Supplement to

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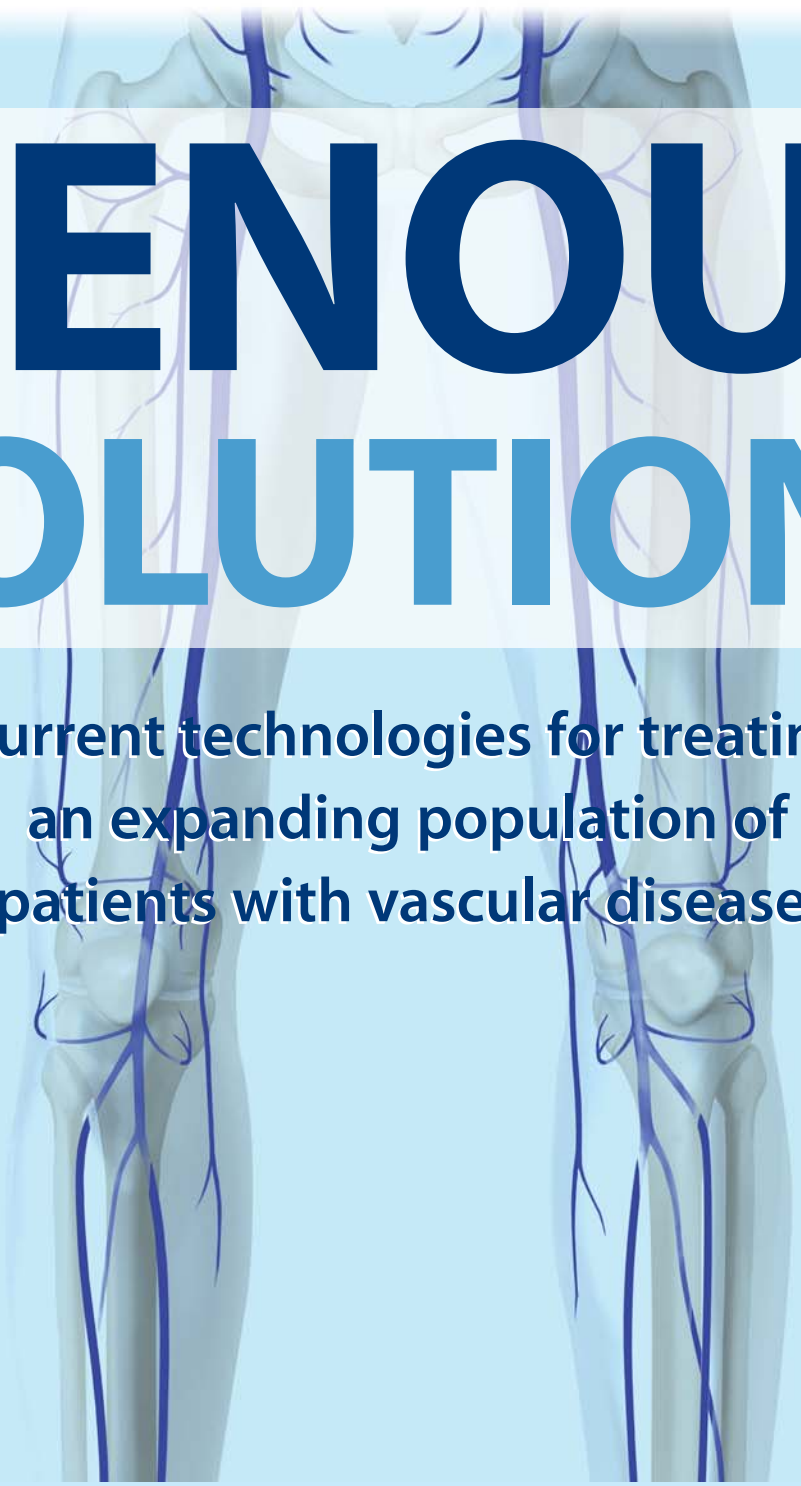
VENOUS SOLUTIONS



Current technologies for treating an expanding population of patients with vascular disease.

Venous Solutions

With an aging population and an increasing number of patients with vascular disease, there is a tremendous need for new and more advanced medical technologies for treating potentially serious conditions such as chronic venous insufficiency and deep vein thrombosis (DVT).

In this supplement to *Endovascular Today,* a diverse panel of physicians representing interventional medicine/cardiology, emergency care, and vascular surgery will address the opportunities for medical device innovators to develop safe and effective technologies, as well as provide the clinical evidence to support their use, allowing physicians to make the most informed clinical decisions for their patients.

Included in the supplement, Anthony J. Comerota, MD, explains the role that venous hemodynamics play in the decision-making process when trying to decide which type of mechanical prophylaxis and leg or foot compression technologies to use.

Next, Luis R. Leon Jr, MD, RVT, FACS; John Paul Pacanowski, MD, FACS; and Nicos Labropoulos, PhD, DIC, RVT, share their insights into which methods physicians can employ in order to have the best chances of treating DVT in a single setting.

Heramb Singh, MD, discusses his experience in treating thrombosed dialysis fistulas and the tools and techniques he uses for optimal patient outcomes.

Finally, Jennifer Heller, MD, FACS, provides an overview of the current options for treating chronic venous insufficiency, as well as two case studies that show how she applies an algorithmic approach in order to make treatment decisions.

In my role as Chief Medical Officer for Covidien Vascular Therapies (Mansfield, MA), our team looks for ways to deliver a broad range of innovative, noninvasive, and endovascular devices for the treatment of vascular disease worldwide. Covidien currently offers clinically proven solutions for the prevention and treatment of DVT, chronic venous insufficiency, dialysis access, peripheral vascular disease, and neurovascular disease. We develop and support new technologies, products, and programs focused on improved patient outcomes and safer, more efficient health care practices throughout the continuum of care across the globe.

I hope that readers will benefit from this supplement and the principles covered by these experts, further validating the need for advanced endovascular treatments that will lead to improved patient outcomes.

—Mark A. Turco, MD, FACC

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Intermittent Pneumatic Compression for DVT Prophylaxis

Which device characteristics and hemodynamic metrics are important for physicians to consider in making the best patient-specific treatment decisions?

