

# Overview of Endovenous Thermal Ablation of Varicose Veins

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Endovenous interventions have transformed the treatment of varicose veins during the past decade. Interest in minimally invasive endovenous thermal ablation of the saphenous vein has substantially increased due to multiple reasons. Both radiofrequency ablation (RFA) and endovenous laser therapy (EVLT) can be performed as an office procedure; they are less invasive and usually less painful than conventional open surgical stripping and appear to be equally as effective. In addition, there is apparent benefit of earlier return to work and less temporary decrease in quality of life. Public awareness of varicose veins and venous disease has increased considerably, in part because of activities of the American Venous Forum and the American College of Phlebology, but also because of increasing public advertisement of minimally invasive techniques by the medical industry. Informed patients seeking medical help for aching legs with unsightly veins or venous ulcers request RFA or EVLT for treatment of venous disease.

In a recent issue of *Endovascular Today*, leaders of the field expressed their opinion of currently used techniques for varicose veins including RF, EVLT, endovenous chemical ablation with ultrasound-guided foam sclerotherapy, as well as the conventional open surgery of saphenous stripping and high ligation.<sup>1</sup> This article reviews currently used endovenous thermal treatments for saphenous vein ablation in patients with varicose veins and presents the most recent results. We also provide an insight of what is on the horizon from the medical industry to improve efficacy, expand indications, and decrease complications of these procedures.

## ENDOVENOUS THERMAL ABLATION DEVICES

The principle of treatment using either RFA or EVLT is to inflict direct endovenous thermal damage to the vein wall resulting in destruction of the intima and collagen denaturation of the media, with eventual fibrotic occlusion of the vein. EVLT may also cause thermal damage by indirect heating of the vein wall by generation of intravascular steam bubbles in the venous blood. For EVLT, laser wavelengths from 810  $\mu\text{m}$  to 1,320  $\mu\text{m}$  have been used with similar success (Table 1).

TABLE 1. ENDOVENOUS ABLATION DEVICES APPROVED FOR USE IN THE US

Device Name	Manufacturer	Wavelength ( $\mu\text{m}$ )
Laser		
EVLT	Diomed, Inc. (Andover, MA)	810
Venacure	AngioDynamics, Inc. (Queensbury, NY)	810, 980
Medilas	D Dornier MedTech (Kennesaw, GA)	940
VariLase	Vascular Solutions, Inc. (Minneapolis, MN)	810
CTEV	CoolTouch, Inc. (Roseville, CA)	1,320
Pro-V	Sciton (Palo Alto, CA)	1,319
Radiofrequency Closure	VNUS Inc. (San Jose, CA)	N/A

**TABLE 2. KEY STEPS TO PERFORM ENDOVENOUS THERMAL ABLATION OF THE SAPHENOUS VEIN**

- Use the micropuncture kit and needle to gain access under ultrasound guidance into the saphenous vein in the patient placed in the reversed Trendelenburg position.
- Position tip of the catheter in the great saphenous vein 1 cm distal to confluence of the superficial epigastric vein.
- Use a single-dose, intraoperative, low-molecular-weight heparin for DVT prophylaxis.
- Infiltrate tumescent anesthetic solution (50 mL 1% lidocaine with and 1 mL epinephrine [1:1,000] diluted in 1 L normal saline) into the saphenous subcompartment.
- Place the patient in the Trendelenburg position and check position of the tip of the laser or RF device with ultrasound immediately before treatment.
- Image the vein after treatment, re-treat if needed.
- Apply compression bandage from toes to groin with selective padding over the treated saphenous vein to optimize local compression.
- Ambulate immediately after surgery.
- Patients should take nonsteroidal anti-inflammatory drug (ibuprofen, 400 mg three times daily po) for 5 days after therapy to minimize aching and inflammation.
- Perform postoperative ultrasound within 24 to 72 hours.

**INDICATIONS**

EVLT and RFA are now widely accepted as minimally invasive percutaneous endovenous techniques for ablation of the great saphenous vein (GSV). They are also used with increasing frequency to treat the small saphenous vein (SSV), accessory saphenous veins, and the perforating veins. Indications for endovenous ablation are identical to those for surgical high ligation and stripping: reflux at the saphenofemoral or saphenopopliteal junction identified on duplex ultrasound in patients with varicose veins or advanced chronic venous insufficiency, including venous ulcers. It is prudent to avoid endovenous thermal ablation in patients with large saphenous varices or venous aneurysm located within 2 cm of the saphenofemoral junction, or in patients who have the great saphenous vein located immediately under the skin.

