Superficial venous insufficiency of the lower extremities is a common affliction. Various sources report rates of chronic venous insufficiency (CVI) ranging from 1% to 40% in females and 1 to 17% in males. The reported incidence of varicose veins ranges from 1% to 73% for females and 2% to 56% in males. The prevalence of ulceration in patients with CVI has been reported around 0.3%. For many years, the only available treatment for varicose veins was operative stripping and ligation. Approximately 10 years ago, endoluminal treatment of varicose veins with radiofrequency ablation (RFA) became available to patients. This article will examine the history, mechanism, evolution, and results of endoluminal RFA for varicose veins.

**Catheter Evolution**

Treatment of varicose veins by endoluminal RFA became possible through development of special catheters designed to carry a radiofrequency (RF) signal (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009). The first generation of RF catheters was available in a 5F size and employed prongs, which were expandable to a maximum of 8 mm. These first-generation RF catheters could be used to treat veins 2 to 8 mm in diameter. The original catheters accepted up to a 0.014-inch guide wire and came in two lengths, 60 and 100 cm. For use, the catheter was connected to a RF generator via a resterilizable cable. A thermocouple on the catheter monitored the endoluminal wall temperature and relayed this information back to the generator, which made power adjustments as necessary to avoid damage to the vein wall. The recommended treatment temperature was 85°C (185°F). The original power generator displayed treatment time, temperature, impedance, and power output, which typically ranged from 2 to 4 watts, with a maximum output of 6 watts.

The first case of varicose veins treated with the RF catheter was reported from Bern, Switzerland in 1998 (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009). In this case, general anesthesia was used. Tumescent local anesthesia was not used at this time. The authors employed high ligation in addition to RF ablation, and used a continuous pull-back technique. Upon completion of the procedure, they placed an Esmarch bandage from toe to groin.

In December 1998, RFA closure was performed without concomitant high ligation of the saphenous vein. A study by Chandler and colleagues in 2000 examined results of high ligation versus no ligation in patients who underwent RFA treatment of great saphenous vein (GSV) reflux. Inclusion
criteria were documented 1-second GSV reflux on Valsalva or compression-release. Patients were excluded if they demonstrated dominant deep system reflux or postthrombotic changes. There was one instance of thrombus propagation into the common femoral vein (CFV) in a patient who did not undergo high ligation. Follow-up with duplex scanning found one or more patent tributaries in 6% of limbs (3/49) treated with high ligation and 35% of limbs (34/97) without high ligation. Chandler et al found that patent tributaries were not specifically associated with recurrence of varicose veins or reflux. Clinical-etiological-anatomical-pathophysiological (CEAP) classification and symptom scores were significantly improved in both groups (86% of high ligation limbs and 88% of limbs without high ligation). The actuarial data predicted >90% freedom from reflux at 1 year in 94% of high ligation limbs and 87% of limbs without high ligation.

Another study by Gradman examined reports of >21,000 cases of endovenous obliteration of the GSV with either laser, RFA, or foam sclerotherapy. This study also found no significant differences in outcomes between patients who had high ligation versus those who did not.

Between 1998 and 1999, an 8F catheter was introduced. The electrodes in this catheter expanded to a diameter of 12 mm. However, the manufacturer recommended that treated veins be in the range of 2 to 12 mm. Maximal vein diameter treated was 18 mm when combined with high ligation. This catheter added a continuous saline drip to the technique in order to prevent thrombus formation in the electrodes and thermocouple.

In 2006, the ClosureFAST (VNUS Medical Technologies Inc., San Jose, CA) catheter was introduced. This new catheter allowed for segmental ablation as opposed to continuous pull-back. This catheter treats a 7-cm vein segment in one 20-second energy cycle. The vein wall is heated conductively by a 7-cm coil at the distal end of the catheter. The treatment temperature is 85°C (185°F) protocol in which it was recommended that the initial pull-back speed be 1 cm per minute for the first 5 cm of the treated vein. Thereafter, pull-back speed could be increased to 2 to 3 cm/min for the remaining length of the treated segment. Under this revised protocol, the treatment time for a 45-cm vein was approximately 21 to 25 minutes (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009).

In 2003, the ClosurePlus catheter (VNUS Medical Technologies Inc., San Jose, CA) was introduced, replacing the original devices. This catheter was available in 6F and 8F sizes and came in 60- and 100-cm lengths. The catheter handle was smaller and lighter weight, with the connection cable integrated into the handle for a one-piece design. Additionally, with US Food and Drug Administration approval, diameter limitations for treated veins were removed from the device’s instructions for use (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009).

