Treating Chronic Venous Disease With the Venclose Maven™ Perforator Catheter

Vascular Disease Management **spoke with Nathan Tomita, DO, MPH, CWSP, from Pacific Vascular Institute, Inc., in Kailua-Kona, Hawaii, about treating patients with chronic venous disease (CVD) and how the Venclose Maven™ Perforator Catheter (BD) has given him a modernized, 360° RF solution to treat patients with incompetent perforator veins (IPVs).**

Can you tell us about your practice and strategy for treating patients with CVD?

Our practice is a comprehensive multidisciplinary team of Vascular Surgeons and Interventionalists who streamline the collaboration and coordination of care for our patients. We have surgeons who deal with arterial and deep venous and another group who primarily focuses on superficial venous and the wound care center. Many patients in our practice have C5 or C6 CEAP classification (clinical, etiologic, anatomic, and pathologic) disease that often requires the expertise of different physicians to develop a more thorough treatment plan.

Before treating, it's critical to have alignment with your vascular technologists on scanning expectations and techniques. An experienced tech can make or break your practice, the good ones can find reflux where others might miss it. Our techs are trained to look for IPVs in the standing position and they will take off patient bandages to scan around the wound and identify the cause of venous reflux, either from an incompetent tributary or perforator vein. Approved advanced skin substitute products for venous ulcer treatment are typically on for a week and these should not be placed too early or before an IPV is treated. During the first week that a skin product is placed, our techs cannot remove them and will not have access to scan the ulcer site. Timing of the exam is so important and wound care center collaboration is key to obtaining an optimal outcome for IPV treatment, especially when related to venous ulcer management.

To start, always check and treat the arterial system, then treat the veins. If there is an open wound, you want to make sure the inflow is good before any vein ablations. My approach includes radiofrequency ablation (RFA) first for above-the-knee great saphenous, and then closing the IPV with RFA, followed by a nonthermal closure of the great saphenous below the knee.

How do you approach treatment for venous ulcers?

When building a care plan, our approach includes reviewing the history and physical exam to determine the etiology of the wound. Prior to treating anything below the knee, it's critical to close the IPV with the ultimate goal being venous wound closure. Nonhealing venous ulcers can at times have more extensive venous bleeding that occurs during debridement. This is also an initial clue that there is an underlying IPV that may be decreasing the oxygen to the wound bed.

Nathan Tomita, DO, MPH
Co-owner
Pacific Vascular Institute
Kailua-Kona, Hawaii

In general, arterial wounds are lateral. More common venous ulcers are medial malleolar in location with skin changes and ankle edema.[1] The chronic complicated wound that has been present for months to years sometimes will require further partnership with your wound clinic for a more thorough plan of action.

Review of the surgical history is important, especially if stents were placed or prior above-knee ablations were done. This is so we can identify how low the great saphenous vein was actually treated below the knee and how close the treatment was done in proximity to the nonhealing venous wound. I'm more concerned about finding the IPVs near the wound area as part of our patient evaluation.

What tools do you currently have to assist treating incompetent perforator veins?

We currently use the Venclose Maven™ Catheter. We follow the Society for Vascular Surgery and American Venous Forum guidelines; a pathologic perforator vein should have an outward flow of greater than 500 milliseconds and a diameter of greater than 3.5 mm located beneath a healed or open venous ulcer CEAP class C5 to C6 or patients with skin changes at risk for venous leg ulcers (C4b). The IPVs should be beneath areas of skin changes or open or closed wounds.[2]

Often, more than one perforator vein is present. To identify multiple refluxing IPVs, we label each one by measuring the bottom of the foot up and tibia over. By using an X-Y coordinate system we avoid any confusion or mislabeling of which IPVs were treated and which were not treated when there is more than one present. This especially helps during ultrasound evaluation and follow-up. Photographs are also used to follow these patients over time.

