

# Endovenous Ablation Without Anesthesia?

Early experience with a new laser wavelength that is highly absorbable by water.

BY JOSE I. ALMEIDA, MD, FACS, RVT

**T**he past 10 years have seen endovenous therapy displace traditional surgery as the primary treatment modality for saphenous vein incompetence. Prospective randomized clinical trials have shown the benefit of reduced side effects from endoluminal thermal ablative techniques compared to traditional stripping, with comparable efficacy.<sup>1,2</sup> There is an increasing focus on reducing perioperative pain and bruising in the field of saphenous ablation. It has always been the belief throughout the endovenous community that patients treated with radiofrequency (RF) ablation have had a smoother postoperative recovery than those treated with endovenous laser (EVL). This has now been confirmed by the RECOVERY (Radiofrequency endovenous ClosureFast [Vnus Medical Technologies, Inc., San Jose, CA] versus laser ablation for the treatment of great saphenous reflux) study,<sup>3</sup> the only prospective randomized trial comparing RF ablation to EVL. The RF group of patients reported significantly lower pain levels than the laser group at the 48-hour, 1-week, and 2-week visits ( $P < .0001$ ). Differences in ecchymosis also favored RF and were most marked at the 48-hour, 1-week, and 2-week postoperative visits ( $P < .0001$ ).

Although it is not known exactly how much damage to the individual layers of the vein wall is required, it seems that at least intimal and medial coagulation are necessary to result in long-term closure. The original bipolar RF device, which operated at 85°C, used the vein wall as a resistive element for transfer of energy from anode to cathode. However, in the contemporary RF device operating at 120°C, the vein wall is the direct recipient of conducted heat from a 7-cm-long heating element. Qualitative analysis with optical coherence tomography in an ex vivo model, when compared with histological cross sections, showed a

symmetrical, complete, and circular disintegration of intima and media structures without any transmural tissue defects after RF ablation.<sup>4</sup> EVL, on the other hand, which originated with hemoglobin-specific laser wavelengths (HSLW) based on the hemoglobin's affinity for infrared light, destroys incompetent veins by combining two effects: (1) direct fiber contact with the vein wall and (2) the generation of steam bubbles by boiling blood. With optical coherence tomography and histologic examination of the veins treated with an HSLW laser, pronounced semicircular tissue ablations and complete vessel wall perforations were detected at moderate energy densities.<sup>4</sup> Therefore, laser works at the expense of causing robust perivenous inflammation, likely because of venous perforation (Figure 1) and subsequent recruitment of the cytokine system. The



Figure 1. Top vein untreated with EVL, middle vein treated with EVL (unopened), bottom vein treated with EVL and opened—notice carbonization and perforation.

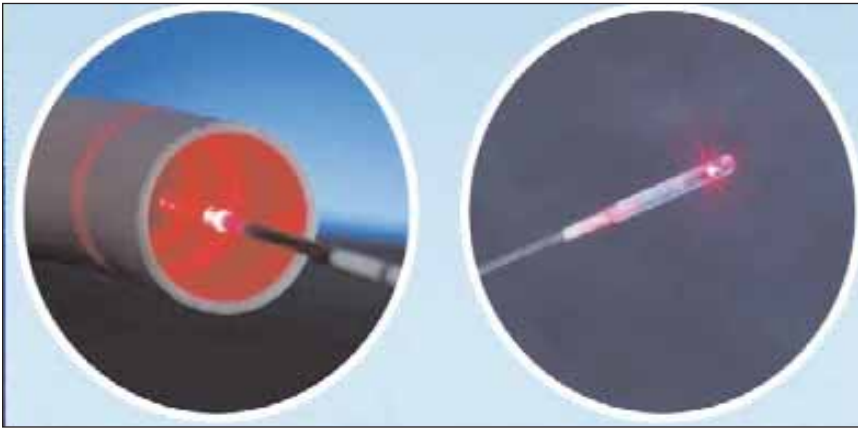


Figure 2. Radial-emitting fiber dispenses laser circumferentially 360°.

smoother recovery profile of RF ablation is likely due to the absence of transmural perforation.

