scheduled electively based on the patient’s convenience. Typically, the patients will come in early in the morning and have a fairly rapid Power Pulse™ spray thrombectomy procedure that usually takes about an hour, and then they’ll go to our recovery room and receive a short duration of catheter-directed thrombolysis for anywhere from 4 to 6 hours. Then they’ll come back into a procedure room and have the offending lesion, typically in the pelvis, corrected with a stent, as Prof. Kucher mentioned. As soon as the stent is implanted and it’s dilated, all the sheaths and equipment are removed from the patient. They will get an injection of Lovenox, as Dr. Garcia said, and they’ll go home in a few hours.

Dr. O’Sullivan: That’s exactly where we should be going in my view—we want this to be a 1-day case, we want it to be safe; it is safe. Cross-sectional imaging looking for an offending lesion typically near the confluence of the iliac veins is critical. Once you get the thrombus out and you stent that lesion—and the vast majority of patients do need a stent—their leg is almost normal in a day or two, and they go back to full activity quickly.

Dr. Wang: I [treat my patients] in an office-based lab, so there are some considerations that you need to make sure you take there. I also Power Pulse™ lytic, leave a lytic catheter mainly to hold my place, put the patients in the holding area, do some other cases, and then bring them back and do secondary intervention.

The most important thing in making sure you have a successful, stress-free experience for your patients is to make sure that you give them significant education that their urine will turn brown or red, and that they need to be well hydrated so it disappears in 24 hours. For male patients, this is exceedingly important. If they do not stay well hydrated, there are untoward complications you can have that you don’t want.

Dr. Garcia: I have only one additional cautionary comment: in patients who present with either chronic or acute renal insufficiency, we back off from doing pharmacomechanical therapy only because of the risk of worsening their renal condition. We have found that clearly there is a direct correlation to worsening kidney failure and using pharmacomechanical technique. In that population, we may go to the “standard of care,” if you want to call it that, with catheter-directed lytic therapy to try to obviate any of the renal complications that may occur from hemolysis and hemoglobinuria.

Prof. Kucher: I also have one additional cautionary comment on sending patients home after thrombolytic therapy the same day. If you do catheter-directed thrombolysis with 50 mg over 50 hours as it was done in the CAVENT study, there was a major bleeding rate of 9%. This is one of the reasons our medical community is still conservative and says, “For stable disease like DVT, if you have a major bleeding rate of 9% with your intervention, then we will not refer patients to you.” They are correct, and that’s why if you do catheter-directed thrombolysis, you should stop your treatment and terminate your lysis at 24 hours, maybe even earlier. We stop at 15 hours in all cases, but you still have a 2% to 3% major bleeding rate if you do this. Especially if you also treat fragile patients, those with an increased risk of bleeding, or those who had postsurgical thrombosis—there is a risk of bleeding, and I would not send patients home the same day who have received thrombolytic treatment. This is a potentially dangerous drug, and I will always keep the patients in the hospital at least one night, even if I have done a single-session procedure.

EVT: How has the new 8-F AngioJet™ ZelanteDVT™ Catheter (Boston Scientific Corporation) impacted your practice so far?

Prof. Kucher: I see an advantage in comparison to a 6-F device. I have the feeling it’s more powerful, not only because of the bigger device lumen, [but also the] rotational thrombectomy. With the [other] current devices, you are not able to torque the device and change the angulation where the clot is being sucked in at the tip. I think it’s very important because in many cases, the catheter is not centrally located in the vessel, and often the catheter is at the vessel wall. Now, by changing the angulation of the device, you will reach the clot even in eccentric positions of your device. I think this is probably one of the main advantages that [makes] the 8-F ZelanteDVT catheter more effective. Especially in combination with Power Pulse™ thrombolysis, I think the device is very effective.

Dr. Lookstein: I think the new catheter is uniquely designed to address the anatomic issues that we’re facing as we move more proximally in the lower extremity. In the last several years, we’ve been able to identify that
the iliac vein diameter, especially in the setting of acute thrombus, can range anywhere from 14 mm to even 20 mm. There was clearly an unmet clinical need for a catheter with the ability to extract clot from a large luminal surface.

The 8-F system is clearly moving toward addressing that space, and the goal is that you’ll be able to extract a greater percentage of the thrombus in those patients in a single session. I think the goal here is to try and get 90%-plus clot removal using a reliable, efficient method. This is a step in the right direction.

**Dr. O’Sullivan:** It’s been very successful. Dr. Garcia showed me that by putting the 6-F AngioJet device inside an 8-F torque catheter, you could generate what I would call *rotational thrombectomy*. A lot of the focus at the moment in arteries is directional atherectomy—this is directional thrombectomy. With the 8-F device, you can do it without the 8-F catheter as an adjunct, and you can get over 90% [clot removal] in probably under 20 minutes.

**Dr. Wang:** I do think that being more confident in the device’s ability to extract thrombus may lead toward modification to what we do now. As the technology progresses, people are going to modify their practice patterns if given additional tools to do better in that situation.

**Dr. O’Sullivan:** [For me to change my practice pattern], it really has to happen in 2 hours. ICU beds are very difficult to come by. What they do in Bern as Professor Kucher describes, where the patients stay overnight … is a great technique, I just don’t have access to it. So for me, it has to work in 2 hours, and it does with this.