BY ANTHONY J. COMEROTA, MD, FACS, FACC

There is a large body of evidence documenting that intermittent pneumatic compression (IPC) is effective in preventing deep vein thrombosis (DVT) in hospitalized, high-risk patients.[1-8] Early randomized studies show a significant reduction in venographically proven DVT following total hip and knee replacement.[1-3] Early trials compared IPC to no treatment,[1,2] and subsequent trials compared IPC to pharmacologic (heparin) prophylaxis.[3-6,8] When heparin was the comparator, IPC results continued to appear favorable, and as might be expected, wound drainage and bleeding complications occurred less often in patients in the IPC groups.[3,4]

Subsequent studies of high-risk trauma patients have allowed insight into the relative benefit of IPC, the potential differences of foot compression versus calf-thigh compression, and the relative risk of IPC versus low-molecular-weight heparin (LMWH) prophylaxis.[8] Knudson et al performed a randomized trial evaluating LMWH versus optimal compression in high-risk trauma patients. Patients who were eligible to receive heparin were classified as "the heparin group" and were randomized to either LMWH or optimal compression. Optimal compression was defined as a sequential compression device (SCD) applied over antiembolic stockings. If a patient could not wear an SCD because of associated wounds or other clinical factors, a foot arteriovenous impulse device was used.

The combined use of compression stockings and an IPC device was shown by Abu-Own and colleagues to produce more effective venous flow velocity and volumetric venous flow associated with a smaller diameter of the femoral vein.[9]

Patients who were not candidates for heparin were placed into a "no heparin group" and likewise were managed with optimal compression using the same decision matrix. Venous duplex imaging was performed every 5 to 7 days until discharge. The results are summarized in Figure 1. DVT was detected in 0.8% of the LMWH-treated patients, in 3% of the SCD patients, and in 6% of the arteriovenous impulse device patients. One major bleeding complication was potentially associated with the use of LMWH.

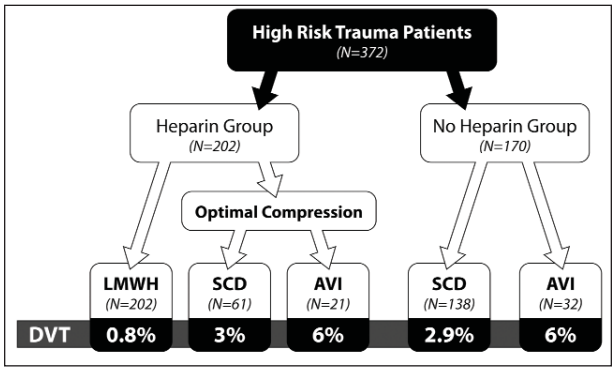

Figure 1. Design and outcomes of a randomized trial of DVT prophylaxis in trauma patients.[8]

In addition to orthopedic patients undergoing total hip or knee replacement and high-risk trauma patients, those suffering neurologic trauma or stroke or those undergoing general surgery have benefited from IPC for DVT prophylaxis. When physicians evaluate methods of DVT prophylaxis, the question should not be whether IPC is effective but what characteristics (specifications) of IPC devices position them to be most effective.

THE PLEIOTROPIC EFFECTS OF IPC

Most health care professionals think of IPC in terms of the venous hemodynamics produced by the mechanical effects of compression on the soft tissue of the extremity. The hemodynamic consequences of moving venous blood include increased venous velocity, pulsatile venous volume, volume of venous blood returned per unit time (as a result of increasing arterial inflow), and shear on vascular endothelium.

There are other pleiotropic effects of IPC that have an important effect on clinical outcomes; however, to date, these additional effects have not been correlated with clinical outcomes. These include increasing fibrinolytic activity[10]

(not by increasing tissue plasminogen activator antigen release but by reducing plasminogen activator inhibitor), decreasing factor VIIa, increasing tissue factor pathway inhibitor,[11] stimulating endothelial-derived growth factor mRNA,[12] and stimulating the endothelium to alter production of at least three isoforms of nitric oxide synthase.[13] These are the pleiotropic effects that have been studied. There are probably numerous others that have yet to be identified.

The clinical benefits of these pleiotropic effects include prevention of DVT, healing of venous ulcers, healing of arterial ulcers, improved management of patients with critical limb ischemia, improved blood flow through lower extremity bypass grafts, increased walking distance in patients with intermittent claudication, reduction in generic leg edema, improved management of lymphedema, and anecdotal improvement of causalgia (posttraumatic pain syndrome). Undoubtedly, there is a complex interaction of the hemodynamic parameters affecting endothelial and vessel wall response in addition to the variety of venous and arterial blood flow alterations. The remainder of this discussion will focus on the effect IPC has on venous hemodynamics.

CONSIDERATIONS REGARDING IPC

Just as there are differences in the outcomes of similar pharmacologic agents used to treat the same disease, one can expect there to be differences in outcomes when similar mechanical devices are used, depending on their device specifications and compression characteristics.

Importantly, it appears that the indication for the use of an IPC device may dictate the important hemodynamic characteristics. That is, patients with arterial ischemia may require different pump characteristics than patients with lymphedema, and the specifications required for both of these patient groups may be different than pump specifications for patients requiring DVT prophylaxis.

Focusing on the venous system in general, and DVT prophylaxis in particular, there is little argument that randomized clinical trials with objective endpoints related to venous thromboembolism are the ultimate arbiter in decision making, assuming the trial design and conduct are appropriate. Confounding variables must be clearly recognized and addressed. This is well illustrated in a study performed by Gallus et al,[2] who randomized patients undergoing total hip replacement to IPC versus no treatment. One of two operative techniques was used by the orthopedic surgeons, either the modified Charnley technique or the posterior approach. Fortunately, the two operative techniques were stratified when the patients entered the trial.

The investigators found that IPC was very effective in reducing DVT in patients who underwent the posterior approach (14% IPC vs 57% control). However, IPC was not effective in those patients who underwent the modified Charnley technique. Overall, venographically proven DVT occurred in 40% of patients who underwent the modified Charnley technique and 9% when the posterior approach was used. This is a graphic example of a confounding factor that may not be readily apparent but may substantially alter outcomes. This also alludes to the fallacy of comparing outcomes of one trial to another because internal controls in such analyses would be absent. When evaluating clinical trials, one must be aware of trial design and efforts to standardize all patient management except for the variable being examined.

HEMODYNAMICS OF IPC THAT DRIVE DECISION MAKING

What are the important characteristics of IPC that lead to prevention of DVT? Until trials are performed that address the important outcomes (ie, DVT and pulmonary embolism), one must look to the surrogate metrics of venous hemodynamics and perhaps some of the hematologic changes (although these add a significant level of complexity and labor). That raises the question of which hemodynamics are most likely to produce an antithrombotic environment. This important question is difficult to answer because few comparative studies have been performed on the same subjects.

