

The Trellis System for DVT Treatment

A guide to isolated, single-session, pharmacomechanical thrombectomy using the Trellis-8 peripheral infusion system for acute DVT treatment.

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The standard of care for acute deep vein thrombosis (DVT) is systemic heparin administration followed by oral anticoagulants. This treatment aims to lessen both clot propagation and the risk of pulmonary embolism (PE). However, this approach has been challenged because rapid symptom resolution does not often occur, with secondary complications being quite common. This is because anticoagulants alone do not lyse thrombus, and in fact, the fate of the clot depends on the vein's intrinsic fibrinolytic functions. Large clot burdens, particularly in the iliofemoral system (Figure 1), often overwhelm these mechanisms, leaving residual thrombi that can lead to venous hypertension and postthrombotic syndrome (PTS).

Catheter-directed and, more recently, pharmacomechanical thrombolysis (PMT) have been shown to debulk thrombus faster and may reduce recurrence and PTS. Currently, in the United States, the PMT devices most frequently used include the Trellis-8 system (Covidien, Mansfield, MA), the AngioJet Ultra thrombectomy system (Medrad Interventional, Indianola, PA), and the Ekos ultrasound accelerated thrombolysis device (Ekos Corporation, Bothell, WA). The use of the Trellis-8 peripheral infusion system during single-session PMT combined with tissue plasminogen activator administration is our preferred approach for treating patients with acute iliofemoral DVT.

The Trellis-8 peripheral infusion system is an isolated thrombolysis catheter with two occluding balloons, drug infusion holes between the balloons, and mechanical drug dispersion capabilities. Some of the challenges with the Trellis-8 system and other pharmacomechanical devices is that they can require 24 hours or more of adjunctive catheter-directed thrombolysis, thus requiring access to a monitored bed, multiple trips to the suite to assess progress, prolonged bed rest, patient discomfort, large doses of tissue plasminogen activator,

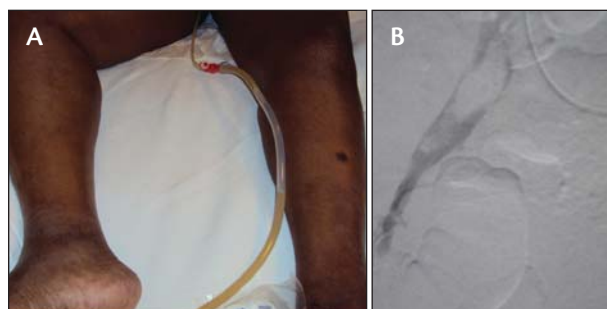


Figure 1. A 61-year-old woman with severe swelling of the right lower extremity caused by iliofemoral DVT (A). Venography shows a large filling defect within the lumen of the right common iliac vein with stenosis at the level of the right external iliac vein (B).

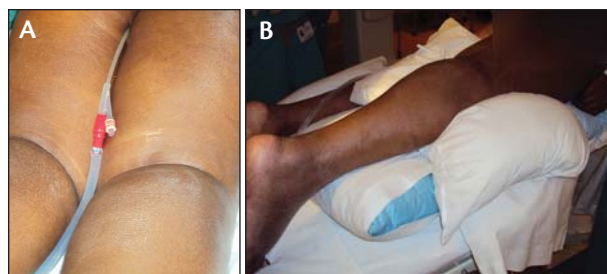


Figure 2. The patient has been endotracheally intubated and subsequently placed in the prone position for percutaneous access of the popliteal vein (A). Her right knee has been propped up with several pillows to raise the popliteal vein closer to the skin level for easier access (B).

and multiple laboratory blood work evaluations. During the last 3 years, we have modified the use of this device to minimize those shortcomings. In fact, this modification has allowed us to perform some of these procedures in the ambulatory setting. Starting in July 2008, we have followed our modified protocol in more than 140 patients affected by DVT in both upper and lower



Figure 3. Ultrasound-guided access to the right popliteal vein is being achieved. The ultrasound image shows an enlarged popliteal vein as a consequence of the presence of intraluminal thrombus, which facilitates percutaneous access. The popliteal artery, typically located below the vein level with this approach, is also shown.