It was also during this time that a treatment protocol using a 90°C (194°F) catheter was investigated. Although the higher set point temperature allowed a faster pull-back time and was well-accepted by the physicians, clinical study results were not consistent, so the 90°C protocol was not launched. However, a further modification was made to the 85°C (185°F) protocol in which it was recommended that the initial pull-back speed be 1 cm per minute for the first 5 cm of the treated vein. Thereafter, pull-back speed could be increased to 2 to 3 cm/min for the remaining length of the treated segment. Under this revised protocol, the treatment time for a 45-cm vein was approximately 21 to 25 minutes (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009).

In 2004, a second-generation radiofrequency generator was launched, the RFG2. This RF generator replaced the numerical readouts for temperature with continuous monitoring of impedance and temperature. This new configuration allowed for discontinuation of pretreatment impedance testing. A radiofrequency stylet was introduced for the treatment of incompetent perforating veins. The radiofrequency stylet received 510(k) clearance, making it the only endovascular device cleared for percutaneous treatment of refluxing perforating veins (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009).

In 2006, the ClosureFAST (VNUS Medical Technologies Inc.) catheter was introduced. This new catheter allowed for segmental ablation as opposed to continuous pull-back. This catheter treats a 7-cm vein segment in one 20-second energy cycle. The vein wall is heated conductively by a 7-cm coil at the distal end of the catheter. The treatment temperature is 120°C (248°F) with an actual tissue temperature of 110°C (230°F). The manufacturer recommends that the catheter tip be positioned 2 cm distal to the SFJ. A tumescent anesthesia volume of approximately 10 mL per cm of treated vein is also recommended. The new procedure also entails two 20-second treatment cycles in the segment closest to the SFJ using
external compression with the ultrasound probe and two fingertips distal to the probe applied over the coil during each treatment cycle. This new catheter reduces treatment time to approximately 5 minutes. A continuous saline drip through the catheter is no longer needed. The first cases with the new catheter were performed in Europe in April 2006. In August 2006, the US Food and Drug Administration granted 501(k) approval for the ClosureFAST catheter and it was launched in the United States in 2007 (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009). A second-generation radiofrequency stylet catheter was also launched to treat incompetent perforator veins. This new stylet has an integrated sterile cable and a shortened device shaft for easier vein access.

**Mechanism of Action**

The mechanism of radiofrequency vein occlusion is illustrated in Figure 1. The RFA method of venous closure primarily acts by inducing vein wall collagen contraction through heat-induced denaturation of the collagen matrix, followed by fibrotic sealing of the vessel lumen due to injury and inflammation of the vein wall. Secondary methods involved in vein closure include endothelial denudation and swelling of the vein wall components due to heat-induced inflammatory processes that occur as responses to the temperature gradient created during the treatment from the intima to the adventitia. The total injury to the vein wall collagen and subsequently the total shrinkage of the vein wall is determined by the intima to adventitia temperature gradient and the duration of the time of heating.

An article by Schmedt et al in 2006 examined the histologic effects of radiofrequency ablation on the vein wall in an ex vivo bovine vein model. This study employed the VNUS Closure system for RFA. A 6F catheter was pulled back at a mean velocity of 3 cm/s and set at a temperature of 85°C (185°F). Under macroscopic evaluation, veins treated with RFA showed no evidence of thermal damage in the surrounding tissue layers. Although there was no vessel occlusion in the veins treated with RFA, the veins did demonstrate induration and thickening of the vein wall and contraction of the vein lumen, and the endothelium of the RFA veins demonstrated a whitish discoloration. There was no evidence of transmural lesions in the RFA veins. Under microscopic analysis, RFA-treated veins demonstrated circular disintegration of the intima cell layer. The RFA-treated veins also showed homogeneous cylindrically affected medial lesions with intercellular splits and gaps. No evidence of transmural thermal lesions or vessel perforations was seen in the RFA-treated veins. The authors theorized the circular expansion of the RFA probes as well as the computer controlled regulation of the RF generator were factors that promoted circular homogeneous distribution of thermal energy, which may result in a lack of wall perforation.

**Set Point Temperature and Pull-Back Speed**

Recommendations for set point temperature and pull-back speed are based on the equation that “energy equals temperature multiplied by contact time.” The manufacturer recommendations for temperature have been a set point of 85°C (185°F) for its first two generations of RFA catheters (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009). These recommendations also included a pull-back speed of 2 to 3 cm/s. Although the first two generations of catheters were in use, various adjusted set point temperatures, as well as variable pull-back rates were used for treatment.