One such study, however, serves as an example, which was performed by Griffin et al.[14] They compared the hemodynamic effectiveness of three full-leg compression devices: (1) a circumferential sequential gradient device; (2) a posterior uniform compression device; and (3) a posterior sequential rapid inflation device. The hemodynamics measured included peak velocity in the common femoral vein, single-cycle venous volume flow, and refill time, and venous volume flow per hour was also calculated. The hemodynamic results are summarized in Table 1.

All devices significantly increased venous velocities and flow compared to baseline. Single-cycle volume expelled dur-

TABLE 1. HEMODYNAMIC RESULTS OF THREE FULL-LEG COMPRESSION DEVICES[14]

Device	Peak Velocity (cm/s)	Cycle Volume (mL)	Refill Time (s)	Volume Per Hour (mL)
CSG	37	104	28	7,800
PU	32	88	26	5,500
PSR	68	58	20	3,500

Abbreviations: CSG, circumferential sequential gradient; PSR, posterior sequential rapid inflation; PU, posterior uniform.

ing compression was 105, 85, and 58 mL in the circumferential sequential gradient, posterior uniform compression, and posterior sequential rapid inflation devices, respectively. The total venous volume per hour was 7,800, 5,500, and 3,500 mL, respectively.

It seems intuitive that increasing the total venous volume per hour would be the metric most likely to be associated with improved clinical outcomes (reduced risk of DVT). It was interesting to observe that the unit with the most rapid pressure inflation (pressure rise time) had the highest peak velocity but the shortest refill time, the lowest cycle volume, and the smallest volume per hour. This raises the question as to whether peak velocity is an important hemodynamic metric (although it is the easiest to measure). A characteristic not included in the previous analyses is bladder size. If the bladder in the device is small, it is easier to achieve a rapid pressure rise, resulting in a transiently high venous velocity but at the expense of a relatively smaller volume of blood being expelled. It would be helpful to know the bladder sizes of the devices used in addition to the other specifications reported. A small bladder should reduce expectations regarding the clinical effectiveness of the device.

Proctor et al[15] performed a prospective observational cohort study using five IPC devices to determine relative clinical effectiveness in hospitalized patients. Devices included rapid gradient sequential compression of the calf; foot, calf, and thigh intermittent compression; two foot, calf, and thigh gradient sequential devices; and one intermittent calf compression device. The authors listed the manufacturers of the devices used in their study but blinded the reporting of device results.

Over 5 months, 1,350 patients were studied—1 month each in sequential fashion. They found that calf compression alone was inferior to devices that compressed the foot, calf, and thigh. However, their analysis was limited to peak venous velocity measurements, which is the easiest parameter to measure but may not be the most relevant hemodynamic parameter responsible for reduction of DVT risk. They also found that devices differed with regard to patient comfort and nurse satisfaction.

Technology is now available to sense postcompression refill time.[14] It seems evident that the cycle time of the device should be linked to the venous refill time of the leg and that the efficiency of compression will improve if the next compression occurs as soon as the tissue refills with blood. This generally results in the highest volume of blood expelled per compression cycle and should result in the largest volume of venous blood expelled per hour, assuming appropriate bladder size. If there is one monitor per device, and if there is a different refill time in each leg, it would result in one of the legs being compressed either too early or too late.

The next technology question is: should the compression device read both legs independently, and therefore compress both legs independently, based upon their individual refill times? Devices are now available to monitor individual leg refill times and be compressed independently.[16] It would seem that this method should result in the most favorable clinical outcome.

CONCLUSION

It is common for authors to conclude articles with statements regarding the importance of additional randomized clinical trials. Of course that is also true here. However, if one were to design a definitive clinical trial to address specific hemodynamic parameters that optimally reduce DVT risk, correct for confounding variables, and target the relevant outcomes of symptomatic DVT, pulmonary embolism, and all-cause mortality, thousands of patients would be required. Until results of such studies are available, physicians must rely on the available literature. Reports of smaller randomized studies, prospective nonrandomized studies, and analyses of hemodynamic responses to IPC can assist physicians and patient care teams to make appropriate decisions regarding IPC for DVT prophylaxis. ■

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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.

BY LUIS R. LEON JR, MD, RVT, FACS; JOHN PAUL PACANOWSKI, MD, FACS; AND NICOS LABROPOULOS, PHD, DIC, RVT

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,

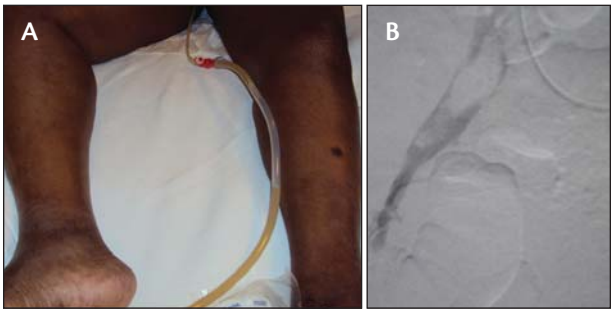

Figure 1. A 61-year-old woman with severe swelling of the right lower extremity caused by iliofemoral DVT (A). Venography shows a large filling defect within the lumen of the right common iliac vein with stenosis at the level of the right external iliac vein (B).

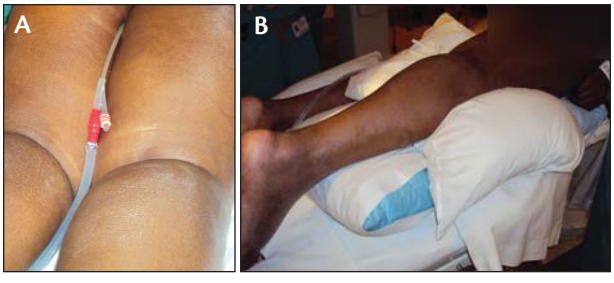

Figure 2. The patient has been endotracheally intubated and subsequently placed in the prone position for percutaneous access of the popliteal vein (A). Her right knee has been propped up with several pillows to raise the popliteal vein closer to the skin level for easier access (B).