**TECHNIQUE**

Endovenous ablations can be performed as office procedures under femoral block and/or local anesthesia, with minimal discomfort and high patient satisfaction. The patient is placed in the reversed Trendelenburg position, and the target vein is accessed percutaneously under ultrasound guidance at the knee (GSV) or ankle level (SSV) using a micropuncture kit and needle (Table 2). A guidewire is inserted into the vein followed by placement of a 5-F sheath.<sup>2,3</sup> The laser catheter or RF probe is introduced through the sheath into the vein and

**TABLE 3. RESULTS OF RFA AND EVLT**

Investigator, Year	Type of Study	No. of Limbs	Procedure	Follow-Up (y)	Total Occlusion (%)	Partial Occlusion (%)
Rautio, <sup>6</sup> 2001	RCT	33	RFA	1	75	26
Lurie, <sup>4,5</sup> 2003, 2005	RCT	44	RFA	2	89	7
Merchant, <sup>26</sup> 2002	CS	125	RFA	3	85	4
Pichot, <sup>27</sup> 2004	CS	65	RFA	2	90	10
Merchant, <sup>28</sup> 2005	CS	55	RFA	5	92	
Nicolini, <sup>29</sup> 2005	CS	330	RFA	3	75	17
Merchant, <sup>8</sup> 2005	CS	1,222	RFA	5	87	8
Min, <sup>9</sup> 2003	CS	499	EVLT	2	93	
Sadick, <sup>30</sup> 2004	CS	30	EVLT	2	97	
Timperman, <sup>31</sup> 2005	CS	100	EVLT	1	91	4
Puggioni, <sup>3</sup> 2005	CS	53	RFA	<1	94	
Puggioni, <sup>3</sup> 2005	CS	77	EVLT	<1	91	
Kavuturu, <sup>32</sup> 2006	CS	66	EVLT	0.75	97	3
Myers, <sup>33</sup> 2006	CS	396	EVLT	3	80% (95% CI, 69%-87%)	
Ravi, <sup>34</sup> 2006	CS	1,250	EVLT or RF	3 (143 limbs)	100% (GSV) 95% (SSV)	

RCT = randomized controlled trial; CS=case series; RFA=radiofrequency ablation; EVLT=endovenous laser therapy; GSV=great saphenous vein; SSV=small saphenous vein.

advanced proximally to the saphenofemoral or saphenopopliteal junction. When treating the GSV, the tip of the catheter is positioned 1 cm distal to the superficial epigastric vein. For treatment of the SSV, the tip of the probe is positioned 1 cm to 1.5 cm distal to the saphenopopliteal junction. The patient is then placed in the Trendelenburg position, and the vein is emptied by elevation and by instillation of perivenous tumescent anesthetic solution (50 mL 1% lidocaine with and 1 mL epinephrine [1:1,000] diluted in 1 L normal saline) into the saphenous subcompartment. The instilled fluid ensures good contact of the vein wall with the treating catheter for optimal therapeutic effectiveness; it also provides analgesia and a heat sink around the treated vein thereby decreasing heat-related injury to surrounding tissues and reduces the risk of skin burns and paresthesias. The vein is then ablated by withdrawing the catheter to a few centimeters above the puncture site. The EVLT catheter is withdrawn at a rate of 1 to 2 mm/s for the first 10 cm and 2 to 3 mm/s for the remaining distance to deliver 60 to 70 J/cm using 14 W continuous laser energy. With RFA, the target temperature is either 85°C or 90°C. When 85°C is used, the pullback rate is approximately 2 to 3 cm/min, and when 90°C is used, the pullback rate is commonly 4 cm/min. The pullback rate is less for treatment of the 4-cm to 5-cm segment of the GSV closest to the saphenofemoral junction. At the end of the procedure, the saphenous vein is imaged with ultrasound to confirm occlusion and absence of thrombus in the common femoral or popliteal veins. If a patent segment is identified, re-treatment is advisable. Direct compression of the saphenous vein with pads under the compression stocking or elastic bandage is advised. It is important to get the patients ambulatory as soon as possible. Data to support the routine administration of thromboprophylaxis with heparin are not available. Because we have observed extension of the saphenous thrombus into the femoral vein, in our practice, a single dose of low-molecular-weight heparin is used routinely.<sup>2,3</sup> If one prefers selective prophylaxis, it should be used for patients with a history of thrombophlebitis, deep vein thrombosis (DVT), obesity, or in patients older than 50 years of age.<sup>3</sup>

