Endovenous ablation of the great saphenous vein (GSV) is the treatment modality of choice in the setting of symptomatic varicose veins. Endothermal Heat Induced Thrombosis (EHIT) of the GSV is an expected outcome, but what remains unclear is the natural history of patients who present with thrombus extension into the common femoral vein. With an incidence in the literature of common femoral thrombus ranging from 0% to 16%[1-3], EHIT has gained the attention of physicians treating this disease process. Herein we describe a classification system and algorithm for treatment.

Introduction

Chronic venous disease and the associated impairments to a patient’s quality of life, afflicts a great number of individuals worldwide[4]. The choice of treatment modalities may vary amongst treating clinicians. Recent advances in ultrasound, radiofrequency and laser technology have made endovenous saphenous vein ablation (EVA) a new, exciting alternative to traditional ligation and saphenectomy for the treatment of varicose veins and superficial venous insufficiency. First radiofrequency (RF) ablation, and then in 2002, endovenous laser ablation (ELA) was approved by the FDA for use in the United States for the ablation of the great saphenous vein. Early theories of this technology advocated a pulsed delivery of laser energy combined with manual compression during the delivery of energy; however, this proved to cause profuse vessel perforations that contribute to increased pain and bruising postoperatively. Treatment parameters where modified to deliver energy in continuous mode without compression, producing excellent results. Similar to RFA, the ELA technology has undergone several improvements and modifications since its inception. ELA utilizes a 600-micron bare-tip or jacket-tip fiber to deliver laser energy in a continuous fashion to a target area, causing an intense thermal reaction forming steam bubbles within the vein lumen. The heat caused by the reaction coupled with steam bubbles destroys the endothelial lining of the vessel, causing an inflammatory reaction. A subsequent thrombotic occlusion occurs that closes off the vein and leads to eventual fibrosis.

One of the most prominent evolutions of ELA has been the introduction of numerous wavelengths, each of which has different absorption characteristics:

- The 810-nm wavelength is specific for hemoglobin absorption;
- The 940-nm wavelength provides a balanced ratio between the light irradiated into the tissue and the absorption by hemoglobin and water;
- The 980-nm wavelength is such that it is specific for hemoglobin and water;
- The 1319-nm / 1320-nm wavelength is specific for water absorption, targeting collagen in the vein wall;
- The 1470-nm wavelength features an absorption coefficient in water that is 40 times greater than that of 810- and 980-nm wavelengths.

Although further research is needed, a small number of studies have compared various wavelengths, all of which revealed a trend of less postoperative pain and bruising with higher wavelengths.

The ELA procedure is very similar to the RFA procedure; access is gained in a similar fashion using a 21 G needle under ultrasound guidance, followed by a microsheath over guidewire technique. Upon removal of the inner dilator, a 0.035” guidewire is advanced to the saphenofemoral junction and the microsheath is removed. Based on the targeted treatment segment, a long sheath (typically 45 cm) is selected and back loaded over the guidewire. Once advanced to a point just distal to the superficial epigastric vein, the inner dilator and guidewire are removed and a 600-μm bare-tip or jacket-tip fiber is advanced into the sheath. The fiber is connected to the machine and held in place while the sheath is withdrawn to the locking mechanism of the fiber. This mechanism is designed to leave approximately 2 cm of the fiber outside of the sheath to prevent damage to the sheath. As with RFA, perivenous tumescent anesthesia is delivered, with the saphenous compartment being the target delivery area.
A second evolution of the ELA procedure relates to the catheter pullback method during the procedure. Early methods focused a pullback distance (centimeters or millimeters) per second, which delivered variable energy depending on the wattage at which the generator was set. In 2004, Timperman et. al. approached the procedure from a different perspective and evaluated the amount of energy (Joules) delivered per centimeter of vein treated[5]. Their study found a direct correlation between energy delivered and treatment efficacy, with higher energy delivery per centimeter producing better results. Many experts now focus on total energy delivered and gauge pullback during ELA procedures according to Joules delivered per centimeter. Currently, 60 J/cm to 80 J/cm is the average treatment energy most often utilized for ELA procedures. Continuous pullback is used, watching the real-time energy readout on the generator and gauging speed with the 1 cm marks on the sheath. This method has proven to be more consistent than using time to gauge pullback because the same amount of energy is delivered in each case, regardless of the wattage.

The use of endovenous lasers in the continuous mode has demonstrated a relatively low incidence of procedure-related complications. The most common complication associated with ELA is ecchymosis, with varying reported incidences in the literature. The mechanism of the ELA procedure that causes pain and bruising remains unclear, although some experts speculate that these complications are caused by vein wall perforations from laser energy. Aside from laser wavelengths and pullback methods, a third novel adaptation to the ELA procedure involves laser fiber design. An innovative type of laser fiber that has shown an effect on vein wall perforations is the newly-introduced jacket-tip fiber. This technology features either a stainless steel or ceramic jacket that completely covers the tip of the fiber, with the end of the tip recessed within the jacket. This design prevents the flat emitting face of the fiber tip from coming in contact with the vein wall.