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

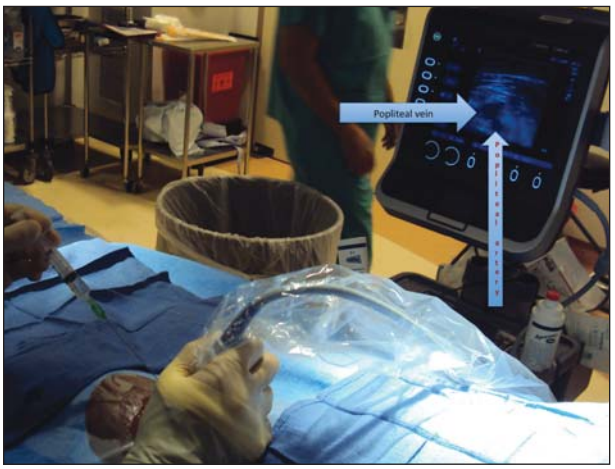

Figure 3. Ultrasound-guided access to the right popliteal vein is being achieved. The ultrasound image shows an enlarged popliteal vein as a consequence of the presence of intraluminal thrombus, which facilitates percutaneous access. The popliteal artery, typically located below the vein level with this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

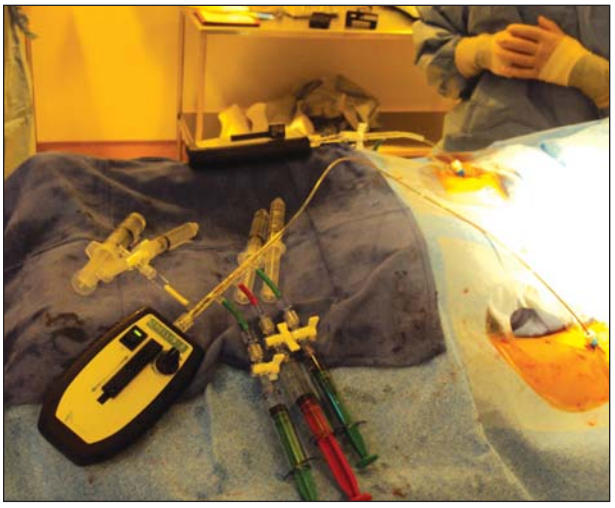

Figure 5. A patient with an inferior vena cava (IVC) occlusion secondary to a thrombosed IVC filter (IVCF) in which bilateral Trellis devices have been advanced to achieve larger luminal clearance.

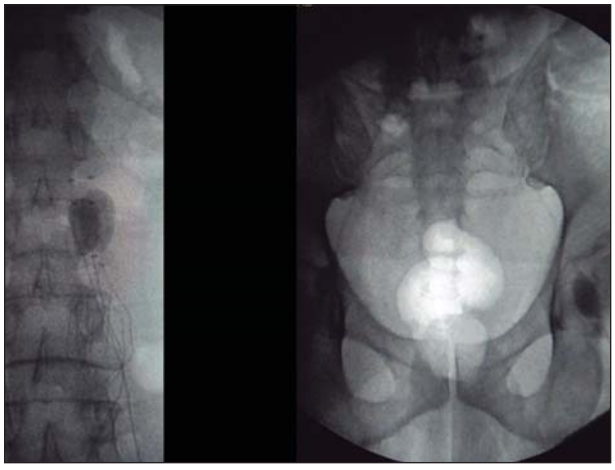

Figure 6. Proximal and distal balloons are now inflated in this patient who is undergoing venous thrombectomy for an IVCF occlusion. The distal balloon has been inflated above the occluded IVCF, and by using a 30-cm Trellis device in this particular case, the proximal balloons are inflated in the junction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

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.

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

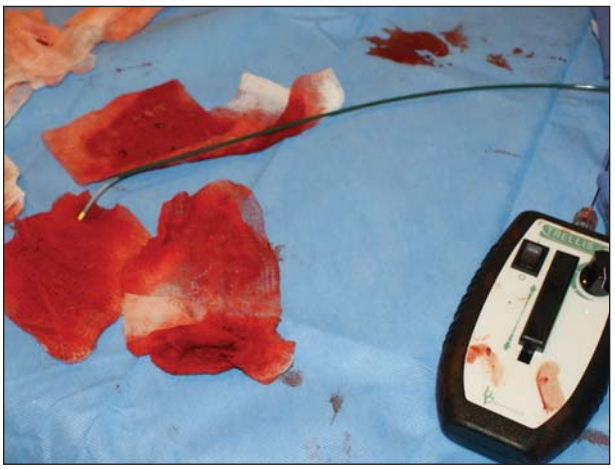

Figure 7. The multipurpose catheter can be seen along with the gauze used to strain the blood retrieved with the catheter. Some of the gauze is shown containing some thrombus.

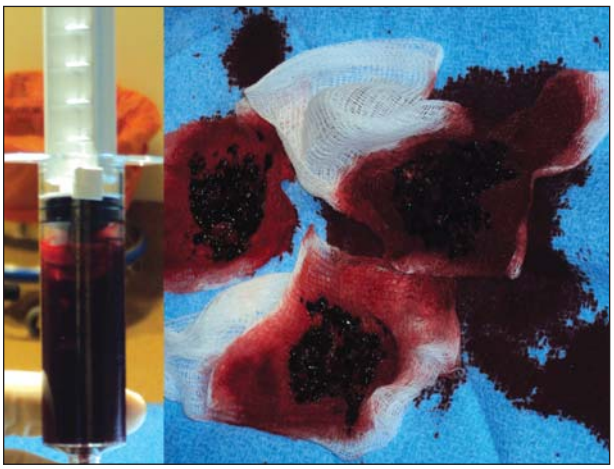

Figure 8. Typical amount of blood thrombi retrieved per session. The dark color of these clots indicates the acuteness of the thrombotic process.

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).

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

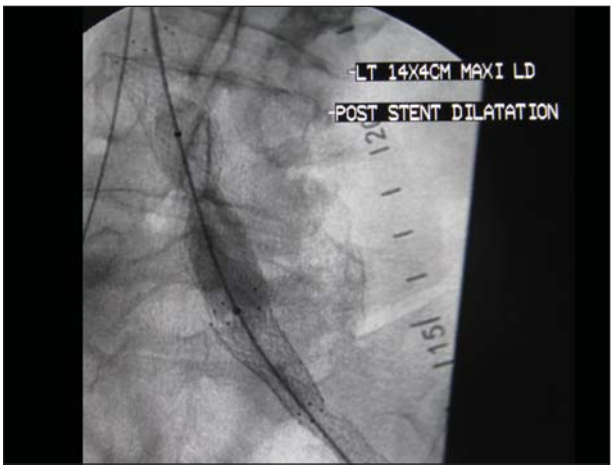

Figure 9. A stent has been placed in a 69-year-old woman who was affected by a chronic left lower extremity DVT secondary to May-Thurner syndrome. A typical "waist" is seen along the length of the stent caused by the chronic compression of the left common iliac vein by the right common iliac artery.