## RESULTS

### Radiofrequency Ablation

The RFA system received Food and Drug Administration (FDA) clearance in March of 1999. As of mid-2006, there were more than 135,000 RFA procedures performed worldwide. The Closure technique (VNUS Inc., San Jose, CA) is well tolerated with minimal short- and long-term morbidity. The clinical benefits of RFA have been demonstrated through randomized clinical studies comparing this technique with conventional vein stripping. The

EndoVenous Obliteration versus Ligation and Vein Stripping (EVOLVeS), a company-sponsored prospective randomized trial, demonstrated a 91% initial occlusion rate with RFA and a complication rate that was similar in both groups.<sup>4</sup> The study found that postoperative pain was significantly less severe, absence from work was shorter, and physical function was restored faster after RFA than stripping (Table 3). At 2 years, recurrent varicose veins were noted in 14% of the RFA group versus 21% in the surgical group, with statistically maintained better quality-of-life scores in the RFA group.<sup>5</sup> A prospective randomized study by Rautio also showed less pain and more rapid recovery after RFA versus stripping.<sup>6</sup> Hinchliffe randomized 16 patients with recurrent GSV reflux to RFA and stripping; RFA was faster, and the pain and bruising score was less after RFA versus stripping.<sup>7</sup> The Closure Study Group studied more than 1,200 limbs;<sup>8</sup> occlusion rates at 1, 2, and 5 years were 87.1%, 88.2%, and 87.2%, respectively (Table 3). Duplex ultrasound identified 185 limbs with anatomical failures, most (70%) due to recanalization of the occluded saphenous vein; in 12%, the vein failed to occlude initially and never occluded during follow-up, whereas in 18%, the treated vein remained occluded, but an accessory saphenous vein produced reflux.

### Endovenous Laser Therapy

Large, single-center experiences with lasers have achieved 97% to 98% early occlusion rates and have maintained occlusion in 93% of limbs at 3 years, with the majority of recurrences occurring by the first 3 months.<sup>9-11</sup> Min recently reported 98% occlusion up to 5 years after laser treatment of 1,000 limbs.<sup>12</sup> In an international registry that included 5,262 patients, Kabnick et al reported a 96% early success rate after GSV ablation with the 980- $\mu$ m laser.<sup>13</sup> Navarro et al reported a 95% success rate with follow-up extending to 4 years; recurrence was due to saphenous recanalization and not neovascularization.<sup>14</sup>

The success of EVLT has been shown to depend on the amount of energy delivered, with nonocclusion and early reopening of the GSV seen more frequently when <70 J/cm laser energy is used for saphenous vein occlusion.<sup>15,16</sup>

A systematic review of EVLT was performed by Mundy et al.<sup>17</sup> None of the 13 studies analyzed had an open surgical control group. Occlusion of the GSV and abolition of venous reflux occurred in 87.9% to 100% of limbs, with low rates of re-treatment and recanalization. The study concluded that EVLT benefits most patients in the short-term, but rates of recanalization, re-treatment, occlusion, and reflux may change with longer follow-up and that there is a need for a randomized trial of EVLT versus conventional surgery.

A recent study by Mekako et al<sup>18</sup> compared early quality-of-life outcomes after EVLT and surgery between two

nonrandomized groups of patients. Seventy patients were in the EVLT group and 62 were in the surgery group. The quality-of-life scores were significantly better in the EVLT group at 1 and 6 weeks, but not at 12 weeks. The investigators concluded that EVLT removed the quality-of-life limitations experienced by patients in the early postoperative period.

**COMPLICATIONS**

Major complications after endovenous thermal ablation of the saphenous veins are rare, but minor complications have been reported in 3% to 20% of patients, including bruising around the puncture site, bleeding, transient paresthesias, superficial phlebitis, skin burns, or pigmentation. In the Closure Registry, paresthesia was observed in 12.3% (121 of 985 limbs) at 1 week, in 7.3% at 6 months, and in 2.6% at 5 years.<sup>8</sup> The incidence of skin burns and paresthesias decreased to less than 1% with increasing operator experience and with routine use of tumescent anesthesia.<sup>8</sup>

Patients undergoing laser therapy frequently experience a tight, pulling sensation in the medial thigh along the course of the GSV, due to a mild-to-moderate form of saphenous thrombophlebitis. Because blood is a chromophore for all laser wavelengths used, any blood present in the vein will predispose to thrombosis and thrombophlebitis.

Major complications of EVLT include DVT and pulmonary embolism (PE). Although both DVT and PE are rare, extension of thrombus from the saphenous into the femoral or popliteal vein has been reported to occur in 0% to 6% of the patients: in one study by Hingorani, extension of thrombus occurred in 16% of the limbs after RFA.<sup>19</sup> Kabnick recently introduced the term "endovenous heat-induced thrombus" (EHIT).<sup>20</sup> The natural history of EHIT is likely more benign than that of a frank DVT; the registry of Kabnick identified 16 observed cases with class 2 EHIT (thrombus protruding into the femoral vein and occluding up to 50% of the lumen). Currently, short-term (2 to 6 weeks) treatment with anticoagulation is recommended to prevent thrombus progression or PE.