ELA and RF ablation, both associated with a relatively short learning curve for technique, plus an overwhelming rate of patient satisfaction, have combined to make EVA very appealing to both patients and clinicians. Early results utilizing this minimally invasive modality have demonstrated equal to or better efficacy to treatment with traditional ligation and saphenectomy. But with new technology, comes a new host of challenges and potential complications. Despite the encouraging results associated with EVA, there has been a mounting concern by clinicians over the incidence of deep vein thrombosis (DVT) and the risk for potential fatal pulmonary embolism following this new, less-invasive procedure. Endothermal Heat Induced Thrombosis (EHIT) of the GSV is an expected outcome following EVA. What remains unclear in the literature is the clinical outcome of those patients who present with EHIT in close proximity or extending into the sapheno-femoral junction. There are several reports in the literature citing the concerns of the progression of de-novo isolated superficial thrombophlebitis (STP) of the great saphenous vein into the deep venous system and potential risk of pulmonary embolism[6, 7]. This has prompted a debate in the medical community regarding whether to treat STP of the great saphenous vein. We report the results of three independent vein centers as well as our subsequent follow-up and evolving treatment protocol when EHIT extends to and beyond the sapheno-femoral junction. Also, discussed in this paper is a new classification for EHIT to help with the management of this new clinical entity.

Patients and Methods
From May 7, 1998, to December 31, 2004 consecutive patients with superficial venous insufficiency and varicosities, treated with EVA underwent a chart review. The patients’ charts of 7 physicians from 3 independent vein centers, The Vein Institute of New Jersey, Morristown, New Jersey, The Day Surgery Center in Padua, Italy and the Miami Vein Center, Miami, Florida were examined. The purpose of the review was to establish the extent of GSV EHIT into the deep system at the SFJ and the subsequent individualized treatment strategies amongst participating physicians. Also reviewed were the post-operative venous duplex of several hundred endothermal GSV ablation cases at the Vein Institute of New Jersey. A closer look at these studies confirmed that there was a recognizable pattern that developed...
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when an endothermal thrombus was recognized. Thus, in order to grade the extent of thrombus, a new classification system was developed and each patient identified as having EHIT was subsequently placed within each category. At the Vein Institute of New Jersey four EHIT classes were developed and defined as the following:

Class 1: Venous thrombosis to the superficial-deep junction (i.e.; sapheno-femoral junction or saphenopopliteal junction, but not extending into the deep system) Fig. 1

Class 2: Non-occlusive venous thrombosis, with an extension into the deep system of a cross sectional area of less than 50%. Fig. 2

Class 3: Non-occlusive venous thrombosis into the deep venous system, with an extension into the deep system of a cross sectional area of more than 50%. Fig. 3

Class 4: Occlusive deep vein thrombosis of the common femoral vein. Fig. 4

The post-operative treatment of each individual patient identified as falling within one of the aforementioned classes was collected, evaluated and examined to determine if a specific treatment pattern existed. Also examined was the extent of echogenicity within the thermally induced thrombosis and this was compared with de-novo thrombosis seen within a typical DVT.

Results
The data registry revealed hundreds of limbs in the EHIT Class 1. Most physicians elected not to treat this type of thrombus because early and repeated duplex ultrasound did not reveal any progression of the thrombosis; however, two physicians in their early experience with EVA elected to treat these patients with low molecular weight heparin (LMWH) for 10 to 14 days. LMWH was stopped at 10-14 days depending on the lack of thrombus progression or evidence of spontaneous regression 1-2 cm peripheral to the SFJ. There were 15 patients that matched the criteria for EHIT Class 2. Of the 15 limbs cohort, 9 patients were not treated with anticoagulation; 6 patients were treated with LMWH for 10-14 days depending upon when the patient was reclassified by ultrasound to Class 1. At that time of reclassification, LMWH was stopped. Duplex done on a weekly basis revealed no propagation of thrombus. There were no patients in class 3 or 4.

Discussion
In some regards, this unique clinical entity of EHIT can be compared to superficial venous thrombophlebitis (SVT). The treatment of SVT of the lower extremities remains controversial. Many clinicians have in the past regarded SVT as a relatively benign disease process, which can be observed with little or no consequence and treated with traditional therapy consisting of analgesics, non-steroidal anti-inflammatory medications and application of heat therapy. Others citing a high incidence of proximal thrombus progression, resultant DVT and increased risk of pulmonary embolism aggressively treat this finding with anticoagulation therapy and/or saphenofemoral junction (SFJ) ligation. Chengelis et al reported an incidence of 11% progression of SVT to DVT, prompting them to treat isolated SVT with anticoagulation[8]. Verlato et al reported a 33% rate of objectively proven pulmonary embolism in patients with SVT of the great saphenous vein[9]. Based on these and similar studies, it would therefore seem clinically prudent to treat isolated STP of the GSV with anticoagulation and/or SFJ ligation, particularly if it is located in proximity to the SFJ.