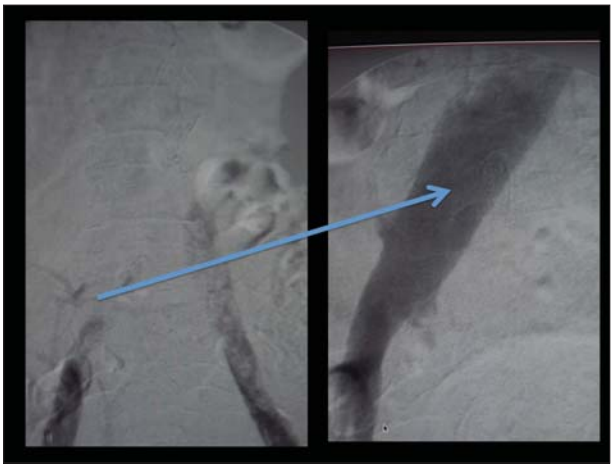

Figure 10. Typical satisfactory results achieved with the Trellis device in a single-session therapy with achievement of venous patency of ≥ 75% (in this case, of the left common iliac vein), with antegrade blood flow to the IVC.

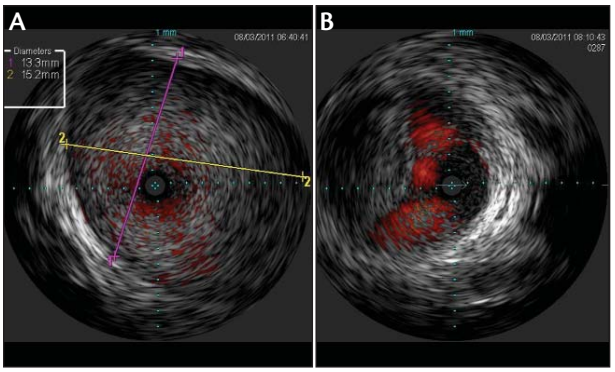

Figure 11. The use of intravascular ultrasound has recently been incorporated into our protocol. It allows clear visualization of the thrombotic material within the venous lumen before (A) and after therapy, minimizing the use of iodinated contrast, as well as allowing precise venous caliber measurements (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).

> "The Trellis-8 peripheral infusion device is a minimally invasive tool that allows safe, rapid, and effective clearance of thrombi in the venous system . . ."

We consider the achievement of venous patency of ≥ 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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Treating Dialysis Fistulas

Heramb Singh, MD, discusses his experience using pharmacomechanical thrombolysis with the Trellis device to treat thrombosed dialysis fistulas.

How did you initially begin treating thrombosed dialysis access shunts and fistulas? What training and proctoring was required?

I have been doing this for more than 15 years, starting with my interventional training at the University of Pittsburgh and my fellowship thereafter. When I finished my fellowship 20 years ago, these types of treatments were evolving, and as they evolved, I evolved with them. I did not go through a particular training program specifically to learn this procedure, but as new devices like Trellis (Covidien, Mansfield, MA) and AngioJet (Medrad Interventional, Indianola, PA) became available on the market, the interventional community was trying to figure out what would work best for treating our patients.

I tried many different techniques, and I believe that I have found what works best for me and for my patients, which is pharmacomechanical thrombolysis using the Trellis device.

Which members of your facility's staff are involved in the evaluation of patients and decision making regarding therapeutic options?

I receive consults from the nephrologists and the dialysis nurse when they have problems with a dialysis access. These problems usually include thrombosis of a fistula or shunt. Then I evaluate the fistula. The best method of evaluation is with fistulagraphy to see if the access is completely thrombosed or partially thrombosed. Based on this status, I decide which therapeutic option will be employed. During this process, I have an interventional nurse and interventional technologist assisting me. It is not a one-man show. I have a whole team of people working with me.

What are your criteria in evaluating candidates for pharmacomechanical thrombolysis? Which patients are ideal candidates, and which patients are not?

If the patient is not doing well on dialysis (ie, not getting sufficient blood return), I perform fistulagraphy. I administer a local anesthetic, place a small 6-F catheter and sheath, and inject dye to image the vessel. From there, I can evaluate the problem. Typically, imaging will show a partially or completely thrombosed fistula.

> "I have tried using many other devices in the past, but I have come to conclude that the Trellis works best."

How would you describe your technique for declotting thrombosed shunts and fistulas?

First, I document where the clot is—whether it is in the fistula or shunt or extending into the native vein (ie, the subclavian or basilic). Then I clean it out using pharmacomechanical thrombolysis with the Trellis device. During this process, I use two balloons with a wire inside that peaks at 3,000 rpm. We administer 10 mg of tissue plasminogen activator (tPA) for 10 minutes, which is the "pharmaco" portion of the pharmacomechanical thrombolysis, and then aspirate the clot and the tPA.

Which imaging modalities are ideal in these cases?

My patients are brought directly into the cath lab. I do not perform ultrasound or use any modalities found outside the lab in order to avoid unnecessary added cost to the patient. When the dialysis nurse and/or the nephrologist let me know that the access is not working well, I determine how severe the problem is while performing the procedure with a fistulagram or venogram with which we can see the anatomy and the problem area(s) and make a diagnosis fairly quickly. I believe that this is the gold-standard method of imaging for this procedure.

What has your experience with pharmacomechanical thrombolysis been to date? What are some of the advantages and disadvantages you see in declotting using this technology versus other modalities?

I have tried using many other devices in the past, but I have come to conclude that the Trellis works best. My measure of this is based on whether after using a device, the patient returns within a few weeks with problems, which, in my experience, is rarely the case with this device. It removes the acute thrombus and, at times,

> "Each case is unique; these are not just textbook cases with the same exact process over and over."

has also worked well on older thrombus. When you aspirate, you can see acute clot, which has a reddish tone, and chronic clot, which has a gray appearance, and it removes both types of clot well. With other devices that do not incorporate aspiration, clot can end up in the lungs and cause pulmonary embolism. This is especially problematic in cases when the patients have preexisting comorbidities. You do not want to compound any potential health concerns.

Another advantage is that instead of patients returning to my office within a few weeks or months, I have found that most patients have no need to return to my office for approximately 1 year or longer.

Overall, the more I use Trellis, the more I like it. However, one potential negative aspect is the cost, but I believe that the cost is justified because with other devices, patients have to return for follow-up visits more frequently. If they do not have to return for a long interval, this justifies the cost. Secondly, the procedure with Trellis can be somewhat time consuming. I think a lot of patients and interventionists want it done as quickly as possible, but by doing it so quickly, you might only remove the acute clot, thereby missing some residual, chronic clot.