In 2004, Zikorus and Mirizzi examined the effects of increasing set point temperature and pull-back speed on RFA in a bovine vein model. The authors used a set point temperature of 90°C (194°F) and a pullback speed of 6 cm/min. With the use of a 2-mm saline tumescent anesthesia layer, the
Radiofrequency ablation

authors found comparable temperature at the adventitial surface between the veins treated with a set point of 85°C and a pullback of 3 cm/min versus veins treated with a set point of 90°C and a pullback of 6 cm/min.4

A report by Dunn and coworkers in 2006 reported on 85 limbs treated with RFA at a higher set point and pull-back speed.7 The authors used a set point temperature of 90°C (194°F) with a pull-back speed of 2 to 3 cm/min in the proximal 5 cm of vein and 5 to 6 cm/min in the rest of the treated vein. The study found an overall success rate of 88%, which was comparable to a set point of 85°C and a pull-back rate of 2 to 3 cm/min. By increasing the set point and pullback speed, the authors found that mean treatment times decreased from approximately 18 to 8 minutes. Again, it is important to note that the manufacturer still recommended a set point temperature of 85°C (185°F) and a pull-back speed of 2 to 3 cm/min. These issues are no longer relevant with the latest generation of ClosureFAST catheters.7

Tumescent Anesthesia

Tumescent anesthesia allows the vein to be displaced further from the underlying skin. A tumescent solution consists of Lactated Ringer’s or saline combined with lidocaine, epinephrine, and bicarbonate (see Tables 1 and 2). Using ultrasound guidance, this solution is instilled percutaneously below the saphenous fascia and above the deep muscular fascia to surround the vein.5,9

This solution provides a fluid bath “heat sink” to displace heat radiating up to 1.5 mm beyond the vein wall. This results in decreased skin burn and sensory nerve injury rates. A dry “saphenous vein” with inflow tributaries eliminated by compression is also created.

In 2004, Zikorus and Mirizzi demonstrated significant decreases in peak adventitial mean temperatures with the addition of a tumescent anesthesia layer.4 At a set point temperature of 85°C and a pull-back speed of 3 cm/min, they demonstrated that the peak adventitial mean temperature was reduced from 64.4°C (147.9°F) to 51.3°C (124.3°F). At a set point temperature of 90°C (194°F) and a pull-back speed of 6 cm/min, they demonstrated a decrease in the peak adventitial mean temperature from 64.9°C (148.8°F) to 47.7°C (117.9°F).

In 2005, Merchant and colleagues demonstrated a significant reduction in the incidence of paresthesia after the authors introduced tumescent anesthesia to the RFA procedure.10 Rates of paresthesia dropped from 14.5% (70/484) to 9.1% (34/374) after implementation of tumescent anesthesia. The overall incidence of paresthesia decreased to 6.7% and 2% at 6 months and 4 years with the use of tumescent anesthesia.

Data from the clinical registry showed that the rates of skin burn before tumescent anesthesia was 1.8% (10/542 patients).10 After the use of tumescent infiltration it was 0.5% (2/394). These complication rates may also be decreased by limiting treatment of the GSV to the thigh segment.

Table 1 Tumescent Solution

<table>
<thead>
<tr>
<th>Normal Saline Solution</th>
<th>1000 mL</th>
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<tr>
<td>Lidoctaine 1%</td>
<td>500-1000 mg</td>
</tr>
<tr>
<td>Epinephrine 1 mg</td>
<td></td>
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<tr>
<td>Sodium Bicarbonate 12.5 mEq</td>
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Tumescent anesthesia formulation used at TriHealth Inc. hospitals in Cincinnati, OH (Good Samaritan and Bethesda North) (B. Steele, Bethesda North Hospital Pharmacy, personal communication, April 29, 2010).

Results of Radiofrequency Ablation on GSV Reflux and CEAP Classification

In 2006, Marston and colleagues looked at the effects of endovenous saphenous ablation on patients with CEAP scores of 3 to 6 without deep venous insufficiency.11 Fifty-eight limbs were treated with RFA and 31 limbs were treated with endovenous laser (EVLT). All GSVs treated with RFA were <12 mm in diameter. Tumescent anesthesia and an Esmarch bandage were used. The temperature set point was between 85°C and 90°C (185°F and 194°F), with a pull-back speed of 1 cm/min for the initial 5 cm and 2 cm/min for the remaining vein segment treated.

There were no significant differences in the frequency of complete closure, partial closure, or failure to close between the RFA- and EVLT-treated veins. There was a significant improvement in venous filling index (VFI) in all patients with no significant difference between those treated with RFA and EVLT. An improved VFI was found in 95% of limbs after ablation, with normal VFI (<2 mL/s) found in 78% of the limbs and a mildly abnormal VFI (2 to 4 mL/s) found in 17% of the limbs. Specifically, the average preoperative VFI in RFA-treated veins was 5.1 mL/s and the average postoperative VFI in EVLT-treated limbs was 2.1 mL/s. Veins with partial or unsuccessful ablation were more likely to exhibit an abnormal postoperative VFI. Overall, the venous clinical severity score (VCSS) for both groups (RFA and EVLT) improved from an average of 11.5 to 4.1.

