EVL Ablation Using Jacket-Tip Laser Fibers

Treatment outcomes reveal improved postoperative recovery in endovenous laser ablation patients.

BY LOWELL S. KABNICK, MD, FACS, FACPh, AND JAYNE A. CARUSO, RN

Early endovenous laser (EVL) ablation methodologies used bare-tip fibers to deliver pulsed laser energy via a slow pullback of the fiber, combined with manual compression (Figure 1).[1-3] Initial findings using this method revealed that perforations occurred at the site of direct impact of the bare-tip fiber with the vessel wall, leading to a high rate of postoperative ecchymosis and pain.[1-6] In an attempt to decrease these side effects, thought leaders began using continuous laser energy as opposed to pulsed and eliminated manual compression.

Since these initial findings, several investigators have concluded that vein perforations and the permeation of extravasated blood into adjacent structures are the causes of postoperative hematoma and tenderness.[4,5] Only a small number of studies have evaluated the effects of vein perforations, generating considerable debate over the laser-tissue interaction of bare-tip laser fibers.

Min et al[6] studied a 600-µm, bare-tip fiber and concluded that the compression derived from tumescent anesthesia created vein wall apposition, leading to circumferential heating of the vein wall. Conversely, Proebstle et al[4] studied bare-tip fibers of the same dimension and sustained that the pathophysiological mechanism of action stemmed from indirect local heat injury of the inner vein wall by steam bubbles that destroy endothelium. Regardless of the mechanism of action, unintentional vein wall contact and perforation cannot be avoided with any certainty when using a bare-tip fiber.[4,5]

As data have emerged, the treatment methodology has changed and evolved to improve treatment outcomes. Parameters such as delivered energy, wavelength, and pullback time have been modified from the protocols performed by early users. Timperman[7,8] and Proebstle[9] have studied the correlation between delivered laser energy and vein occlusion, each concluding that higher linear endovenous energy densities yield a higher rate of efficacy. Although an increase in the delivered joules per centimeter demonstrated improvement in outcomes, there was no difference noted in postoperative bruising, pain, or phlebitis.[7-9]

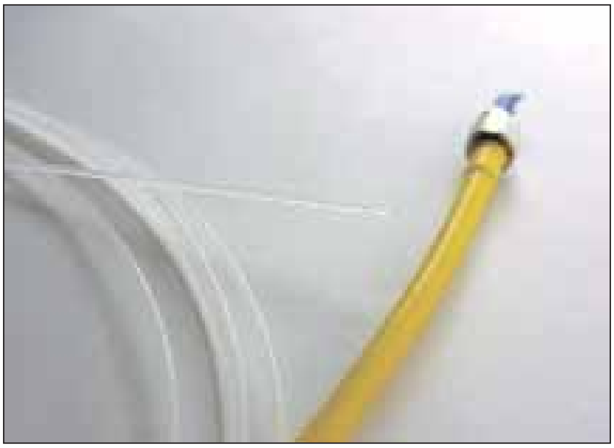

Figure 1. Bare-tip laser fiber.

Others have focused on the wavelength characteristics of the available lasers, which currently range from 810 to 1,470 nm. Kabnick[10] and Proebstle et al[11] compared 810 nm versus 980 nm with 940 nm versus 1,320 nm, respectively. Kabnick noted that patients who underwent treatment with the 980-nm laser reported lower bruising scores ($P < .005$) and less pain intensity ($P < .05$).[10] Similarly, the patients who were treated with a 1,320-nm laser were reported to have less pain ($P < .005$) and less ecchymosis ($P < .05$) than those treated with the 940-nm laser.[11] The rationale for these results was

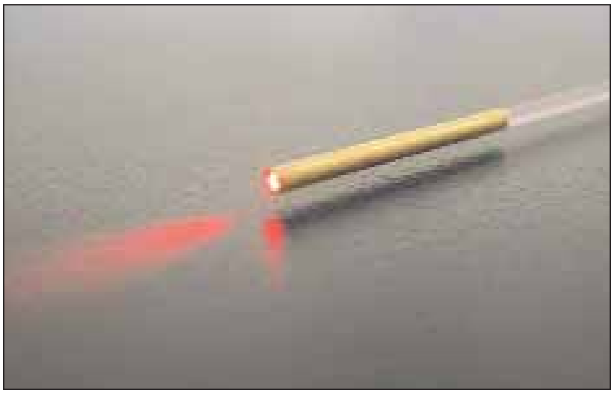

Figure 2. Jacket-tip laser fiber.

attributed to the absorption characteristics of various wavelengths; higher wavelengths are thought to be more optimal for water absorption and less prone to hemoglobin absorption, reducing the potential for vein perforations.[11-13] Water-specific laser wavelengths target the water within tissues, resulting in collagen contraction similar to what is observed with radiofrequency ablation.[13] Conversely, hemoglobin-specific wavelengths depend on the presence of blood to act as a chromophore to conduct thermal energy and inflict damage and perforations to the vein wall.[14] Although these studies showed a lower incidence of pain and bruising with higher wavelengths, there was no difference between the wavelengths in treatment efficacy.[10,11]

Treatment modifications to delivered energy and wavelength have improved the endothermal venous ablation procedure; however, the issues of postoperative pain and bruising remain the most frequent side effects, which are largely due to the exposed tip of a bare-tip laser fiber. The most substantial difference in treatment outcomes may not be related to wavelength or energy output but rather to the type of laser fiber being used.