Water-specific laser wavelengths (WSLW) were developed to better target the interstitial water in the vein wall, with a goal of minimizing perforation and the side effects of pain and ecchymosis.<sup>5</sup> When performing EVL at comparable linear endovenous energy density with either 940- (HSLW) or 1320-nm (WSLW) lasers, there was an observable reduction in postoperative pain and bruising with the 1320-nm device.<sup>6</sup> The most recent WSLW to become available is the 1,470-nm ELVeS Endo Laser Vein System (biolitec, Inc., East Longmeadow, MA). Preliminary data demonstrate a paucity of pain and ecchymosis postoperatively that is comparable to RF ablation. The 1,470-nm wavelength has a high affinity for absorption by water, thus allowing successful vein ablation with very low-energy densities. This has sparked interest in laser ablation without perivenous anesthesia.

The placement of tumescent anesthesia is usually done percutaneously through multiple injections along the inner thigh following the course of the target vein. However, it can be a somewhat tedious and time-consuming procedure, especially in the hands of a novice endovenous surgeon. Some patients find the needle sticks to be quite uncomfortable, because they are noxious stimuli. Recently, there has been an interest in developing a procedure that completely eliminates the need for tumescent anesthesia. For example, catheter-directed sclerotherapy chemically injures the venous endothelium without requiring perivenous anesthesia; however, it was found to be inferior to thermal ablation with regard to vein closure efficacy.<sup>7</sup>

We recently presented a study at the American Venous Forum<sup>8</sup> whereby 67 veins in 58 patients were operated on in two separate groups with a 1,470-nm wavelength endovenous laser. The objectives of this

study were threefold: (1) to estimate the safety of a new water-specific endovenous laser wavelength, (2) to investigate whether this system can close a saphenous vein painlessly in the absence of perivenous anesthesia, and (3) to develop a low-energy protocol for this device. Twenty-six veins in group A were treated with a radially emitting fiber at low energy ranging from 20 to 30 J/cm linear endovenous energy density. Perivenous anesthesia was added only to patients experi-

encing pain and was titrated in small amounts to provide individual patient comfort; there was no attempt to shrink the vein. In group B, 41 veins in 33 patients were treated with 30 J/cm using standard perivenous tumescent anesthesia (vein compression and shrinkage) in all cases. Group A patients received less energy than group B (23 vs 31 J/cm). Postoperative pain and bruising were minimal in both groups. The primary closure rate was 87.5% in group A and 100% in group B as determined by duplex ultrasound. We concluded that the 1,470-nm wavelength endovenous laser system would successfully close saphenous veins with a dramatic reduction in energy. Postoperative sonographic vein wall changes suggested the vein wall is acting as a strong chromophore for this new water-specific wavelength. Clinical findings demonstrated a marked reduction in postoperative pain and ecchymosis when compared on a historical basis to the author's substantial experience with hemoglobin-specific laser wavelengths, implying that vein wall perforations are minimized at 1,470 nm.

Although higher energies were used in group B, we believed that the main increase in closure efficacy seen in this group was due to the addition of perivenous tumescent anesthesia, which allowed the target (vein wall) to be brought into closer proximity to the energy source (laser fiber tip). We know that the majority of activity between the photon and the chromophore occurs at a distance of 0.3 mm from the fiber tip; therefore, we believe good apposition of the vein wall to the laser fiber is critical for successful energy transfer during thermal ablation. Clearly, there are subgroups of patients presenting with differing severity of venous disease, and those with small-diameter saphenous veins may be amenable to low-energy thermal ablation without any anesthetic support. However, we only saw this in one patient from group A.