Another point I would like to make is that once the thrombus is removed, there is usually an area of vessel narrowing, which requires balloon inflation and, occasionally, stenting. You have to clean the clot out, but you also have to treat the underlying problem. This is important to remember with all declotting procedures.

How is using PMT in dialysis access declotting different than in DVT cases?

It is the same technology, and the same principles apply: you place the balloons in the segment of the vessel that you want to work on (whether it is a leg clot, arm clot, fistula, or shunt), run the device, aspirate the clot, and then image the vessel to see if the clot has been cleared. I should note that I have never used > 20 mg of tPA for any application.

What medical regimens do you place the patient on before and after the procedure?

Because this is an outpatient procedure, I do not medicate patients beforehand, other than with some sedation. After the procedure, if stenting was performed, I recommend the patient be anticoagulated for 6 months.

How do you decide whether or not to place a stent/stent graft?

Stents are placed when the vessel does not respond to angioplasty. Stent grafts are used when there is leaking, hemorrhaging, or for treatment of an aneurysm.

What is your follow-up protocol (ie, junctures at which the patient comes back to the office and types of imaging used)?

Hopefully, the patient will not need to come back for a while, but the dialysis nurse and/or nephrologist will notify me if the patient is having problems again. Because they see the patient on a more consistent basis than I do, I can usually count on them to provide me with feedback on whether the procedure worked well or not. Occasionally, if the surgical anastomosis fistula is simply not done correctly, I will refer the patient for surgical revision.

Each case is unique; these are not just textbook cases with the same exact process over and over. Every patient's anatomy and the way the surgeon has created the shunt or fistula is a little different. That is why performing fistulagraphy will give you a good idea of what you are dealing with as far as knowing exactly where the problem is so that you can properly treat it.

Do you have any tips on managing patient expectations in this challenging population?

I am very straightforward with these patients. I tell them that the shunt or fistula has the possibility of failing at any time. It may last a day, a month, a year, or it may last forever. Sometimes blood pressure fluctuations affect it, or the patient may lie on the shunt and it occludes. Anything can cause it to fail again, including elevated blood pressure, infection, and many other causes. That is the main warning I give them about the procedure.

I also let them know that they can come to me if they are having any problems, and that way, I can do some touch-up work here and there instead of waiting for it to become a bigger problem. ■

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Treatment of Chronic Venous Insufficiency

How current technology is changing our approach.

BY JENNIFER HELLER, MD, FACS

In the United States, an estimated 23% of adults have varicose veins, and 6% have more advanced chronic venous disease (CVD).[1,2] Although varicose veins are still considered by many laypeople and health care practitioners to be a benign condition, varicose veins can be a harbinger of future CVD, which is associated with debilitating symptoms, chronic skin changes, phlebitis, and ultimately, venous stasis ulceration.[1,3,4] Further, severe CVD can result in the loss of a limb and death.[5] The direct medical cost of CVD (or chronic venous insufficiency [CVI]) in the United States has been estimated to be between $150 million and $1 billion per year.[4,5]

In an effort to improve these statistics and ultimately decrease the prevalence of venous stasis ulceration, the Pacific Vascular Symposium was developed. This group identified a number of research priorities in the categories of clinical practice, basic science research, and education. These priorities still hold and, ideally, should be fulfilled as we strive toward improving comprehensive care of venous insufficiency.

In May 2011, however, the Society for Vascular Surgery and the American Venous Forum shifted the focus from research to the development of clinical practice guidelines for the evaluation and treatment of patients with CVI.[2] The authors clearly state that the guidelines should not be construed as the standard of care, which must be determined by the individual patient's condition, treatment setting, and other factors. They further note that the approach to treatment and management is driven largely by proper diagnosis along with a thorough understanding of the patient's medical history, clinical presentation, and diagnostic imaging studies.

The practice guidelines are required reading for any physician treating venous disease. In this article, I describe an algorithmic approach used to determine treatment decisions for CVI that focuses not only on the great saphenous vein (GSV) and small saphenous vein (SSV) but also on the anterior and posterior accessory veins. I have included two case studies to show how I apply this approach.

CVI ALGORITHM

There are many factors that contribute to the complexity of treatment for venous insufficiency. First, the lower extremity venous anatomy is variable. Duplicate systems are commonly encountered, and the perforator veins vary in function, size, and location. Patients may present with a chronic course of venous disease and not be aware of postthrombotic or secondary venous insufficiency as the predominant cause of their problems. Therefore, the importance of taking a thorough patient history and performing a comprehensive physical examination cannot be overemphasized, and the findings can dramatically alter the treatment approach.

My initial evaluation concludes with a determination of the severity of the patient's venous disease. I group patients into one of two categories: uncomplicated and complicated. Uncomplicated venous disease is a stage of venous insufficiency composed of mild-to-moderate symptoms devoid of complications or advanced stigmata on physical examination. I consider complicated venous disease to be > C4 (CEAP classification) or when patients report symptoms that are debilitating, disabling, and are not improved with conservative management.

CONSERVATIVE TREATMENT

The cornerstone of conservative treatment for CVI is compression stocking use, and it is the responsibility of the physician to communicate the advantages and role of compression care in treatment. Stockings are noninvasive, safe, and in patients who manifest mild or uncomplicated venous disease, compliant compression stocking use may be sufficient. Compression stockings are a required treatment component during travel in patients who require surgical intervention and in those with advanced CVI > C4 disease. Patients who demonstrate resolution of symptoms with compliant compression stocking use are instructed to return to the office every 6 months for surveillance. If the patient develops breakthrough symptoms or if physical examination findings deteriorate, the patient is counseled for intervention. In my practice, patients who demonstrate mild disease and are compliant with stocking use

require delayed operative intervention approximately 15% of the time.

Although I am an advocate of conservative management, there are many patients for whom stockings alone do not suffice. This is when the comprehensive history becomes so important, as it can reveal factors that suggest when a more aggressive intervention is warranted. These include: multiparity with deteriorating symptoms with progressing pregnancies, bleeding varicosities, superficial phlebitis, and a standing occupation.

During the physical examination, it is important to evaluate CVI symptoms, their location, history of onset, and factors associated with their exacerbation and alleviation. After a clinical evaluation is performed, a reflux examination is indicated. Duplex examination is the gold standard for evaluating superficial venous reflux. Further, this examination provides information on the presence of reflux in the deep venous system and whether stigmata are present that are consistent with postthrombotic disease, such as recanalized flow, thickened walls, or atrophic nonvisualized vein segments. Treatment cannot be performed until the reflux examination results are obtained and evaluated. Further, intervention is contraindicated when acute deep venous thrombosis (DVT) is present. The presence of chronic deep venous disease is a relative contraindication to treatment. In my practice, I will intervene on these patients if they manifest severe C4b, C5, or C6 disease. I use my duplex findings to help tailor an approach that is as localized as possible.