In 2007, Vasquez et al examined the results of RFA on venous clinical severity score and CEAP classification in 682 limbs treated with RFA.12 RFA was offered to those patients with persistent symptomatic venous disease and a CEAP classification of 2 to 6. Patients were excluded if they presented...
with deep venous thrombosis (DVT), venous outflow obstruction, arterial insufficiency, or an ankle brachial index <0.8, planned future pregnancy, noncompliance with initial conservative measures, or obesity. Patients were not excluded if they presented with a postthrombotic syndrome or concomitant deep vein or perforator vein reflux. Tumescent anesthesia was used in all patients.

Eighty percent of treated limbs had a pretreatment CEAP classification of 3 or 4. RFA significantly reduced symptoms of pain (95.7% to 15.2%), the percentage of limbs with multiple or extensive varicosities (80.8% to 6.6%), venous edema (92.4% to 17%), skin pigmentation (15.3% to 5.4%), cellulitis (10.2% to 1.9%), and induration (17.1% to 7%). RFA was also found to improve ulcer healing. The overall rate of ulcer healing was 80%. Overall mean baseline venous clinical severity scores were 8.8 at baseline and 3.6 at last follow-up visit.12

### Comparison to Stripping and Ligation

For many years, the only treatment for varicose veins consisted of various forms of surgical therapy. The most frequently used method was stripping and ligation of the varicose vein. Several studies have compared results of RFA closure to operative stripping and ligation. A prospective randomized trial (EVOLVeS [Endovenous Radiofrequency Obliteration (Closure Procedure) Versus Ligation And Stripping]) by Lurie et al in 2003 randomized patients to either operative stripping and high ligation or RFA closure with the VNUS device.13 Inclusion criteria were reverse flow in the GSVs >0.5 seconds, age between 21 and 80 years, CEAP classes 2 to 4, ambulatory status, saphenous vein diameter <12 mm, and availability for follow-up. Exclusion criteria included vein diameter >12 mm or <2 mm, duplication of the saphenous trunk, incompetent accessory saphenous vein tributaries, thigh varicosities, previous DVT, an ankle brachial index <0.9, axial deep vein reflux, and GSV tortuosity. After randomization, RFA was performed in 45 limbs and stripping and ligation was performed in 36 limbs.

The authors examined procedure-related complications, patient recovery, and quality-of-life outcomes scores. Immediate complications included one intraoperative hematoma in each treatment arm, one perforation in the RFA group, and two vein tears in the stripping and ligation group. At 3-week follow-up, the RFA group was found to have significantly fewer overall complications, including less ecchymosis and fewer hematomas. The authors did find that the RFA patients demonstrated a slight trend toward higher incidence of paresthesia. Notably, the authors were not using tumescent anesthesia during this study period. Immediate success was 95% in the RFA group and 100% in the stripping and ligation group. The authors found a statistically significant difference in both time until resumption of normal activity and time until return to normal activity in the two groups. On average, the time to return to normal activity in the RFA group was 1.15 days compared to 3.89 days in the stripping and ligation group. Mean values for return to work averaged 4.7 days in the RFA group compared to 12.4 days in the stripping and ligation group. At 3 weeks, the authors found that the RFA group demonstrated statistically significant differences with regard to decreased pain and better global and physical scores in quality-of-life measurements.13

The Lurie group also examined the 2-year follow-up of the EVOLVeS patients.14 At 2 years, there was a difference, although not statistically significant, in recurrent varicose veins, with 14% of RFA patients demonstrating recurrence versus 21% in the stripping and ligation group. Global quality-of-life scores, as well as pain scores, remained statistically significant in favor of RFA at 2 years.14

A 2005 study by Peralta et al reported a study of 28 patients randomized to RFA versus stripping and ligation.15 The study included 15 patients in the RFA group and 13 patients in the stripping and ligation group. All patients underwent a 3-year follow-up with duplex ultrasonography and clinical evaluation with calculation of a Venous Clinical Severity Score (VCSS), Venous Segmental Disease Score, and Venous Disability Score. There were no statistically significant differences between groups in terms of improvement in VCSS, Venous Segmental Disease Score, or Venous Disability Score. At 3 years, there were no statistically significant differences between the two groups in terms of recurrence of varicose veins, although there was a trend for higher recurrence in the group treated with endovenous therapy. The authors postulated that patients with a VFI ≥ 2 mL/s, reflux at two or more sites, and deep venous incompetence may have a poorer outcome with RFA therapy.