It is doubtful that thermal energy, as the sole source for ablation, will provide enough delivered energy density without the use of some anesthesia. All but one group A patient tolerated lasing without lining the vein with an anesthetic. Perhaps low energies delivered in synergy with another means of damaging the intima and media (ie, sclerosing solution, mechanical scraping device, etc.) would produce the desired destruction without producing a noxious stimulus to the patient. Combining two modalities, which stay below the threshold for side effects, can be more effective than a single modality pushed into a toxic dose range. With the group A patients, we were 88% successful at 3-month follow-up in closing veins <10 mm in diameter with local (not tumescent) anesthesia with the 1,470-nm device at 23 J/cm. However, we see no clinical advantage of local over tumescent anesthesia, since both require delivery with multiple needle sticks along the course of the target vein.

Perhaps a two-step plan will produce painless, 100% closure without anesthesia, for example: (1) catheter-directed sclerotherapy to denude the vein of its endothelial lining and expose the media while concomitantly causing vasospasm and bringing the vein wall closer to the energy source, followed by (2) low-energy WSLW laser ablation with a radially emitting fiber (Figure 2). The photons can now be brought into closer proximity to the media and more readily exposed to the water and myoglobin chromophores, both present in smooth muscle cells. While sparing the adventitia from thermal energy, sympathetic nerve fibers will remain inactivated (no pain), and the source of fibroblasts for collagen deposition will be left intact (luminal fibrosis). Bush et al<sup>9</sup> have shown that the source of fibroblasts needed for long-term fibrosis come mainly from the adventitial layer of the vein wall.

## CONCLUSION

EVL technology continues moving further toward the development of wavelengths that target the last peak of water absorption at near-infrared wavelengths of 2,000 nm. The idea is that hemoglobin absorption is totally bypassed, allowing more robust absorption of laser photons by interstitial water and myoglobin in the vein wall. It is unknown at this time if this wavelength will emerge as the anesthesia-less thermal ablation technology. ■

*Jose I. Almeida, MD, FACS, RVT, is Director, Miami Vein Center, and Voluntary Associate Professor of Surgery at the University of Miami – Jackson Memorial Hospital in Florida. He has disclosed that he has received a research*

*grant from biolitec for this work. Dr. Almeida may be reached at dralmeida@mac.com.*

1. Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVE Study). *J Vasc Surg.* 2003;38:207-214.
2. Rasmussen LH, Bjoern L, Lawaetz M, et al. Randomized trial comparing endovenous laser ablation of the great saphenous vein with high ligation and stripping in patients with varicose veins: short-term results. *J Vasc Surg.* 2007;46:308-315.
3. Almeida JI, Kaufman J, Gbckertiz O, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: a multicenter, single-blinded, randomized study (RECOVERY). *J Vasc Interv Radiol.* In press.
4. Schmedt CG, Meissner OA, Hunger K, et al. Evaluation of endovenous radiofrequency ablation and laser therapy with endoluminal optical coherence tomography in an ex vivo model. *J Vasc Surg.* 2007;45:1047-1058.
5. Goldman MP, Mauricio M, Rao J. Intravascular 1320-nm laser closure of the great saphenous vein: a 6- to 12-month follow-up study. *Dermatol Surg.* 2004;30:1380-1385.
6. Proebstle TM, Moehler T, Gul D, et al. Endovenous treatment of the great saphenous vein using a 1320 nm Nd:YAG laser causes fewer side effects than using a 940 nm diode laser. *Dermatol Surg.* 2005;31:1678-1683; discussion 1683-1684.
7. Almeida JI, Raines JK. FDA-approved sodium tetradecyl sulfate (STS) versus compounded STS for venous sclerotherapy. *Dermatol Surg.* 2007;33:1037-1044; discussion 1044.
8. Almeida JI, Mackay EG, Javier JJ, et al. Saphenous laser ablation at 1470-nm targets the vein wall, not blood. Presented at the American Venous Forum; February 2009; Phoenix, Arizona.
9. Bush RG, Shamma HN, Hammond K. Histological changes occurring after endoluminal ablation with two diode lasers (940 and 1319 nm) from acute changes to 4 months. *Lasers Surg Med.* 2008;40:676-679.