With the increasing popularity over the last several years of endothermal vein ablation for the treatment of varicose veins, the potential for thermally induced thrombosis of the great saphenous vein propagating into the femoral vein peri-operatively, has become a clinical reality. Hingorani et al. reported a 16% incidence of duplex documented DVT following radiofrequency ablation of the GSV[2]. Although at the
Vein Institute of New Jersey the occurrence of EHIT with propagation into the SFJ, has not been as high (6/800; 0.75%), when documented by duplex ultrasound, it requires immediate clinical evaluation by a physician. All patients are examined and treatment options are discussed with the patients. Currently, our treatment algorithm is as follows:

All patients undergo duplex imaging within the first week post-endovenous ablation. If EHIT-1 is seen, the patient will undergo serial duplex imaging on a monthly basis until clot regression into the GSV is noted. If EHIT-2 is found on duplex imaging, LMWH is initiated and patients are re-imaged 10-14 days after treatment. If the clot extension into the common femoral vein (CFV) persists, anti-coagulation is continued and the patient is re-evaluated and re-imaged every 7-10 days until the patient converts to an EHIT-1 or the thrombus completely regresses. In this situation, the anticoagulation is stopped and the patient is closely monitored. EHIT 3 and EHIT 4 have not been seen in our practice, but we believe that these entities should be treated as a DVT and full anticoagulation intitiated according to the most recent 2008 American College of Chest Physician guidelines[10].

To date, the exact mechanism for EHIT has not been elucidated. In a recent review, Van den Bos has suggested pre-existing thrombophilic disorders, incorrect positioning of the laser or radiofrequency fiber, and/or the use of general or epidural anesthesia, which does not allow for immediate ambulation after the procedure, all as potential risk factors for developing EHIT[11]. Although most physicians do not routinely administer low molecular weight heparin (LMWH) before or after EVA, some have incorporated this into their practice[12, 13]. A recent study by Knipp et. al. did not demonstrate any significant reduction in EHIT complications with prophylactic heparin administration, however all of the patients in that study underwent their procedure under general anesthesia. Moreover, their study did not demonstrate any
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difference in the incidence of EHIT among patients with or without documented pre-procedure deep venous insufficiency[14].

At the participating centers we have seen and repeatedly demonstrated that a venous thrombus produced by endothermal ablation (EHIT) displays a different sonographic echogenicity. Fig 4 Within a relatively short period of time (less than 24 hours), the thrombus is sonographically echogenic whereas a spontaneously occurring thrombus may remain hypoechoic for many days or even weeks after its initial identification. Also, we have looked at the potential for further thrombus propagation after the initial post-operative documentation of EHIT and found the thrombus to remain stable, often demonstrating regression or complete resolution of the DVT within 10-14 days.

Where are we going in the future with the treatment of this disease process? In recent months we’ve accumulated two additional EHIT-2 patients who underwent treatment with LMWH for 10-14 days. Re-imaging at two weeks demonstrated the disappearance of the thrombus extension into the common femoral vein. Both of these patients were asymptomatic, but did undergo contrast spiral chest CT. Neither chest CT demonstrated the presence of a pulmonary embolism. Whether the thrombus resolves, retracts, or even embolizes remains to be determined, but at this point in time, the clinical significance appears to be negligible. We believe that the future of EHIT treatment will be more clearly elucidated as clinicians gain more experience with this unique disease entity. Perhaps, we will realize that EHIT is an ultrasound finding without any clinical significance and the entity will be historical. Postoperative ultrasound will be used primarily for efficacy and not for Endovenous Heat Induced Thrombosis.

Conclusion
Based on our observations, we feel that a thermally induced thrombus appears to behave differently than a spontaneous occurring deep venous thrombosis, displaying ultra-sonographic chronicity at a much earlier time. Presently, based on our evolving experience, we cannot formulate any definitive conclusions; however, we are currently suggesting: 1) Close duplex ultrasound observation of Class 1 EHIT without pharmacologic treatment. 2) Treatment of Class 2 EHIT with LMWH until the EHIT can be reclassified to Class 1 by duplex ultrasound. 3) At the present time, since we have no reported cases of EHIT for Class 3 or 4, we strongly recommend treating these entities according to the suggested guidelines for DVT. As EVA continues to grow in popularity and both successful and adverse outcomes reported, we will continue to have a better understanding of the clinical significance of EHIT in proximity and beyond the SFJ. This will ultimately allow us to make more definitive recommendations regarding treatment options.

Fig 1
Class 1-Venous thrombosis at the saphenofemoral (or saphenopopliteal) junction. Not extending into the deep system.
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Fig 2
Non-occlusive thrombus (arrow) extending into the deep venous system. Thrombus with a cross sectional diameter of less than 50% (cross sectional and sagittal views)

Fig 3
Non-occlusive thrombus extending into the deep system. Cross sectional diameter >50%

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Fig 4
Thrombus Echogeneity
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References