**Dr. Lookstein:** I think that any time you’re admitting somebody overnight, it accelerates the cost of the procedure so much that it becomes unpalatable to a health care delivery system. The only way that this is going to catch on, if you want to look at health care economics in the United States, is to move it into the ambulatory space. If you are not utilizing such intensive hospital resources, then it becomes palatable to a health system.

**Dr. Garcia:** Early results suggest a more efficient thrombus removal aided by the size and directionality of the catheter. This highlights a very important point in our data review. One of the things that we looked at was the cost benefit of a successful single-session pharmacomechanical thrombolysis versus the cost of overnight lytic therapy in the ICU compared to infusion in our step down… Everyone who has done these procedures knows that infusions can sometimes go 2 or 3 days in those who don’t use pharmacomechanical techniques. All of our patients for the last 3 or 4 years have gone to the vascular floor bed—they no longer go to the ICU for overnight infusion if it happens.

One thing we looked at was the [single] session, which is what the AngioJet rapid lysis technique was allowing us to do, and we calculated the cost savings, since one of the complaints that has been written about is the upfront cost of these devices. We found that in 147 patients, if you were to take that single session and do an overnight infusion, we were seeing an approximate savings of $1.5 million—just in that small population.

The benefits from increased upfront costs of using this device can be seen downstream by minimizing the need for catheter thrombolysis by increasing the efficiency of pharmacomechanical thrombolysis as is seen early with the ZelanteDVT.

**Dr. Lookstein:** The cost of an ICU [stay] can be upwards of 10 times the cost of a thrombectomy catheter—that’s the hidden truth. So you’re paying a slight modicum of cost up front, but you’re saving a tremendous amount by keeping the patients’ care at the same level of intensity and not escalating their care overnight.

[The CAVENT trial] really answered the open vein hypothesis. Patients with an open vein did dramatically better in terms of their quality of life afterward. How can we get more patients’ veins open to improve their quality of life? At least among the practitioners here, I think that involves the use of a thrombectomy system. ■
Case Report: Significant Removal of Fresh Large-Vessel Thrombus With the New 8-F AngioJet™ ZelanteDVT™ Catheter

BY ERIC G. SCHOCH, MD, AND CHRISTOPH A. BINKERT, MD, MBA

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.

Eric G. Schoch, MD, is Senior Consultant of Interventional Radiology, Institute of Radiology and Nuclear Medicine, Kantonsspital in Winterthur, Switzerland. He has stated that he has no financial interests related to this article. Dr. Schoch may be reached at eric.schoch@ksw.ch.

Christoph A. Binkert, MD, MBA, is Director, Institute of Radiology and Nuclear Medicine, Kantonsspital in Winterthur, Switzerland. He has disclosed that he is a consultant to Boston Scientific Corporation. Dr. Binkert may be reached at christoph.binkert@ksw.ch.

References
Clearing the Clot

His 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-
Clearing the Clot

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Jeffrey Y. Wang, MD, FACS, is a Partner of Horizon Vascular Specialists and the Director of Vascular Research for Shady Grove Adventist Hospital in Rockville, Maryland. He has disclosed that he is a consultant for Gore & Associates and a speaker for Boston Scientific Corporation and Cardiovascular Systems, Inc. Dr. Wang may be reached at jeffrey.y.wang@gmail.com.

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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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

WARNING 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 other thrombectomy catheters were used during treatment of pulmonary embolism.
• The use of the ZelanteDVT Thrombectomy Set has not been evaluated for use in the carotid or cerebrovascular system.
• The Thrombectomy Set has not been evaluated for use in the corona.
• 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 AngioJet Ultra System IFU.
• Systemic heparinization is advisable to avoid percutaneous thrombosis 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, the catheter should be flushed with saline solution at the access site, prior to removal of the catheter.
• 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 potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Set is 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 - hemotoma - hemoptysis - hemorrhage - hypotension/hypertension - hypotension/hypertension, death/embolus/tissue necrosis

CAUTION:
• Do not reposition or push the console from any point other than the handle designed for that purpose. A ping or pinching fingers during operation and care must be exercised to avoid injury.
• Do not bypass any of the Console safety features.
• If the catheter is removed from the patient and/or is nonoperative, the waste lumen, catheter guide, and waste tubing should be flushed with saline solution to clear any thrombus from the catheter set 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 guide catheter as a unit to prevent backstreaming of thrombotic particulate debris.
• Do not attempt to bypass any of the Console safety features.
• To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protection against electric shock.
• Do not use the ZelanteDVT Thrombectomy Set with any fluid containing alcohol or alcohol-containing compounds as it may cause degradation of the device and associated components. Do not use 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.
• None known.

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• 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 run. Discontinue the operation if the patient's risk tolerance and renal function are contrary to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's 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 thoracic, debifluid flow exiting the Thrombectomy Set via the waste tubing during use.

This material is not intended for use or distribution in France.
ZelanteDVT offers the strongest thrombus removal for large vessel DVT treatment.* Power Pulse™ enabled and 8 F in diameter having four times the removal power of previous AngioJet catheters – ZelanteDVT puts you in the position to dominate DVTs.

See ZelanteDVT in action:
bostonscientific.com/zelanteDVT

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only.
Please see page 14 for Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.
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