In 2008, Luebke et al performed a meta-analysis of RFA versus stripping and ligation.16 This review examined eight studies and included both previously mentioned studies by Lurie et al.13,14 In contrast to the Lurie group, the meta-analysis demonstrated no significant difference in complications between RFA and stripping and ligation at 4 weeks. However, after 1 week, RFA showed lower rates of tenderness and ecchymosis. RFA also resulted in fewer hematomas at 72 hours, 1 week, and 3 weeks. There was no significant difference between groups in terms of recurrence of varicose veins, with 14% of RFA patients demonstrating recurrence versus 21% in the stripping and ligation group. At 3 years, there were no statistically significant differences between the two groups in terms of recurrence of varicose veins, although there was a trend for higher recurrence in the group treated with endovenous therapy. The authors postulated that patients with a VFI ≥ 2 mL/s, reflux at two or more sites, and deep venous incompetence may have a poorer outcome with RFA therapy.

### Comparison to Endovenous Laser Therapy

In 2005, Puggioni and colleagues compared RFA to EVLT in terms of efficacy and complication rates.17 Their study sam-
ple included 53 limbs treated with RFA and 77 limbs treated with EVLT. Immediate success rates were not statistically significant between groups (96% for RFA vs 100% for EVLT).

The authors found a statistically significant difference in the number of veins requiring a second intervention, with 17% of the RFA treated veins requiring retreatment versus 0% of the EVLT-treated veins. Only the EVLT group demonstrated protrusion of thrombus into the CFV (2.3%). There was a nonstatistically significant trend toward lower complication rates with RFA (7.6%) versus EVLT (20.8%). Puggioni et al concluded that EVLT had somewhat higher immediate occlusion rates, but also higher complication rates than RFA. They also suggested that DVT prophylaxis might be considered in patients older than 50 years of age.

In 2006, Almeida and Raines compared 819 endovenous laser ablation (EVLA) treated limbs to 128 RFA-treated limbs. Both treatment groups received tumescent anesthesia. Primary closure rates were 92% for the EVLA-treated veins and 85% for the RFA-treated veins. This suggested a statistically significant advantage for EVLA in terms of immediate closure. Complication rates were similar between the two groups, with two instances of paresthesia in each group. However, thrombus extension into the CFV requiring anticoagulation occurred in two patients treated with EVLA and no patients treated with RFA.

Almeida and colleagues evaluated RF thermal ablation using the ClosureFAST system to investigate whether it offered better outcomes for recovery and improved quality of life (QOL) versus 980-nm endovenous laser thermal ablation of the GSV. This prospective, single-blind study was conducted at five American sites and one European site and studied 87 veins in 69 patients who were randomized to ClosureFAST or EVLA. Primary outcomes measures included postoperative pain, ecchymosis, tenderness, and adverse procedure sequelae. Secondary outcomes included VCSS and QOL scores. All outcomes were measured at 48 hours, 1 week, 2 weeks, and 1 month after treatment. Pain, ecchymosis, and tenderness were all statistically lower in the ClosureFAST group at 48 hours, 1 week, and 2 weeks. Minor complications were more prevalent in the EVLA group (P < .21).

No major complications were reported. VCSS and QOL measures were statistically more favorable in the ClosureFAST group at 48 hours, 1 week, and 2 weeks. It was concluded that RF thermal ablation was significantly superior to EVLA with respect to the recovery and QOL outcomes measured in this multicenter prospective trial. Short-term results from other studies are summarized in Table 3, while intermediate and long-term results are presented in Table 4.

Overall short-term occlusion rates are similar between EVLA and RFA. RFA does appear to confer some advantages in terms of complications. Although there is not much literature using the latest ClosureFAST catheter, it does seem that the small advantages over EVLA will become even more significant.

### Complications

Thrombus extension into the CFV can lead to DVT if not recognized and may be treated with either low molecular weight heparin or operative thrombectomy. Duplex ultrasound is a crucial component of the protocol and should be performed within 72 hours of the initial procedure. Figure 2 shows an ideal duplex image after RFA of the CFV.

At the 2007 American Venous Forum, Kabnick et al presented data advocating the concept of endovenous heat-induced thrombosis. It was suggested that treatment could be stratified based on the amount of thrombus extension from the SFJ into the CFV. Anticoagulation was recommended for >50% CFV involvement.

The great saphenous nerve is adherent to the GSV in the distal limb. Injury to the nerve in this area is increased with

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Therapy</th>
<th>n</th>
<th>Follow-Up (years)</th>
<th>Recanalization (%)</th>
<th>Recurrent Varicose Veins (%)</th>
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<tr>
<td>Lurie et al.,2005</td>
<td>RFA</td>
<td>65</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Merchant et al.,2005</td>
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<td>Cabrera et al.,2000</td>
<td>Foam</td>
<td>500</td>
<td>3</td>
<td>5</td>
<td>14</td>
</tr>
</tbody>
</table>

Abbreviations: EVLT, endovenous laser treatment; NR, data not reported; RFA, radiofrequency ablation.

