

VIU REVIEW

The Official Journal of Venous Insufficiency University

Volume 3, Issue 1

Center for
Vein Restoration



Love your legs *again!*

- Annapolis, MD
- Baltimore/Towson, MD
- Easton, MD
- Glen Burnie, MD
- Glenn Dale, MD
- Greenbelt, MD
- Prince Frederick, MD
- Rockville, MD
- Takoma Park, MD
- Waldorf, MD

Phone: 800-FIX-LEGS or
301-860-0930
www.centerforvein.com

IN THIS ISSUE

Long-term Outcomes of Radiofrequency Ablation Therapy. 1 & 3

VI University Presents Local CME Events..... 1 & 4

Endovenous Radiofrequency or Laser Ablation in the Treatment of Chronic Venous Insufficiency..... 2

Insert: Clinical Evaluation of Venous Insufficiency

Long-term Outcomes of Radiofrequency Ablation Therapy

Endovascular radiofrequency (RF) ablation has been used as an alternative to conventional vein stripping surgery for more than a decade. The technique, also known as the VNUS Closure™ procedure, is far less invasive than surgery and has been shown to have far lower complication rates.

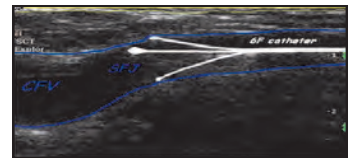
Candidates for RF ablation are patients with persistent symptoms of venous disease plus documented reflux as a source of their symptoms. The procedure is principally of use in the treatment of truncal varicose veins, such as the great saphenous vein, though RF ablation is also used with small saphenous vein incompetence.

The Closure procedure delivers infrared energy to vein walls by directly heating a catheter tip with radiofrequency energy. The procedure is well-tolerated by patients, and produces good cosmetic results. Excellent clinical results are seen at 4-to-5 years, and the long-term efficacy is now known with 10 years of procedural experience.

Published Results

The clinical benefits and treatment outcomes of RF ablation have been reported by several groups. Published results show a high early success rate with a very low subsequent recurrence rate.

In a study published in *Journal of Vascular Surgery*, Merchant and Pichot¹ report the 5-year follow-up results of an ongoing multi-center registry to demonstrate the long-term treatment outcomes and to determine the risk factors that affect treatment efficacy. There were 1,006 patients (1,222 limbs) treated, their mean age was 47.4 ± 12.1 years, and 78.1% were female. To page 3 ►



A catheter with retractable electrodes delivers RF energy to vein walls and these electrodes come in varying sizes to best match vein diameter.

VI University Presents Local CME Events

In one evening, the faculty of Venous Insufficiency University (VIU) delivers the most current data on the diagnostic and treatment methods available to patients suffering from chronic venous disease.



The monthly, complimentary CME-accredited program offers physicians and clinical health care providers a comprehensive overview of chronic venous disease — prevalent in more than 30 million people in the United States today. To page 4 ►

Through brief presentations and open discussions, participants gain knowledge pertaining to venous anatomy, pathophysiology, and diagnostic and treatment options for venous disease.

Endovenous Radiofrequency or Laser Ablation in the Treatment of Chronic Venous Insufficiency

Robust clinical data are available comparing radiofrequency ablation (RF) versus endovenous laser ablation (EVL), much of it focused on the safety and efficacy of either technique. However, a recent multi-center, prospective, randomized trial² compared postoperative recovery differences and quality-of-life factors between RF and EVL ablation. The primary clinical intent of the procedure did not differ between randomization groups; 80% of the patients in both treatment groups were enrolled for symptom relief.

Published in *The Journal of Vascular and Interventional Radiology*, the study was designed to address the hypothesis that RF thermal ablation, as represented by the ClosureFAST™ system, is associated with improved recovery and quality-of-life (QOL) parameters compared with 980-nm endovenous laser (EVL) thermal ablation of the great saphenous vein (GSV). ClosureFAST utilizes Segmental Ablation Technology™ which allows for rapid and uniform heating of the vein.

Demographics	ClosureFAST	EVL	P Value*
Limbs	46	41	
Age (y)	51.6±12.8 (35)	52.4±15.3 (41)	.8215
Female sex	29 (82.9%)	31 (75.6%)	.5748
Height (inches)	69.4±13.5 (35)	66.6±3.6 (41)	.1986
Weight (lbs.)	157.6±19.6 (35)	165.0±28.4 (41)	.1960
VCSS	4.7±3.1 (46)	4.9±2.8 (41)	.6907
CEAP (Class 2)	43 (93.5%)	36 (87.8%)	.4671
Mean length of treated segment (cm)	35.6±13.4 (45)	42.2±14.0 (41)	.3785
Diameter 3 cm from SFJ (mm)	5.1±2.3 (46)	6.0± 2.8 (41)	.1154

Demographic Characteristics of Study Patients²

Note—Values expressed as means ± SD. Values in parentheses are the numbers of patients in which measurements were available unless otherwise indicated. CEAP = Clinical/Etiology/Anatomy/Pathophysiology. * Fisher exact test.

Methods

Eighty-seven veins in 69 patients were randomized to ClosureFAST or 980-nm EVL treatment of the GSV. Reflux was considered significant if reversal of flow was present for more than 0.5 seconds after distal compression in the standing position.

The study was prospective, randomized, single-

blinded, and carried out at five American sites and one European site. Investigators were required to have documented clinical experience with RF and EVL devices.

Primary endpoints (postoperative pain, ecchymosis, tenderness, and adverse procedural sequelae) and secondary endpoints (venous clinical severity scores and QOL issues) were measured at 48 hours, 1 week, 2 weeks, and one month after treatment. Patients were asked to complete a questionnaire at each visit that focused on pain assessment and QOL issues. Visits at 1 and 2 weeks were limited to clinical assessment and patient questionnaires. The final visit at one month included duplex.