Figure 4. A short, 8-F sheath is now in place, and a soft Glidewire (Terumo Interventional Systems, Somerset, NJ) is used to traverse the thrombosed venous segment.

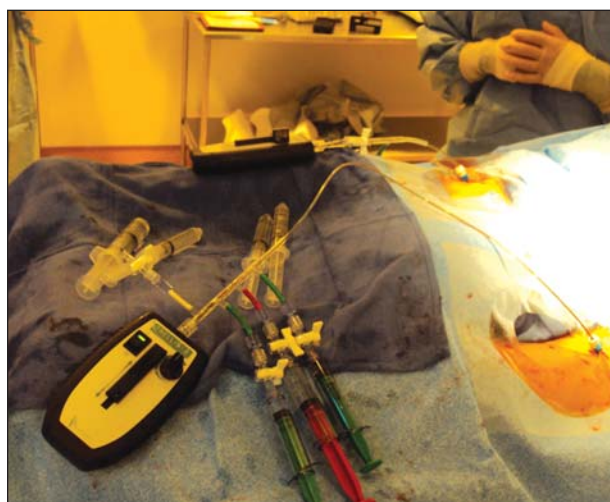


Figure 5. A patient with an inferior vena cava (IVC) occlusion secondary to a thrombosed IVC filter (IVCF) in which bilateral Trellis devices have been advanced to achieve larger luminal clearance.

extremities. These patients are currently being followed in order to describe the effects of thrombus removal using our technique on the subsequent development of PTS; this article details our technique.

PROCEDURE

Our cases are performed in a hybrid operating room suite or in a cardiac catheterization laboratory under general anesthesia and in the prone position (Figure 2). In some patients with prohibitive surgical risk, we have successfully performed the procedure under conscious sedation. It is not necessary to stop the anticoagulation regimen that has been chosen for a particular patient.

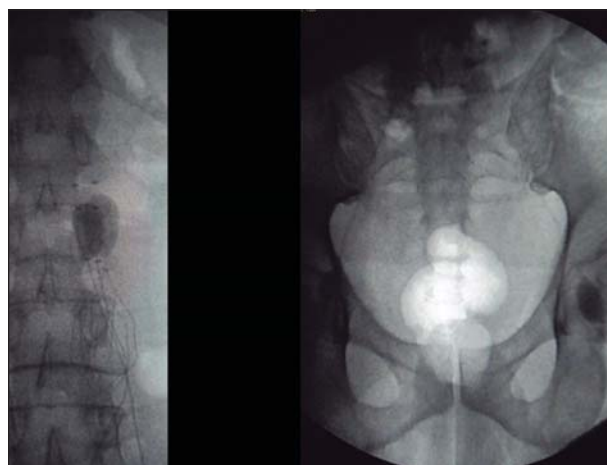


Figure 6. Proximal and distal balloons are now inflated in this patient who is undergoing venous thrombectomy for an IVCF occlusion. The distal balloon has been inflated above the occluded IVCF, and by using a 30-cm Trellis device in this particular case, the proximal balloons are inflated in the junction of the distal external iliac with the common femoral veins bilaterally.

An ultrasound-guided ipsilateral antegrade popliteal vein approach is preferentially used (Figure 3). In the case of an acute popliteal clot, vein wall dilation caused by thrombotic intraluminal material makes access relatively easy to perform, even in cases with occlusive thrombus in which a wire can be easily negotiated through. To facilitate access, the ipsilateral knee is propped up with several pillows to raise the popliteal vein closer to the skin level (Figure 2). Micropuncture kits are generally used. Often, more than one 0.018-inch microwire is used in the process. Once access is obtained, an 11-cm-long, 8-F sheath is used (Figure 4). Typically, a soft 0.035-inch Glidewire is used to traverse