both RFA and surgical intervention. Limiting treatment to the above-knee segment can significantly decrease nerve injury rates. Skin burns were initially seen with early RFA treatment, but have become almost nonexistent with the addition of tumescent anesthesia. Phlebitis and hyperpigmentation may occur as a result of residual blood trapped within the veins.27

These conditions usually resolve over several weeks without any specific treatment. Anatomic failures may be categorized into three groups, as illustrated in Figure 3.27

Type I is described as failure of closure. Nonocclusion occurred in 12.4% according to a 2005 report by Merchant and Pichot from the Closure Study Group.27 Recanalization resulted when initially occluded veins recanalized either partially or completely (type II failures). This was the most common anatomical failure; 2.4% of the time, this was associated with a refluxing tributary or an incompetent perforating vein.

Type III (groin reflux) failure refers to a situation in which the vein trunk is occluded, but reflux is detected in the groin, often involving an accessory vein. This failure type makes up 17.8% of anatomical failures.27

Technical challenges include difficult access, difficulty advancing the catheter, treatment interruption, inability to insert the catheter, tortuous or GSV of unequal sizes.28 Patients may complain of painful incision sites or symptoms of heat, and may have saphenous nerve pain. Dysrhythmias and vasovagal reactions may also occur.

RFA and Long-Term Follow-Up

In 2005, Ogawa and colleagues followed up 25 legs that had undergone RFA with the 6F RF VNUS Closure system (VNUS Medical Technologies) at 1 day and 1 month with duplex ultrasound.29 All procedures were performed with a 6F cath-

Figure 2 Ideal duplex image after radiofrequency ablation. Vein occluded without thrombus extension into the common femoral vein (CFV). A, artery; CSIV, confluence of the superficial inguinal veins; TA, total occluding acute; W/C, with compression.

Figure 3 Types of anatomical failure are illustrated in the panels (left to right). (A) Type I, great saphenous vein (GSV) failure to completely occlude, with or without reflux present. (B) and (C) Type II, partially recanalized GSV. (D) Type III, the treated GSV is occluded, but reflux is present involving branches near the saphenofemoral junction (SFJ). CFV, common femoral vein. Reprinted from Merchant RF, Pichot O for the Closure Study Group: Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. J Vasc Surg 42:502-509, 2005 with permission.27
eter and tumescent anesthesia. At both 1-day and 1-month follow-up, 1 treated vein demonstrated complete obstruction, 23 treated veins demonstrated complete obstruction with persistent flow in the superior epigastric vein, and 1 vein demonstrated near-complete obstruction with persistent flow in a vein segment <5 cm. No treated veins showed persistent flow >5 cm from the SFJ.

Manfrini et al followed patients for 6 months to 1 year after the RFA procedure. At 6-month follow-up, persistent occlusion was observed in 91% (50/55) of treated veins. Recurrent reflux was demonstrated in only two of the five recanalized segments. Twenty treated veins were available for 1-year follow-up and all of these veins demonstrated occlusion.

In 2002, Weiss and Weiss reported follow-up of patients reevaluated at 1 week, 6 weeks, 6 month, 1 year, and 2 years post-RFA treatment. At 1-week follow-up, 98% (137/140) of treated veins showed vein occlusion. In the three patients with incomplete occlusion, flow was only demonstrated in small segments and was not accompanied by saphenous vein reflux. At 6 weeks follow-up, 4% (5/98) of treated veins demonstrated incomplete obliteration. Three of the five veins with recurrent flow demonstrated complete recanalization at 6 months. The other two were treated with sclerotherapy and demonstrated complete occlusion at 6 months. At 1-year follow-up, there was no new incidence of recanalization. At 2-year follow-up, 19 of 21 treated veins had completely disappeared, resulting in a clinical success rate of 90%.

Nicolini and colleagues followed patients for three years after RFA treatment. At 1 year, 88.5% (223/252) of treated veins had absence of reflux. At 2 years, 87.8% (130/148) of treated veins showed no reflux. At 3 years, 88% (60/68) of treated veins were free from reflux. In the subgroup of veins that were followed for 3 years, percentages of veins without reflux were 94%, 90%, and 88% at 1, 2, and 3 years, respectively.

In 2005, Merchant and colleagues examined up to 4-year results after RFA. Occlusion rates were 97.4% (836/858) at 1 week, 91% (406/446) at 6 months, 88.8% (341/384) at 1 year, 86.2% (181/210) at 2 years, 84.2% (96/114) at 3 years, and 88.8% (87/98) at 4 years. The percentage of veins that were reflux-free at 6 months, 1, 2, 3, and 4 years were 91%, 89.3%, 86.2%, 86%, and 85.7%, respectively. A second report by the Merchant group in 2005 found occlusion rates of 96.8%, 89.2%, 87.1%, 88.2%, 83.5%, 84.9%, and 87.2% at 1 week, 1, 2, 3, 4, and 5 years respectively. Similarly, the percentages of treated veins that did not demonstrate reflux at 1 week, 1, 2, 3, 4, and 5 years were 96.6%, 91.3%, 88.2%, 88.2%, 88%, 86.6%, and 83.8%, respectively.