A possible solution to eliminate vein perforations from laser-tip wall contact is the jacket-tip fiber (NeverTouch, AngioDynamics, Inc., Queensbury, NY) (Figure 2). This type of fiber features a “jacket” at the distal tip of the fiber that covers the energy-emanating portion of the fiber. The jacket prevents the flat emitting face of the fiber from coming in contact with the vessel wall.

Because of their possible differences in mechanism of action, we selected a 600-µm bare-tip and a 600-µm jacket-tip fiber for investigation. This article presents the findings of a randomized, prospective, single-center study comparing the effects of bare-tip and jacket-tip fibers in EVL treatment of great saphenous vein (GSV) insufficiency.

METHODS AND MATERIALS

Twenty male and female patients were selected in succession from a list of individuals waiting to receive treatment of GSV insufficiency. As part of their consent, the patients were informed of their randomization into either the bare-tip or jacket-tip fiber group for treatment of their GSV with a 980-nm laser.

Figure 3. A 0 out of 5 bruising score.

Inclusion criteria included patients between the ages of 20 and 70 who had a minimum symptomatic C2 disease (using current CEAP [clinical, etiologic, anatomic, pathophysiologic] classification for chronic venous disorders), multilevel venous reflux greater than 0.5 seconds, a duplex scan to determine GSV incompetence, and whether they were willing to return for postprocedure follow-up visits. Patients were excluded if they had a previous venous ipsilateral intervention or did not meet the age criterion. Additional exclusion criteria were pregnancy, hypercoagulable state, deep vein thrombosis, or any other medical condition that would prevent safe completion of the procedure.

Surgical Technique

Under ultrasound guidance, access was gained below the knee with a Micro Access set (AngioDynamics, Inc.) using a 21-gauge needle and a 0.018-inch Micro Access wire. Once successfully placed, a 4-F micropuncture sheath was inserted. Next, the inner dilator of the micropuncture sheath and the 0.018-inch wire were removed, and a

Figure 4. A 2 out of 5 bruising score.

Figure 5. A 5 out of 5 bruising score.

0.035-inch guidewire (AngioDynamics, Inc.) was advanced to the saphenofemoral junction. A 45-cm, 4-F sheath (AngioDynamics, Inc.) was backloaded over the guidewire and positioned 1.5 cm below the saphenofemoral junction. After ultrasound confirmation, the sheath's inner introducer and guidewire were removed, and either a 600-µm bare-tip or a 600-µm jacket-tip fiber was placed into the sheath.

Tumescent anesthesia was administered with a 22-gauge needle perivenously along the entire segment that was to be treated. Ultrasound examination was used to ensure that a 10-mm space had been generated between the skin and the vein wall. The laser fiber and sheath were pulled back in a continuous manner through the vein segment at a target standard energy rate of 100 J/cm at 12 W. Once the entire vein segment had been treated, closure was confirmed with duplex ultrasound.

Subsequently, a 0.5-inch adhesive strip and a sterile 2 X 2-inch gauze pad were positioned over the puncture site, and a full-thigh compression stocking (30–40 mm Hg) was placed on the treated leg. All patients were instructed to wear the compression stocking continuously for 24 hours. The patients were then directed to wear the stocking during the hours they were awake and to take 1,200 mg/day of ibuprofen for the extent of their 7-day postoperative period.

The same surgeon performed all the procedures. Patients were monitored within 72 hours after the procedure with a duplex ultrasound and a postoperative visit to the physician at 1 week. Patients were required to fill out a pain score for the first 7 days, which was based on a 10-point analogue pain scale.[14]

In addition, a digital picture of each patient's treated leg was taken at the postoperative visit. Digital pictures were used to analyze the degree of ecchymosis on a standard 5-point graded scale (Figures 3 through 5). Analysis and development of the bruising score was performed by a nurse who was blinded to the fiber use.

TABLE 1. STUDY RESULTS

Variable	Jacket-Tip	Bare-Tip
No. patients	10	10
Average age	56.5 ± 14.2	51.70 ± 11.1
Women/men (%)	F = 90% M = 10%	F = 90% M = 10%
Average length treated	36.25 cm	34.35 cm
Average total J/cm	71.6 ± 10.4	86.2 ± 8.1
Average pain	0.96	1.87
Average bruise	1.05	1.45
Total GSV closed	10	10

RESULTS

All patients were treated unilaterally, and the patient groups were similar in sex distribution and age (56.5 ± 14.2 years for the jacket-tip group and 51.7 ± 11.1 years for the bare-tip group). All treated limbs (20) for both groups were successfully closed when assessed at 72 hours post-procedure (Table 1).