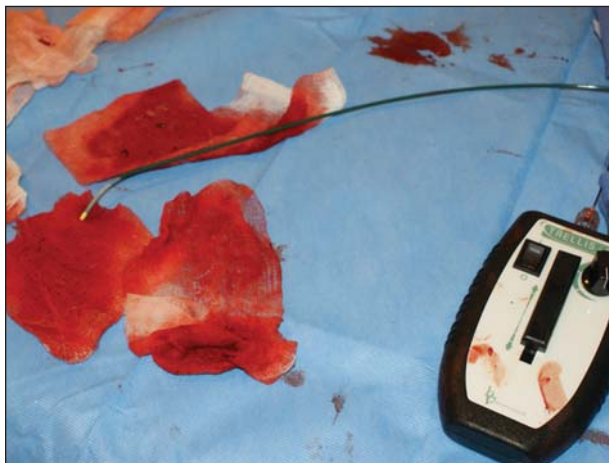


Figure 7. The multipurpose catheter can be seen along with the gauze used to strain the blood retrieved with the catheter. Some of the gauze is shown containing some thrombus.

the entire thrombosed vein, advancing the wire all the way up into the IVC. Intravenous heparin is given up to the physician's discretion, considering preoperative anticoagulation levels.

Insertion of an IVCF through the same venous access is a must while performing our modified technique. Given considerable thrombi manipulation during the procedure with the ensuing increased embolic risk, the use of a temporary IVCF is suggested to prevent PE during and after the procedure. We routinely use the self-expanding, retrievable OptEase IVCF (Cordis Corporation, Bridgewater, NJ). Even though the trapezoidal filter configuration is not our preferred filter design due to its alleged higher thrombogenicity, it is our preferred IVCF for this approach because it allows placement from the popliteal area, given its long 90-cm deployment shaft.

In an average-height patient, however, it is conceivable to deploy the Celect IVCF (Cook Medical, Bloomington, IN) from the knee, given a 65-cm deployment shaft, which should reach the perirenal vena cava in most cases. Alternatively, percutaneous ipsilateral antegrade distal femoral vein access of the popliteal vein under ultrasound guidance could be used instead to gain some length for IVCF deployment until longer deployment shafts with the Celect filter are available. We are currently in the process of incorporating this alternative access site into our procedural protocol.

Next, serial iodinated contrast injections are administered to show proximal and distal clot extent, which will determine the length of the Trellis-8 device to be used (10-, 15- or 30-cm treatment lengths) (Figure 5). The occluding balloons (which, by isolating the clot, minimize systemic lytic release and reduce distal embolization potential) are now inflated (Figure 6).

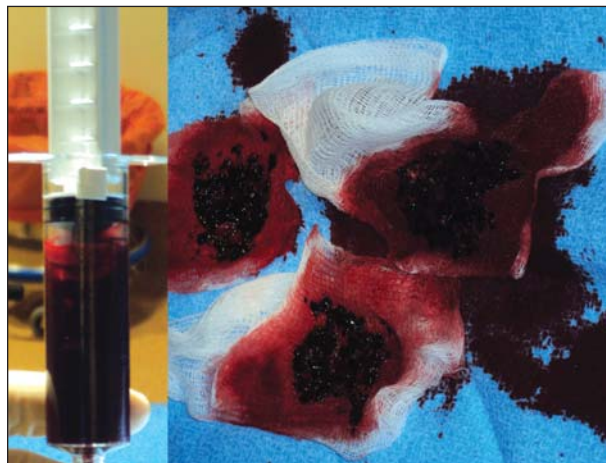


Figure 8. Typical amount of blood thrombi retrieved per session. The dark color of these clots indicates the acuteness of the thrombotic process.

Depending on clot length, one or two runs of the Trellis-8 device are performed. After the dissolution and aspiration of the acute clot through the Trellis catheter, at times, subacute thrombi may remain. These need to be removed to obtain optimal results. With this in mind, a 7-F multipurpose catheter (MPC, Cook Medical) is used to perform suction of the more organized thrombi (Figure 7).