In conclusion, available reports indicate that occlusion rates and reflux-free rates are >85% with 4-year follow-up.

Follow-Up Ultrasound Examination

There have been several reports describing ultrasound findings after RFA of the GSV. Figure 4 demonstrates GSV duplex findings of RFA-treated veins at 6 months and 2 years post-treatment. In a report by Pichot et al in 2004, the authors performed ultrasound examinations in 63 groins of patients who had undergone RFA without concomitant SFJ ligation.
Findings of the post-RFA–treated veins on ultrasound remain controversial. Whether or not small vessel networks or neovascularization can be demonstrated may depend on the sensitivity of the ultrasound equipment. Further standardized reports are needed to clear up this issue.

The Future—The ClosureFAST Catheter

The details of ClosureFAST catheter have been outlined in this article. Briefly, the ClosureFAST RFA catheter treats a 7-cm segment of vein using one 20-second energy cycle (E. Jones, VNUS Medical Technologies Inc., personal communication, June 26, 2009). The temperature set point is 120°C (248°F) and there is no pull-back speed. The catheter tip is placed 2 cm distal to the SFJ and the manufacturer recommends treating the initial segment with two 20-second treatment cycles.

An article by Proebstle and coworkers in 2008 reports on the first clinical experience for the ClosureFAST RFA catheter in 252 limbs. Inclusion criteria were reflux >0.5 seconds continuously from the SFJ to the distal point of reflux, age 18 to 80 years, physical condition allowing for ambulation after the procedure, and availability for posttreatment follow-up. Exclusion criteria included pregnancy, breastfeeding, and evidence of thrombus in the vein segment to be treated. Large vein diameters were not among the exclusion criteria. The average age of the patient was 50.5 years and mean GSV diameter was 5.7 mm. All patients received tumescent anesthesia. A 7F diameter catheter was used with a temperature of 120°C (248°F), and 20-second treatment cycles. Additional treatments included phlebectomy in 71% and foam sclerotherapy in 13.9% of patients. Average procedure time from catheter insertion to catheter removal was 16.4 minutes.

Immediate occlusion was reported to be 100%. According to Kaplan-Meier analysis, vein occlusion and reflux-free rates were 99.6% at 3 days, 3 months, and 6 months. The patent stump length at the SFJ averaged 1.5 cm at 6 months. In limbs that had 6-month follow-up, treated veins decreased in diameter by 19.9% at 3 days, 26.6% at 3 months, and 43.5% at 6 months.

Limb pain, reported in 57.5% of patients at preprocedure, was reduced to 10.8% at 3 days postprocedure. The percent of limbs with edema decreased from 52.8% to 3.2%. The average VCSS of 3.9 decreased to 3.4 at 3 days, 1.6 at 3 months, and 1.6 at 6 months. Return to normal activity occurred on the same day in more than half of the patients, with an average return to normal activity at 1 day. DVT or thermal skin injury was not observed in any of the patients. Paresthesias occurred as localized patches in 3.2% of treated limbs. Thrombophlebitis was demonstrated in 0.8% of treated limbs. Ecchymosis was noted in 16 limbs and hematoma at the puncture site was found in four limbs. Skin pigmentation developed in five limbs.

The most common pattern on ultrasound was a patent SFJ receiving prograde flow from proximal GSV tributaries through a short (<2 cm) segment above an obliterated GSV (Fig 5).

This pattern was found in 81.7% of treated limbs. The authors found long-segment patency (21 and 27 cm) in two limbs. SFJ reflux was present in five limbs and showed no direct relationship to GSV patency length. Ultrasound found 104 open tributaries with reflux demonstrated in only eight of the tributaries (7.7%). There was no evidence of neovascularity in any groin as every visible vein could be classified as a major truncal vein. The authors concluded that the RFA procedure was less likely than stripping and ligation to induce neovascularity in the groin. Furthermore, the authors postulated that the principal cause of recurrent thigh reflux and subsequent varicosities after the RFA procedure is linked to the potential for reflux in the anterolateral and posterior medial thigh tributaries arising from the GSV.