IPVs are very challenging because the angle of entry of them, into the fascia, can be too steep. Ultrasound also has difficulty with

	Arterial[1]	Venous[1]
Cause	Insufficient blood supply to area, causing ischemia (tissue death)	Pooling of blood causing increased pressure in the veins
Risk Factors	Vascular insufficiency, uncontrolled blood sugars in people with diabetes melitus, limited joint mobility or mobility problems, improper footwear	Varicose veins, deep vein thrombosis, incompetent valves, muscle weakness in the legs, immobility, pregnancy
Skin Changes	Shiny, thin, flaky, hair loss, rubor (pinkish red)	Hyperpigmented (hemosiderosis—purple, dark reddish brown), telangiectasias, thickening (lipodermatosclerosis), peri-wound maceration, scaling/crusting
Location	Foot more often than leg	Lower leg, almost never foot
Laterality of Leg	Usually lateral	Usually medial
Wound Edges	Well defined	Irregular, poorly defined
Wound Bed	Pale or necrotic	Dark red, fibrinous slough
Odor	If infected (gangrene)	Usually none
Pain (in Ulcer)	Uncommon unless infected or acute ischemia	Uncommon unless infected
Edema	No	Yes
Example Images	 Image courtesy of Dr. Miguel Montero-Baker	 Image courtesy of Dr. Nathan Tomita

visualization on steep angles. Patients with C5 and C6 often have thick and swollen legs that do not allow angling of the ultrasound probe, so we cannot change that visualization path. Using a stiff, straight catheter or access device is not ideal because it is hard to treat the IPV since the tip is not visible. This is where the Venclose Maven™ Catheter shines; you can guide it in along that vein curvature path in the treatment area, especially with a steep angle.

Based on your experience using RFA, what are best practices and techniques to use with the Venclose Maven™ Catheter?

Having the correct mindset for treating IPVs is essential. Perforators are shorter veins, and sometimes there is only one chance to gain access and positioning. Scan the IPV to visualize your trajectory for treatment. If the vein spasms, do not treat in the dark and consider rescheduling the patient. Best practice is to push one side of the ultrasound probe into the skin to decrease the angle. You can access more laterally with the Venclose Maven™ Catheter and curve it into the subfascial position. The ideal place to treat is below, at, and above the fascia but your ultimate targets are treating below and at the fascia, the critical location segments to ensure better closure rates.

The flexibility of the Venclose Maven™ Catheter truly allows another option of entry for a different angle other than straight, especially with ultrasound tip visualization along the entire way. To ensure treatment is not too close to the skin, ultrasound guidance is used to deliver tumescence around the vein wall to prevent thermal spread and compress the vein. We maintain at least 0.5 cm or more between the vein wall and the skin, and at least 0.5 cm between the distal tip of the catheter and the deep venous system while maintaining the catheter position. Drain the blood in the vein to maximize contact of the vein wall with the heating element, using Trendelenburg and direct pressure while keeping an eye on the catheter tip position.

Figure 1. Patient's left anterior leg before treatment.

Figure 2. Patient's left anterior leg post treatment (approximately 6 weeks)* using the Venclose Maven™ Catheter.

*Note: wound healing can potentially take up to 3 months.

In our practice, we perform 6 treatments at a time with each treatment being 20 seconds. Six treatments below the fascia, 6 at the level of the fascia, and if possible, 6 above the fascia. The Venclose Maven™ Catheter is drawn back 0.5 cm with each incremental treatment location. It's critical that you are intraluminal when performing treatments.

Can you share a recent challenging case where you used the Venclose Maven™ Catheter to treat an incompetent perforator vein?

An 80-year-old male patient had a history of previous right lower extremity endovenous ablation procedures with continued pain and swelling in the right lower extremity. He had a history of lymphedema with weeping and presented with bilateral non-healing wounds and an enlarged perforator vein, which was contributing to some of his swelling and symptoms. The right lower extremity IPV in question was identified using real-time ultrasound. The Venclose Maven™ Catheter was advanced under real-time ultrasound guidance, and easily navigated to the treatment site. The patient tolerated the procedure well. After multiple treatment segments, we confirmed IPV closure and ~6 weeks post procedure the patient's wound finally healed after dealing with it on and off for the past 5 years.

Are there any factors that may impact treatment success?

In my practice, I see favorable closure rates with IPV treatment for our patients. With that said, it's important to know in addition to this that there is a long checklist needed for proper wound closure. These can include patient compliance and other considerations around non-smoking, diabetic control, no infection, good inflow, and outflow—all of which could impact wound healing regardless of IPV closure. I think it goes back to multidisciplinary care. It is the future for closure of venous ulcers. The order of the procedures and the coordination of care between the venous practice and wound clinic can greatly affect the outcome of wound healing.