Patients with postthrombotic syndrome rely on their superficial systems, so removal can precipitate edema, as outflow can be further compromised. In these circumstances, I may ablate a single perforator or attempt to elucidate an accessory segment that can be localized. A staged approach can provide local control in the gaiter distribution while maintaining reasonable venous outflow in the lower extremity. These patients are carefully monitored during follow-up office visits, which are scheduled every 3 months, and are instructed to wear level III grade compression stockings. These evaluations can help to determine how reflux in the saphenous veins contributes to reflux elsewhere in the venous anatomy (eg, anterior, posterior, and lateral accessory saphenous veins, SSV, their terminal anatomy along with perforators) and their clinical impact on CVI overall.

TREATMENT APPROACHES

Perhaps most importantly, duplex scanning helps me decide which veins to treat and which not to treat. Again, using a conservative approach, my goal is to target veins that, if treated, stand a good chance of improving or alleviating other possible problems "downstream." For example, I have found that in patients with incompetence in both the GSV and SSV, oftentimes I do not need to treat the SSV because ablating the GSV alone resolves the SSV insufficiency approximately 80% of the time.

For venous ablation, I have had excellent treatment success with the Closure device (Covidien, Mansfield, MA). Postoperatively, patients experience less pain and bruising compared to traditional vein stripping surgery or endovenous laser treatment. I have used ClosureFast (Covidien), which ablates in 7-cm segments and ClosureRFS (Covidien) for treating incompetent perforator veins. The ClosureFast 3-cm catheter is expected to be available in late 2011 for ablation of shorter refluxing vein segments.

Because it uses segmental ablation technology, ClosureFast provides controlled, consistent energy delivery—no gradual pullback, no subjective determination of adequate energy delivery—resulting in controlled, even heating for more consistent and reliable vein ablation.[6] With the 7-cm catheter and the soon-available 3-cm catheter, the procedure is versatile enough to treat shorter veins (eg, the anterior and posterior accessory saphenous veins, SSV, and intersaphenous) and longer veins simultaneously.

ClosureFast has a reported efficacy rate of 93% at 3 years.[7] In addition to long-term efficacy, I also am finding that, overall, patients are very satisfied with their quick recovery and ability to return to work soon after the procedure. This is also supported by clinical study findings. In the RECOVERY trial,[8] a multicenter, head-to-head, comparative randomized trial, the Closure procedure resulted in patients experiencing less pain and bruising than those treated with endovenous laser, leading to faster recovery and return to normal activities. Other randomized comparative studies have also shown that patients who underwent the Closure procedure returned to normal activity and work significantly faster than those who underwent vein stripping.[9,10]

Finally, regardless of whether the treatment approach is conservative or more aggressive, it is important to communicate clearly with patients about their disease, how best to manage it, and that the disease can progress over time. Those initially managed conservatively (eg, with a compression stocking) need to understand that although this can stabilize the progression of the disease, if their symptoms remain uncontrolled or worsen, radiofrequency ablation (RFA) or surgery will likely be required.

The following cases illustrate how I make treatment decisions based on such factors as those previously described.

CASE 1

Overview: A 57-year-old man with a left lower extremity ulcer that was present for several months.

History and Examination

The patient denied any history of trauma to the site. He had a history of DVT in the right lower extremity. He had no history of thrombophilia and no family history of clotting disorders. He works as an architectural designer and stands on his feet for only approximately 2 hours a day. The patient described symptoms of aching pain, fatigue, and swelling.

The physical examination revealed a 2.2- X 2-cm, laterally based ulcer with a thin layer of fibrinous exudates. He also had a 2/2+ dorsalis pedal pulse/posterior tibial pulse in both lower extremities. The arteries appeared normal.

A duplex scan of the left lower extremity revealed significant reflux of the GSV > 6 seconds through the distal thigh. There was no evidence of SSV reflux and no DVT.

Diagnosis

The patient had varicosity of the anterolateral thigh with extension to the lateral proximal calf and transverse branch communication across the mid aspect of the anterior calf, with distal extension into the 11 o'clock aspect of the ulcer bed.

My first clinical impression was GSV reflux with the refluxing branch being a predominant source for venous hypertension, thereby causing the ulcer. However, I was surprised by the lack of SSV reflux, so I reimaged the patient and carefully explained his presentation to my registered vascular technician. The clinical presentation (ulcer) made me suspicious of additional underlying disease that was not initially discovered.

The follow-up duplex examination revealed reflux of the SSV proximal and mid portions and a small saphenous branch that appeared to course toward the ulcer, but no definitive communication was evident.

Treatment

Based on these findings, I decided to proceed with RFA of the GSV and the anterior branch of the GSV. Following the procedure, the patient was placed in Unna boots and was assessed weekly.

Postoperative Observation and Follow-up

The postoperative course was uneventful, and the postoperative duplex scan was normal. For the first 4 weeks, although the ulcer depth decreased, the size remained unchanged. At postoperative week 5, he developed a second ulcer that was shallow and inferior to the first. This new ulcer appeared to be in direct communication with the SSV branch previously seen on duplex imaging.

SSV ablation with branch phlebectomy was planned. This case is a good example of the importance of closely examining the complex terminal anatomy and having an experienced registered vascular technician help to uncover the true culprit vessel.

CASE 2

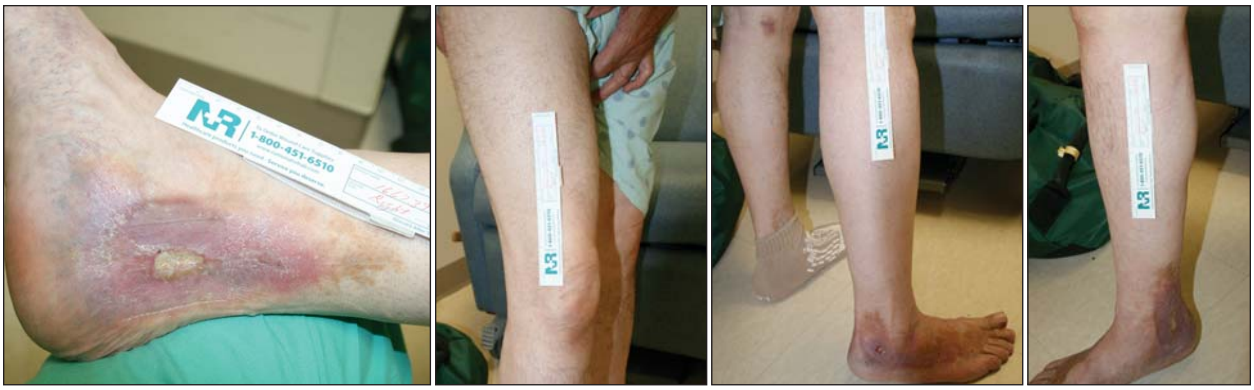
Overview: A 61-year-old man presented for evaluation of a right lower extremity venous stasis ulcer disease that he had for several decades.