Discussion of Results

In this prospective randomized study to compare an RF vein ablation catheter and EVL, RF treatment showed better results than EVL treatment in all primary endpoints and many secondary endpoints. Post-procedural pain, tenderness, ecchymosis, and phlebitis were more prevalent in the laser-treated limbs, likely resulting from high treatment temperatures and vein wall perforation by laser energy.

All scores referable to pain, ecchymosis, and tenderness were statistically lower in the RF group at 48 hours, 1 week, and 2 weeks. Minor complications were more prevalent in the EVL group (P = .0210); however, there were no major complications. All QOL measures were statistically better in the RF group at 48 hours, one week, and 2 weeks.

RF thermal ablation was significantly superior to EVL as measured by a comprehensive array of post-procedural recovery and QOL parameters in this randomized prospective comparison between these two thermal ablation modalities for closure of the GSV.

Call 1-888-855-VEIN or 301-809-0930 for further details on endovenous ablation treatment for your patients.

²Almeida, JI et al. Radiofrequency Endovenous ClosureFAST versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-blinded, Randomized Study (RECOVERY Study). *Journal of Vascular and Interventional Radiology* 2009; 20:6, 752-759.

Long-term Outcomes of Radiofrequency Ablation Therapy

Continued from Page 1

Study Methods

Patients with superficial venous insufficiency, confirmed by duplex ultrasound scanning, were considered as candidates for treatment. Clinical and duplex ultrasound follow-up was performed one week, 6 months, one year, and annually thereafter to 5 years. Treatment efficacy and clinical improvement were analyzed after the procedure.

Three types of anatomical failure were identified, and the impact of anatomical failure on clinical symptoms and varicose vein recurrence was also analyzed. Logistic regression analysis was performed to determine the existence of any significant risk factors associated with anatomical failure. Risk factors considered were age, gender, body mass index, vein diameter, and catheter pullback speed.

Before treatment, 92.8% of limbs were CEAP clinical class 2 to 4, and the most common symptoms in the limbs were pain in 85.3%, fatigue in 78.6%, and edema in 39.2%. The types of veins treated included 89.1% great saphenous vein above-knee segments, 1.2% great saphenous vein below-knee segments, 4.1% great saphenous vein groin-to-ankle, 4.3% small saphenous veins, and 1.3% accessory saphenous veins. Mean vein diameter was 7.5 mm, with a maximum of 24 mm.

Conclusions

Five-year follow-up on patients treated with endovenous RF ablation demonstrated that vein occlusion and clinical improvement are durable (see table below). Most patients experienced clinical improvement, and 70% to 80% were asymptomatic, irrespective of anatomical failure, during the 5-year follow-up period.

Clinical signs	Class 0	No visible or palpable signs of venous disease
	Class 1	Teleangiectases or reticular veins
	Class 2	Varicose veins
	Class 3	Edema
	Class 4	Skin changes ascribed to venous disease
	Class 5	Skin changes as defined above with healed ulceration
	Class 6	Leg ulceration, skin changes as defined above
Etiologic classification	Congenital, primary, secondary	
Anatomic distribution	Superficial, deep, or perforator, alone or in combination	
Pathophysiologic dysfunction	Reflux or obstruction, alone or in combination	

Before treatment, 92.8% of limbs were CEAP clinical class 2 to 4, and the most common symptoms in the limbs were pain, fatigue, and edema.

Vein occlusion and hemodynamic outcomes¹

	1 week	6 months	1 year	2 years	3 years	4 years	5 years
Limbs at risk	1,222	1,220	1,206	1,141	991	833	406
Limbs available for follow-up	985	518	473	263	133	119	117
Vein occlusion	96.8%	89.2%	87.1%	88.2%	83.5%	84.9%	87.2%
Absence of reflux	96.6%	91.3%	88.2%	88.2%	88.0%	86.6%	83.8%

At *Center for Vein Restoration*, our experience shows that patient satisfaction with the Closure procedure is high and downtime is minimal. For more information, call 1-888-855-VEIN or 301-809-0930.

¹Merchant RF, Pichot O. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. *Journal of Vascular Surgery* 2005; 42:3, 502-509.

Center for
Vein Restoration



Love your legs *again!*

7500 Hanover Parkway
Suite 103B
Greenbelt, MD 20770

Phone: 800-FIX-LEGS or
301-860-0930

Additional locations:
Annapolis, MD
Baltimore/Towson, MD
Easton, MD
Glen Burnie, MD
Glenn Dale, MD
Prince Frederick, MD
Rockville, MD
Takoma Park, MD
Waldorf, MD



VI University Presents Local CME Events

Continued from Page 1

Physicians and clinical health care providers can earn up to 2.5 CME credits at no charge through Venous Insufficiency University. During evening events, brief presentations and open discussions participants gain knowledge pertaining to venous anatomy, pathophysiology, as well as diagnostic and treatment options for venous disease.

In addition to the complimentary CME events, Venous Insufficiency University offers Physician Lunch and Learn Programs, Educational Newsletters, and Vascular Ultrasound Training in conjunction with Universities and Accredited Technical Schools.

To attend, call Lorie Frantz at 443-624-8838 or email lorie@centerforvein.com.



CALENDAR OF EVENTS

Registration, cocktails and networking begin at 6:00 pm, followed by dinner and presentations at 6:45 pm.

February 2010
Salisbury, Maryland

March 2010
Takoma Park, Maryland

April 2010
Southern Maryland

May 2010
Rockville, Maryland

RSVP—Lorie Frantz , 443-624-8838 or lorie@centerforvein.com