Pain Scoring

Analogue pain scores were recorded by patients each day of the first 7 days on a standardized scale from zero to 10. The jacket-tip group reported an average score of 0.96, whereas the bare-tip group reported an average score of 1.87 ($P < .005$).

Ecchymosis

Analysis and development of the unbiased bruising score showed an average of 1.05 for the jacket-tip group and 1.45 for the bare-tip group.

DISCUSSION

EVLs were conceptualized to improve patient recovery and outcomes in comparison to the widely used vein stripping method. The efficacy of EVLs was proven from

(Continued on page 81)

(Continued from page 80)

the outset; however, pain and bruising have been a point of contention. The data in the literature evaluating higher energy delivery and higher wavelengths have insufficiently addressed these side effects.

A cause of vessel perforation that has not been discussed in substantial detail is an inadvertent needle puncture of the vein wall that can occur during the delivery of tumescent anesthesia.[10] In our study, the overall physical and symptomatic findings after treatment were qualitatively and statistically better for the jacket-tip group compared to the bare-tip fiber group. The difference in bruising scores can be most credibly attributed to the laser energy during the procedure. Because the energy-emitting portion of fiber is recessed in the jacket, and the tumescent procedure (which can cause perforation) was the same for both groups, the jacket tip is the most logical explanation for the decrease in the bruising score. The protection of the jacket tip demonstrated the ability to prevent perforation that is commonly associated with bruising,[4,5] hence, the difference in bruising scores.

CONCLUSIONS

The results of this study reveal that use of a jacket-tip laser fiber produces a more tolerable postoperative recovery with less ecchymosis and pain. The prevention of vein wall contact and perforation by the jacket tip is the plausible contributing factor to these differences in side effects. In addition, endothermal ablation using a jacket-tip fiber adds evidence that there is no need for laser-tip wall contact to ablate the vein. Being the first study of its kind, further investigations with jacket-tip fibers are needed to solidify these claims. ■

Lowell S. Kabnick, MD, FACS, FACPh, is the Director of the New York Vein Center at the New York University Langone Medical Center in New York, New York. He has disclosed that he is a paid consultant to AngioDynamics, Inc., and BTG International Inc. Dr. Kabnick may be reached at (212) 263-8346; lowell.kabnick@nyumc.org.

Jayne A. Caruso, RN, is with the New York Vein Center of the New York University Langone Medical Center in New York, New York. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein. Miss Caruso may be reached at (212) 263-8346; jayne.caruso@nyumc.org.

1. Min R, Zimmet SE, Isaacs MN, et al. Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Interv Radiol. 2001;12:1167-1171.
2. Min RJ, Khilnani N. Endovenous laser treatment of saphenous vein reflux using continuous mode. J Vasc Interv Radiol. 2003;14(Suppl):S35.
3. Navarro L, Min RJ, BonO C. Endovenous laser: a new minimally invasive method of treatment for varicose veins—preliminary observations using an 810 diode laser. Dermatol Surg. 2001;27:117-122.
4. Proebstle TM, Jehr HA, Kargl A, et al. Endovenous treatment of the greater saphenous vein with a 940 nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser generated steam bubbles. J Vasc Surg. 2002;35:729-736.
5. Weiss RA. Comparison of endovenous radiofrequency versus 810 nm diode laser occlusion of large veins in an animal model. Dermatol Surg. 2002;28:56-61.
6. Min R, Khilnani N, Zimmet S. Endovenous laser treatment of saphenous vein reflux: long-term results. J Vasc Interv Radiol. 2003;14:991-996.
7. Timperman PE, Sichlau M, Ryu RK. Greater energy delivery improves treatment success of endovenous laser treatment of incompetent saphenous veins. J Vasc Interv Radiol. 2004;15:1061-1063.
8. Timperman PE. Prospective evaluation of higher energy great saphenous vein endovenous laser treatment. J Vasc Interv Radiol. 2005;16:791-794.
9. Proebstle TM, Krummenauer F, Gul D, et al. Nonocclusion and early reopening of the great saphenous vein after endovenous laser treatment is fluence dependent. Dermatol Surg. 2004;30(2, pt 1):174-178.
10. Kabnick L. Outcome of different endovenous laser wavelengths for great saphenous vein ablation. J Vasc Surg. 2006;43:88-93.
11. Proebstle TM, Moehler T, Gul D, et al. Endovenous treatment of the great saphenous vein using a 1,320 nm Nd:YAG laser causes fewer side effects than using a 940 nm diode laser. Dermatol Surg. 2005;31:1678-1684.
12. Goldman MP, Detwiler SP. Endovenous 1064-nm and 1320-nm ND:YAG laser treatment of the porcine greater saphenous vein. Cosmet Dermatol. 2003;16:25-28.
13. 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.
14. Proebstle TM, Sandhofer M, Kargl A, et al. Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. Dermatol Surg. 2002;28:596-600.