In 77 EVLT procedures, our group measured the median distance between the tip of the saphenous vein thrombus and the common femoral vein (CFV): the median distance was 9.5 mm (range, -20 mm [protrusion in the CFV] to 50 mm), significantly less in older patients ( $r^2=.12$ ;  $P=.006$ ).<sup>2</sup> Thrombus protruded into the CFV in three limbs after EVLT (2.3%).<sup>3,21</sup> All three patients were treated with anticoagulation; one underwent placement of a temporary inferior vena cava filter because of a floating thrombus in the CFV. Duplex scan at 12, 14, and 95 days, respectively, showed complete resolution of the thrombus in all three patients.

The rate of complications after EVLT in the International

Endovascular Working Group registry were recently reported by Kabnick.<sup>20</sup> In more than 7,000 limbs treated with EVLT in 10 countries, the incidence of bruising was 75% (2,781 of 3,696), paresthesias occurred in 3% (114 of 3,696), thrombophlebitis occurred in 1.87% (69 of 3,696), skin burns occurred in 0.46% (17 of 3,696), DVT/EHIT occurred in 0.27% (10 of 3,696), and PE occurred in 0.023% (one of 3,696).<sup>20</sup>

Labrapoulos et al reported on early development of arteriovenous fistulae in 4.9% of limbs undergoing RFA treatment<sup>22</sup>; our group has observed the same after EVLT. It is likely that arteriovenous fistulae develop during the process of recanalization of the organized saphenous thrombus, although heat injury to small arteries in the vasa vasorum cannot be completely excluded. It is very likely that arteriovenous neovascularization contributes to recanalization or recurrence after endovenous ablation procedures.<sup>22</sup> A rare but severe potential complication of EVLT is a retained foreign body. This complication is extremely rare, and the etiology is unclear. A possible cause is if the probe (RF or laser) is pulled back in the sheath and the tip of the sheath is separated by direct heat.

**INNOVATIONS**

As a result of the lessons learned from initial experience, a number of changes have been introduced by device manufacturers. The newest addition to the RF catheter family, released in early 2006, was the VNUS Closure RFS Stylet for ultrasound-guided ablation of perforating veins. The device has a thermocouple temperature feedback control to allow controlled, consistent delivery of thermal energy to the vein wall. The technique is gaining popularity rapidly, and initial experience has been satisfactory.

A second innovation from VNUS is the next generation of RFA systems, the ClosureFast catheter. Recently cleared by the FDA, the ClosureFast catheter is expected to be launched in the first quarter of 2007. This new catheter eliminates the drawbacks of previous-generation catheters (slow pullback rates, pullback time to measure, high impedance interruptions, normal saline

ClosurePlus	ClosureFAST
Continuous pullback	Segmental ablation
Displays temperature, power, impedance & time	Displays temperature, power & time
Expandable electrodes	Non-expanding heating element
Saline drip required	No saline drip needed
45cm ablation in ~21min <small>(18-24min actual RF delivery time at 85°C)</small>	45cm ablation in ~3-5min <small>(2 Min 12 sec RF delivery time in clinical trial)</small>

Figure 1. Key comparisons between ClosurePlus and ClosureFast.

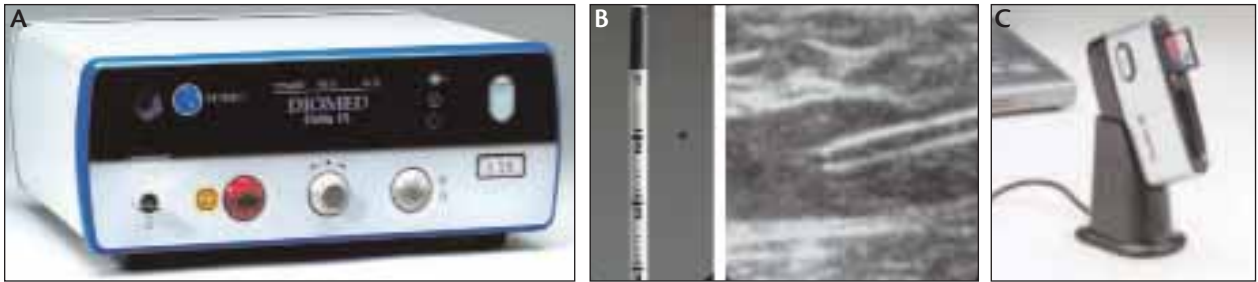


Figure 2. New Diomed EVLT device (A) with Spotlight sheath (B) and multimedia card (C).