A 60-mL syringe is attached at the end of the MPC, and several passes are made through the entire thrombosed segment under constant suction, with frequent contrast injection checks in between suctions to monitor progress. These passes need to be made very carefully, keeping in mind the orientation of the venous

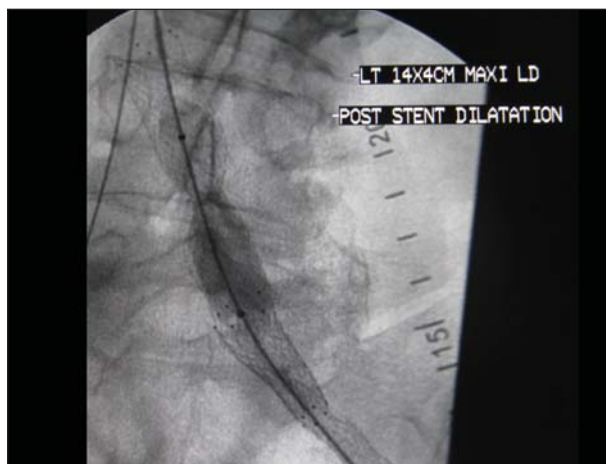


Figure 9. A stent has been placed in a 69-year-old woman who was affected by a chronic left lower extremity DVT secondary to May-Thurner syndrome. A typical "waist" is seen along the length of the stent caused by the chronic compression of the left common iliac vein by the right common iliac artery.



Figure 10. Typical satisfactory results achieved with the Trellis-8 device in a single-session therapy with achievement of venous patency of $\geq 75\%$ (in this case, of the left common iliac vein), with antegrade blood flow to the IVC.

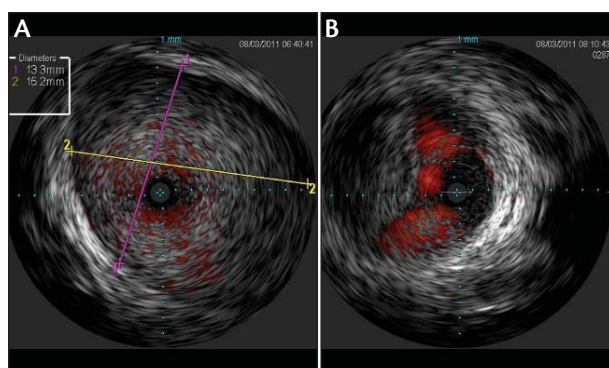


Figure 11. The use of intravascular ultrasound has recently been incorporated into our protocol. It allows clear visualization of the thrombotic material within the venous lumen before (A) and after therapy, minimizing the use of iodinated contrast, as well as allowing precise venous caliber measurements (B). The latter is very useful in cases when angioplasty or stenting are needed to achieve optimal results.

valve cusps. After each pass, the collected blood and clots are strained with 4- X 4-cm gauze (Figure 8). The unclotted blood is returned to the patient's veins to avoid exsanguination. The use of the MPC to extract thrombi may cause them to fragment, thereby resulting in PE. The previously placed IVCF protects from this catastrophic event. To further reduce the risk of PE during catheter passage, the patient is asked to perform Valsalva maneuvers, if awake, to increase central venous pressure. Any residual venous defects (ie, stenosis, extrinsic venous compression) are then treated with angioplasty or stenting as indicated (Figure 9).

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We consider the achievement of venous patency of $\geq 75\%$ with antegrade blood flow to the IVC optimal, as measured by completion venography (Figure 10) or intravascular ultrasound (Figure 11). After this is accomplished, the sheath is removed, and pressure is applied over a V+Pad noninvasive hemostasis pad (Angiotech, Vancouver, BC, Canada) for 10 minutes, which generally achieves perfect hemostasis. Patients are often discharged after 2 hours of bed rest. Thigh-high compression stockings are applied at case completion and prescribed at discharge for a minimum of 2 years after the procedure to further diminish the chances of future PTS. Clinical follow-up is scheduled 2 weeks after the procedure. During this visit, the IVCF removal is scheduled, often within 4 weeks after thrombectomy.

CONCLUSION

The Trellis-8 peripheral infusion device is a minimally invasive tool that allows safe, rapid, and effective clearance of thrombi in the venous system for acute or even subacute iliofemoral DVT cases. This procedure can often be performed in a single session, even in the ambulatory setting. ■

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