What are the benefits of using RF ablation for treating IPVs when compared to other treatment modalities?

In my practice, we have seen good results using RF ablation and adding the Venclose Maven™ Catheter to our toolbox has allowed me to offer another treatment option for my patients. From what I've seen today, not many venous practices have laser. I've experienced variability in heat transfer rates with laser as a modality due to user dependent factors that include inconsistent withdraw speed, selected generator settings and fiber tip placement within the vessel.[3,4] RFA, however, has controlled heat transfer within the targeted treatment segments. For my patients and for what I need to achieve, I like the fact that treating with RFA using the Venclose Maven™ Catheter delivers uniform heat transfer to the diseased vessel. I look forward to seeing how RFA does in the future as more studies come out on IPVs now that the Venclose Maven™ Catheter is on the market.

One of the most rewarding parts of treating IPVs is the closure of chronic venous wounds. My patients with wounds that have been open for months to years can be closed with treatment of the IPV, and we can help patients find relief from their symptoms, with our main goal being to help heal their chronic wounds. It's amazing how grateful they are. Perforators in general are not well understood. Some vein clinics either don't offer IPV treatment as part of their practice or have never trained to scan for them when a chronic venous ulcer is present. It's critical to collaborate with others who are interested in closing IPVs and often, I've found that it is the missing piece to help with wound healing.

What does the reimbursement landscape look like for treating incompetent perforating veins, and how have you overcome those challenges?

By treating IPVs, we have the added benefit to aid in chronic wound healing and to prevent recurrence.[2] With the advent of electronic medical records (EMR), the data on these patients can be used favorably in the future to show insurance payers the benefits of closing the IPV. We asked payers to analyze patients with venous ulcers.

By using EMR, and through good documentation practices, we were able to show that our patients have had good results, which is how we got our carve-outs for treating patients with IPVs. It's possible to overturn a negative coverage decision by providing payers with IPV closure data from your own practice or in partnership with your local wound care center.

The challenging part about IPVs is that studies showing closure and the resulting closure of the wound are scant; that may be one of the hurdles. Until we get a clinical trial, patients will continue to face challenges with getting the necessary treatment covered by payers. There has been an increase on wound care topics for venous conferences, which will continue to help train and spread much needed education. Vein specialists who add IPV treatment to their practices will be able to give better access to patients, who need more solutions, for their chronic venous wound care. ■

Scan the QR code using your phone camera to learn more and see the Venclose Maven™ Catheter in action!

REFERENCES

1. Star A. Differentiating lower extremity wounds: arterial, venous, neurotrophic. Semin Intervent Radiol. 2018:35(5):399-405. doi:10.1055/s-0038-1676362
2. O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2014;60:3S-59S.
3. Van Den Bos RR, Van Ruijven PWM, Van Der Geld CWM, Van Gemert MJC, Neumann HAM, Nijsten T. Endovenous simulated laser experiments at 940 nm and 1470 nm suggest wavelength-independent temperature profiles. *Eur J Vasc Endovasc Surg*. 2012;44(1):77-81.
4. Stokbroekx T, De Boer A, Verdaasdonk RM, Vuylsteke ME, Mordon SR. Commonly used fiber tips in endovenous laser ablation (EVLA): an analysis of technical differences. *Lasers Med Sci*. 2014;29(2):501-507.

Disclaimers: This article is sponsored by Becton, Dickinson and Company (BD). Dr. Tomita is a paid consultant of BD. See important Safety and Risk Information below.

The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study discussed herein may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

Venclose Maven™ Perforator Catheter Safety and Risk Information

Indication for Use: The Venclose Maven™ Catheter is intended to be used with the Venclose digiRF™ Generator as a system. The Venclose Maven™ Catheter is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux.

Contraindications: The Venclose Maven™ Catheter is contraindicated in patients with thrombus in the vein segment to be treated.

Potential Adverse Events: Potential adverse events include but are not limited to the following: vessel perforation; skin discoloration; nerve injury; temporary paresthesia; thrombosis; deep vein thrombosis; phlebitis; hematoma; infection; skin burn; pulmonary embolism; and pain.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions. BD, the BD logo, digiRF and Venclose Maven are trademarks of Becton, Dickinson and Company or its affiliates.