A Technique for Enhanced Distal Embolic Protection in the Endovascular Treatment of Iliofemoral Thrombosis With the Trellis Device

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ABSTRACT: Patients with acute limb ischemia (ALI) require rapid evaluation and emergent definitive therapeutic intervention in order to ensure viability of the affected limb. Catheter-directed therapy is the preferred modality to reperfuse threatened peripheral arteries. Among patients with pre-existing severe atherosclerotic lower extremity peripheral artery disease, the potential of distal embolization can have grave consequences, including ALI or even limb loss. As such, this paper proposes a novel technique of enhanced embolic protection that combines use of the Trellis-6 with the SpiderFX Embolic Protection Device (Covidien) to mitigate this devastating outcome.

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The Trellis-6 Peripheral Infusion System (Covidien) has greatly improved the endovascular armamentarium for treating patients with acute limb ischemia (ALI) or critical limb ischemia (CLI) secondary to arterial thrombosis. The Trellis-6 is used as a pharmacomechanical instrument for treatment of peripheral venous and arterial thrombosis. It has the unique advantage of delivering targeted thrombolytic therapy coupled with maceration of thrombus, without systemic effects of the thrombolytic agent while minimizing the risk of distal embolization of clot. While the incidence of embolism is rare, it has been reported to occur in up to 11% of cases.¹

The Trellis Peripheral Infusion System is designed to treat arterial beds with acute/subacute thrombotic occlusions and is comprised of an oscillation drive unit (ODU), a side-hole infusion catheter with occlusion balloons anchored on each end, through which the thrombolytic agent can be delivered to the isolated segment of the vessel without systemic effects (Figure 1). Traditionally, the device is advanced over a standard 0.035” wire to the target lesion. Once in position, the balloons of the device are inflated to isolate the treatment zone and a desired dose of tissue plasminogen activator (tPA) is infused into this localized area. The 0.035” guidewire is then
removed, the device oscillating wire is introduced, and the Trellis is powered on from the ODU. Once the intended duration of treatment is completed, the wire is removed and aspiration is performed through the port designed for this purpose. The proximal and distal balloons are deflated in a sequential fashion and the device is removed. This is followed by treatment of any residual disease in the affected vessel or vessels by way of percutaneous transluminal angioplasty (PTA) with provisional stenting.

One potentially serious limitation of this technique and device is the risk of distal embolization of residual clot in the treatment segment after deflation of the balloons. The incidence of this complication may be as high as 11% and may increase not only the duration and cost of treatment, but also the risk of limb threatening ischemia. We propose a technique that enhances embolic protection and allows an opportunity to minimize the aforementioned risks.

The ODU of the Trellis unit can be detached from its catheter, and through the catheter lumen the SpiderFX Embolic Protection Device (Covidien) and its delivery sheath can be advanced “bareback” or over a 0.014” guidewire distal to the catheter tip (Figure 2). The operator may encounter minimal resistance as the filter/sheath unit exits the end of catheter due to its hemostatic valve, but nevertheless this can be deployed in standard fashion in the distal vascular bed. Once the filter is in its appropriate location, the aspiration port of the Trellis-6 is suctioned accordingly, the proximal and distal balloons are deflated sequentially, and the Trellis catheter is removed over the SpiderFX wire. Any residual thrombus or microparticles that embolized are successfully trapped in the basket of the SpiderFX filter,
attenuating the risk of jeopardizing distal vessel blood flow. The SpiderFX is retrieved in standard fashion and examined for debris.

The following cases describe the critical importance of providing the additive protection of the Trellis-6 with the SpiderFX filter in two patients with thrombosed superficial femoral artery (SFA) stents causing Fontaine Stage III claudication.

**CASE 1**

A 72-year-old male with dyslipidemia, hypertension, prior tobacco use, and known peripheral arterial disease presented with new-onset numbness of his right foot with severe calf claudication upon minimal ambulation. He reported compliance with all prescribed medications including a dual antiplatelet regimen consisting of aspirin and clopidogrel as well as maintenance of complete tobacco cessation. Approximately 12 months previously, the patient had undergone endovascular intervention to his right lower extremity for a nonhealing ulcer on his right foot. This consisted of PTA and stenting of severely diseased right common and external iliac arteries and placement of Viabahn covered stents (W.L. Gore & Associates) in the SFA after this chronically occluded artery was recanalized. In the weeks that followed, the patient’s ulcer healed completely and his noninvasive vascular studies normalized.

The patient’s current physical examination demonstrated dependent rubor and elevation pallor, no evidence of skin breakdown or tissue necrosis, and monophasic signal by Doppler of the popliteal and pedal pulses. Repeat noninvasive arterial testing demonstrated a resting right-sided Ankle Brachial Index (ABI) of 0.41, and pulse volume recording (PVR) suggesting severe inflow and femoropopliteal disease.

The patient underwent repeat angiography, which demonstrated patency of the right common iliac and external iliac artery stents. However, the profunda femoris artery was found to have severe ostial disease, while the SFA was found once again to be totally occluded with no flow through the stented segment (Figure 3). The popliteal artery received collateral supply from the profunda femoris, and there was 3-vessel run-off evident. The ostium of the profunda femoris artery underwent PTA, and a decision was made to use the Trellis-6 device in the thrombosed SFA.