drip) and allows a shorter treatment time. Instead of the traditional continuous pullback, this device operates with a segmental ablation approach. The catheter is composed of a 7-F-diameter heating element that has no expanding electrodes so that one size fits all. The catheter can be used with 8-F sheaths and is .025-inch guidewire compatible; the device is available in 60-cm and 100-cm lengths. The heating coil is 7 cm long and the shaft marks are 6.5 cm apart, providing 0.5 cm treatment overlap. The main difference between ClosureFast and the old Closure system (or EVLT) is that the amount of energy does not depend on the speed of pullback and that a long vein segment is treated all at once. With this device, a 7-cm segment (0.5 cm overlap) can be treated in 20 seconds with set device temperature of 120°C and

a vein wall temperature of 100°C to 110°C. The RF generator measures temperature continuously to adjust power to the heating element; it detects when the catheter is not in firm contact with the vein wall and the computer advises to apply better compression. It is crucial to collapse the vein around the catheter using elevation and perivenous tumescent solution infiltration (Figure 1). Preliminary data provided by the manufacturer on 70 limbs demonstrate a 98% early occlusion rate and a 100% reflux-free state after an average procedure time of 21 minutes. No DVT, skin burn, or phlebitis occurred, and 83% of limbs experienced no tenderness postoperatively.

New from Diomed (Andover, MA) is the EVLT Procedure Kit with the Spotlight Sheath and enhanced features. The new Spotlight Sheath has an echogenic tip for enhanced visibility under ultrasound, easy-to-confirm location determination, and numbered sheath markings to calculate length of segment treated. The Spotlight Sheath is available in lengths of 45 cm and 70 cm. The sheath is made with a new material that has enhanced lubricity and stiffness to reduce the risk of kinking during insertion. Further innovations in the new device are the fiber recognition system and the multimedia card. The fiber recognition system allows the user to program the procedure presets and activate them upon starting the procedure, while the multimedia card allows for storage of the digital data from up to 100 treatments. The new EVLT laser generator itself also appears more compact and lightweight for portable office use (Figure 2).

The CoolTouch CTEV (CoolTouch, Inc., Roseville, CA) is a 1,320- $\mu$ m Nd:YAG laser with an absorption length of 300  $\mu$ m to 500  $\mu$ m in tissue. The device obtained FDA clearance for treatment of both GSV and SSV. The chromophore for this laser is water (main component of collagen), resulting in a shorter absorption length than diode lasers. Specific absorption of energy only by the vein wall and not the hemoglobin results in a more controlled depth of vein coagulation. Furthermore, the fiber is coupled with an automatic pullback device preset at 1 mm/s. Other advantages of this system are the availability of a number of fiber sizes (600 mm, 273 mm, and the 2.5-F SaphFire [CoolTouch]) and the disposability of the fibers; each can



Figure 3. The CoolTouch automatic pullback device.

be used up to five times after sterilization. The newly introduced SaphFire 2.5-F fiber can be inserted through a smaller and less-invasive 4-F microintroducer and, in many instances, can be passed without the need for a sheath; it travels a tortuous vein with relative ease due to the protected, smooth tip, it is more echogenic than other fibers, and has excellent handling characteristics (Figure 3). Potential advantages of 1,320- $\mu\text{m}$  wavelength are efficacy equal to the diode lasers with less damage to the surrounding tissues. Several investigators reported a significant reduction of pain and bruising with the use of this wavelength.<sup>23-25</sup> A lack of vein wall perforations may account for decreased laser damage of perivenous tissues and decreased rate of side effects after 1,320- $\mu\text{m}$  laser therapy.

## CONCLUSION

The results of case series and registries on endovenous thermal therapy of the incompetent saphenous veins in patients with varicosity and advanced venous insufficiency (some with follow-up data of 5 to 7 years) are reassuring, with high occlusion rates, few side effects, and low recurrence rates. Prospective randomized studies comparing RFA and stripping demonstrate earlier return to work, less pain, and improved quality of life after endovenous procedures when compared to open surgery. No randomized studies are currently available for EVLT. Strict adherence to suggested guidelines and progress in technology will further decrease the low incidence of thrombotic complication rates, perioperative pain, and paresthesias. Although these procedures are clearly less invasive than conventional open surgery, level-1 evidence for long-term superiority over other techniques used for treatment of varicose veins is not available. ■

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