History and Examination

The patient's first problems occurred at age 19 when he sustained a DVT in the right lower extremity and pulmonary emboli. His workup after this episode revealed heterozygosity for factor V Leiden. He was placed on lifelong warfarin maintenance and, over time, not only developed chronic edema, controlled only with level II grade compression, but also venous stasis ulceration. In 1998, he underwent perforator ligation for C6 disease, which healed the ulcer but experienced a recurrence 9 years later that was treated at various centers with various dressings and compression devices. This resulted in multiple healings and recurrences. At presentation, he had a 5-month history of the chronic ulcer.

Physical examination revealed two ulcers—one on the left medial malleolus and the other on the right lateral malleous—both measured at 1 X 2 mm.

A duplex scan of the right lower extremity revealed significant reflux of an anterior branch of the GSV into the distal thigh, with reflux also in one focus in the mid calf. The GSV was atrophied in its infrapopliteal segment. Significant SSV reflux was also demonstrated. There was no acute DVT, but chronic recanalization in the common femoral and femoral veins was seen, which was consistent with the patient's history.



Diagnosis

The patient had CVI with recurrent venous stasis ulcers (C6 disease) against a backdrop of heterozygosity for factor V Leiden, conferring an increased risk of thrombus formation and a need for ongoing warfarin therapy.

Treatment

The patient underwent RFA of the SSV with concomitant phlebectomy. Intraoperative duplex imaging was also used to locate additional branches that communicated with the distal calf and were subsequently phlebectomized under ultrasound guidance. The patient remained on warfarin during the procedure, with international normalized ratio closely monitored and maintained between 2.5 and 3.

Postoperative Observation and Follow-up

The postoperative duplex scan was normal, and both ulcers healed at 4 weeks follow-up. Via verbal communication, the patient continued to have C5 disease at 5-month follow-up.

Teaching Points

This case involved a number of important lessons learned for me:

- Even though the patient manifested anterior branch reflux, it did not require treatment.
- Never take a thrombophilic patient off their anticoagulation therapy for treatment. That is one of the advantages of endovenous therapy.
- Use intraoperative ultrasound to ensure comprehensive care of an area that may not have been adequately imaged in the vascular laboratory. ■

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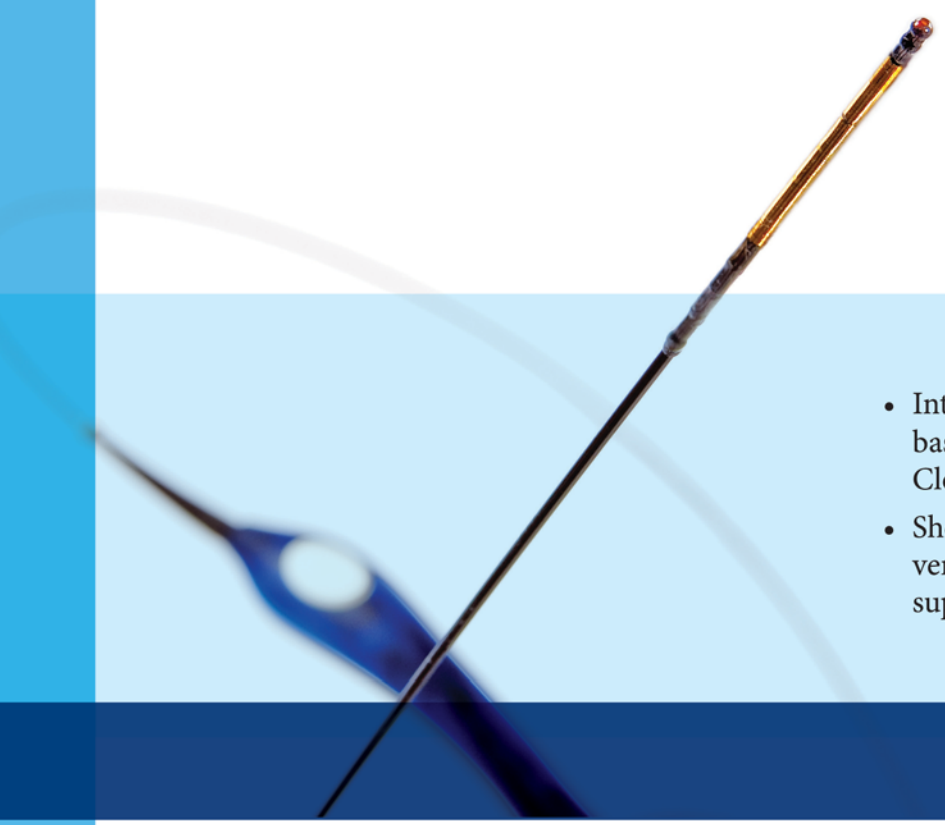
A New Addition to the ClosureFast™ Family



- Introducing ClosureFast™ 3cm catheter; based on the same technology as the ClosureFast catheter
- Shorter segmental ablation with the versatility to treat various sources of superficial venous reflux

Footnote:
*ClosureFast catheter demonstrated:
- 93% Efficacy Rate at Three Years[1]
- Significantly Better Patient Experience[2]

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Indication: The ClosureFast catheter is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux.
Contraindications: Patients with thrombus in the vein segment to be treated. Caution: The vein wall may be thinner in an aneurysmal segment. To effectively occlude a vein with an aneurysmal segment, additional tumescent infiltration may be needed over the aneurysmal segment, and the treatment of the vein should include segments proximal and distal to the aneurysmal segment. Caution: No data exists regarding the use of this catheter in patients with documented peripheral arterial disease. The same care should be taken in the treatment of patients with significant peripheral arterial disease as would be taken with a traditional vein ligation and stripping procedure.
Potential Complications: Potential complications include, but are not limited to, the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, infection, adjacent nerve injury, skin burn, hematoma or discoloration.

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