With a guiding sheath in place, the SFA occlusion was crossed with an angled stiff Glidewire (Terumo Interventional Systems). This was followed by the placement of a Trellis-6 30-cm Peripheral Infusion System into the treatment zone of the SFA. The proximal and distal balloons of the Trellis-6 were inflated under fluoroscopic guidance confirming appropriate apposition against the vessel wall. Tissue plasminogen activator was delivered through the device’s infusion port into the thrombosed segment and the Trellis-6

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**Figure 3.** Digital subtraction angiography demonstrating ostial superficial femoral artery occlusion (A), and infrapopliteal run-off (B).
motor was switched on and handled per instructions. After 15 minutes of therapy, aspiration through the designated port was performed in standard fashion. Thereafter, a 6 mm SpiderFX Embolic Protection Device was delivered through the wire port of the Trellis–6 and “parked” in the distal popliteal artery (Figure 4). The Trellis–6 balloons were then deflated and the catheter removed.

Angiography now demonstrated successful recanalization of the SFA with resolution of the thrombus, and brisk flow through the previously thrombosed segment. However, a prominent filling defect was noted within the filter of the SpiderFX (Figure 5). A culprit stenosis was identified at the distal edge of the lower Viabahn stent. This was treated by placing a Zilver PTX stent (Cook Medical) in an overlapping fashion with the previous stent. The SpiderFX was
removed and upon examination was noted to have trapped thrombus, which was believed to be the cause of the filling defect noted above. Repeat angiography revealed a widely patent femoropopliteal segment, and preserved 3-vessel run-off with no signs of distal embolization (Figure 6).

Following the procedure, the patient recovered uneventfully and his repeat ABI/PVR confirmed persistent patency of the SFA. Also, his ambulation distance was back to his baseline of walking several blocks without claudication.

**Case 2**

An 84-year-old male had hypertension, dyslipidemia, coronary artery disease status post coronary artery bypass surgery, and peripheral arterial disease. Approximately 6 months previously, he had undergone an endovascular intervention on his right lower extremity for treatment of a long segment of chronically occluded superficial femoral artery to facilitate healing of chronic ulcers on the lower leg.

The patient had also received overlapping Viabahn stents and had 2-vessel runoff with a chronically oc-
cluded anterior tibial artery. As a result of the above intervention and meticulous wound care, his ulcers healed completely.

The patient presented with repeat ulceration on his lower right leg and new-onset claudication of 3 weeks’ duration affecting his right calf. He had recently stopped clopidogrel due to a skin rash.

ABI/PVR suggested recurrent severe femoropopliteal disease. Therefore, he underwent repeat angiography, which demonstrated occlusion of the right SFA with thrombosis of the Viabahn stents. A decision was made to treat the thrombotic segment with a Trellis-6 system. The device was prepped in standard fashion. The SFA occlusion was crossed without any difficulty using an angled stiff Glidewire. Over this wire the Trellis-6 device was advanced into the stented segment. The device balloons were inflated and the targeted area was intervened upon successfully in a standard fashion, as outlined in the previous case. Prior to balloon deflation, a 6 mm SpiderFX was advanced and deployed in the popliteal artery.

The Trellis-6 catheter was removed, and angiography confirmed an excellent angiographic result, with return of stent patency and preservation of infrapopliteal flow. As in the prior case, an angiographic filling defect was noted in the SpiderFX filter.

The SpiderFX was then retrieved, and captured thrombus was noted. The patient was ultimately discharged on aspirin and Brilinta (ticagrelor, AstraZeneca). Subsequent follow-up in the vascular medicine clinic confirmed that the patient had successful wound healing, absence of lifestyle-limiting claudication, and ABI/PVR results that demonstrated persistent patency of the SFA.

**DISCUSSION**

Patients with ALI represent a challenging cohort to treat, with a high incidence of mortality and morbidity, including the potential for limb loss. Endovascular intervention has greatly broadened the treatment options available for ALI, while delivering effective results. Catheter-directed thrombolytic therapy (CDT) is a highly effective strategy in the management of threatened limb loss due to thrombosed peripheral arteries. Compared to traditional CDT, the Trellis-6 Peripheral Infusion System offers several attractive features due to its unique pharmacomechanical design, including: (1) lower total thrombolytic dose due to localized drug delivery to an isolated vascular segment, (2) lower bleeding complications due to less systemic absorption of the drug, and (3) rapid reperfusion. These distinct advantages have the potential to decrease the likelihood of ICU admission, to shorten the length of hospital stay, and to reduce the overall cost of care.

However, while the Trellis-6 is an invaluable tool for patients with arterial (or venous) thrombosis, there has been a reported incidence of particulate embolism of up to 11% despite its use. This is of concern especially in patients with severe peripheral arterial disease where compromise of infrapopliteal run-off vessel due to embolized microparticles can erase all hopes of limb salvage.1 To our knowledge, there have been no published cases of deployment of the SpiderFX embolic protection device when using the Trellis-6 Peripheral Infusion System in the setting of a thrombosed arterial stent graft.2

**CONCLUSION**

We present two cases where the Spider-FX filter successfully captured emboli after effective thrombolysis with
the Trellis-6. Although further studies are needed to determine the potential impact of this strategy, these two cases illustrate the feasibility and efficacy of concurrent use of these devices in an attempt to attenuate the risk of distal embolization, particularly in patients with severe underlying peripheral artery atherosclerotic disease.

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