In 2004, Salles-Cunha et al reported significantly different findings than the previously mentioned authors. In this study, 106 extremities in 89 patients were followed with ultrasound examinations at a median of 9 months post-RFA. In contrast to Pichot et al, flush ligation and division of the GSV and ligation and division of the SFJ tributaries were performed in 88% of the RFA-treated extremities. The authors increased the color-flow sensitivity for the post-RFA ultrasound scans to improve detection of recanalized GSV segments, as well as small vessel networks. They defined small vessel networks as veins and arteries <2 mm in diameter. The authors found that 65% of extremities had small vessel networks detected in the SFJ, thigh, or both. GSV recanalization was identified in 18% of extremities. According to Salles-Cunha et al, SFJ ligation did not affect small vessel networks in the thigh or the prevalence of GSV recanalization.
Billing Codes and Additional Supplies

Current Procedural Terminology codes include 36475 endovenous ablation of the first vein and 36476 for subsequent veins; 36470 may be added if sclerotherapy is performed adjunctly. Duplex scan of the complete extremity, 93970, may also be used for the follow-up scan performed 3 to 5 days posttreatment. Alternately, if the duplex scan is a unilateral limited study, the code is 93971. Current Procedural Terminology codes for diagnosis procedures range from 454.0 to 454.8, varicose veins with symptoms or complications. Venous insufficiency may be coded as 459.81. Modifiers should be applied as needed. Sedation codes may also be provided when appropriate, and facility codes may also be applicable to hospital or ambulatory surgery center services.35

Other supplies that may be coded include pressure gradient stockings. Regardless of how many veins are treated in addition to the initial vein, the add-on code is only reportable once for each extremity treated. Reimbursement for office procedures is substantially higher than those done in a hospital setting.35

Conclusion

In conclusion, experience during the past 10 years shows that endovenous ablation is safe, and the evolution of new technologies has improved both safety and efficacy of this therapy. Technical challenges, intraoperative and postoperative risks, and adverse sequelae are rare, and are generally less frequent than with more traditional surgical therapy. Stripping and ligation is the only treatment for varicose veins for which long-term follow-up data are available. Endovenous therapy, traditional, and surgical intervention require long-term prospective comparisons.

The concept that minimally invasive treatment options, including perforating vein incompetence, are uniformly better than traditional approaches needs long-term validation. New catheter designs will afford a wider application of treatment options for perforating vein incompetence. Results of different catheter designs and treatment protocols will need to be validated.

Randomized trials of radiofrequency ablation and vein stripping have suggested improved recuperative time, faster return to work, less postoperative pain and limitation of physical activity, and better QOL than vein stripping. Short-term trials showed fewer complications and adverse effects for radiofrequency-treated patients than for patients with vein stripping. Two-year follow-up showed QOL scores were significantly better than after vein stripping. Adverse effects included numbness and paresthesias, vessel perforation, infection, blood clots, and thromboembolism. RFA of the vein has definite advantages over stripping and ligature. Endovascular GSV treatment has an overall relatively lower complication rate, especially in the tumescent anesthesia era. RFA is safe and well-accepted by patients. The American Venous Forum recommends RFA as a safe and effective treatment for incompetence of the GSV and notes that clinical outcomes are comparable to those for conventional stripping and ligation up to 5 years posttreatment (see Table 5).11 The AVF further suggests that RFA be the treatment of choice for high-risk patients, such as those who are obese, are on anticoagulant therapy, or have problematic medical conditions.

References
4. Zikorus AW, Mirizzi MS: Evaluation of setpoint temperature and pull-

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Table 5

American Venous Forum Guidelines for Treating the Incompetent Saphenous Vein Using Radiofrequency Ablation

<table>
<thead>
<tr>
<th>No.</th>
<th>Guideline</th>
<th>Level of Recommendation (1, recommended; 2, suggested)</th>
<th>Quality of Evidence (A, high; B, moderate; C, low or very low)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.9.1</td>
<td>Incompetence of the great saphenous vein can be treated safely and effectively using radiofrequency ablation</td>
<td>1</td>
<td>A</td>
</tr>
<tr>
<td>4.9.2</td>
<td>Radiofrequency ablation of the great saphenous yields comparable clinical outcomes versus traditional stripping and ligation up to 5 years</td>
<td>—</td>
<td>C</td>
</tr>
<tr>
<td>4.9.3</td>
<td>Due to delayed convalescence, increased complications, and higher morbidity, radiofrequency ablation of the great saphenous vein is suggested for high-risk patients including those who are obese, on anticoagulation, or having significant medical problems</td>
<td>2</td>
<td>C</td>
</tr>
</tbody>
</table>

back speed on vein adventitial temperature during endovenous radiofrequency energy delivery in an in-vitro model. Vasc Endovasc Surg 38:167-174, 2004
32. Nicolini P, the Closure Group: Treatment of primary varicose veins by endovenous obliteration with the VNUS closure system: Results of a prospective multicentre study. Eur J Vasc Endovasc Surg 29:433-439, 2005
35. Venous Codes At-A-Glance. San Jose, CA, VNUS Medical Technologies Inc., 2009