Aggressive Treatment Can Heal Ulcers in Patients with CEAP 6 Venous Disease and Prevent Ulcers in Patients with CEAP 5 Disease

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Scope of Venous Ulcer Problem

- Prevalence (ever had a venous ulcer) is 1-5% of the adult population
- Point prevalence (have an ulcer at any one time) is 0.3%
- 60% take > 6 mo to heal; 33% > 1 yr; 45% housebound
- Average cost to treat a leg ulcer is $15K (more than a pressure ulcer)
- 2% of the US healthcare budget

CEAP Classification System

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Clinical Classifications with examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N</td>
</tr>
<tr>
<td>C</td>
<td>S</td>
</tr>
<tr>
<td>L</td>
<td>L</td>
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<tr>
<td>E</td>
<td>E</td>
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<tr>
<td>C</td>
<td>S</td>
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<tr>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>F</td>
<td>F</td>
</tr>
</tbody>
</table>

Etiology:
- E | Congenital |
- M | Primary |
- S | Secondary |

Anatomy:
- A | Superficial veins |
- D | Deep veins |
- P | Perforating veins |

Pathophysiology:
- K | Hered. |
- O | Obstruction |

A careful application of compression should be performed to prevent swelling and progressive scarring and to facilitate the healing process by improving the venous microcirculation.


The role of perforators in chronic venous insufficiency
Background

- 78/119 Patients followed with healed venous ulcers
  - All patients had lipodermatosclerosis and edema
  - Divided into 2 groups: Compliant and Non-compliant
  - Mean healed ulcer size: 3.2 cm in largest dimension
- Only 1/3 of patients underwent Duplex ultrasound examination for assessment of superficial, perforator, and deep vein valvular incompetence and occlusion

Fifteen-year results of ambulatory compression therapy for chronic venous ulcers

John G. Mayberry, MD, Gregory L. Monette, MD, Lloyd M. Taylor, Jr., MD, and John M. Porter, MD, Portland, Ore.

- The difference between compliant and non-compliant groups was statistically significant (P = 0.0001; chi-squared)

  2 yrs = 17%, 3 yrs = 22%
Endovenous ablation with concomitant phlebectomy is a safe and effective method of treatment for symptomatic patients with axial reflux and large incompetent tributaries.

Michal Harlander-Locke, BS; Juan Carlos Jimenez, MD; P. ACS; Peter F. Lawrenz, MD; Brian D. Durbek, MD; David R. Karpas, MD; and Vaughn A. Gallaher, MD, Los Angeles, Calif

Objective: To examine outcomes following 2008 consecutive endovenous radiofrequency ablation (RFA) closure of saphenous vein and 506 idiopathic phlebectomy procedures for chronic venous insufficiency. Based on the outcomes in this patient cohort, we aim to determine whether concomitant or staged phlebectomy is preferred and examine the rate and spinal treatment of complications using a dedicated treatment algorithm based on our classification system for level of disease following these procedures.

Methods: Patients with symptomatic superficial venous incompetence with venous reflux score RFA of incompetent saphenous vein was identified as well as patients with concomitant or staged saphenous phlebectomy. Intraproperative, postoperative, and complications were recorded. Post RFA Imaging and Classification.

Results: Over 2008 consecutive endovenous radiofrequency ablations (98.2% great saphenous vein and accessory great saphenous vein, 4.8% small saphenous vein) were performed in the endovascular setting (patients n = 776, limbs n = 1552 limbs with large (5 mm) incompetent saphenous tributaries and saphenous saphenofemoral junction with endovenous RFA of incompetent saphenous vein was identified as well as patients with concomitant or staged saphenous phlebectomy. Intraproperative, postoperative, and complications were recorded. Post RFA Imaging and Classification.

Conclusion: The study represents the larger reported series of segmental healing efficacy of the saphenous vein in the current literature. The majority of patients with symptomatic chronic venous insufficiency benefit from endovenous RFA of incompetent saphenous veins with comparable results to published surgical outcomes for saphenous closure. This series contains patients with refluxing tributaries veins greater than 3 mm in diameter requiring phlebectomy in addition to saphenous ablation. These patients may benefit from concomitant phlebectomy along with endovenous saphenous closure. (J Vasc Surg 2013;Sun 3-1-3)

RFA: Technique
- Ultrasound-guided percutaneous access
- Introduction of 7-French sheath into vein
- Catheter positioned 2.5-3 cm caudal to the saphenofemoral junction

Post RFA Imaging and Classification
- All Patients undergo a postoperative duplex scan 24-72 hours following ablation
- Confirm successful closure
- Confirm femoral vein patency
- Rule out DVT
Mean duration 12 ± 2 days

Results: Level of Closure

- 1000 saphenous closures in 735 pts (916 limbs)
  - 955 GSV, 45 SSV
- Five different vascular surgeons
- Mean age 57 ± 12 years
- 536 female, 199 male
- Mean preoperative vein diameter: 7.6 ± 2.8 mm
- 761 veins-Newer generation ClosureFast cath
- 239 veins-1st generation ClosurePlus cath

Results: Primary/Secondary Indications for Treatment

<table>
<thead>
<tr>
<th>Presenting Symptoms</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle limiting pain</td>
<td>n=696 (94.8%)</td>
</tr>
<tr>
<td>Limb swelling</td>
<td>n=485 (66%)</td>
</tr>
<tr>
<td>Lipodermatosclerosis</td>
<td>n=39 (5.3%)</td>
</tr>
<tr>
<td>Venous ulcer</td>
<td>n=69 (9.4%)</td>
</tr>
<tr>
<td>Bleeding varicose veins</td>
<td>n=10 (1.4%)</td>
</tr>
</tbody>
</table>

CEAP Classification of Treated Patients

<table>
<thead>
<tr>
<th>Clinical Severity</th>
<th>Number of Limbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic varicose veins (C2)</td>
<td>217</td>
</tr>
<tr>
<td>Swelling (C3)</td>
<td>346</td>
</tr>
<tr>
<td>Hyperpigmentation and/or Lipodermatosclerosis (C4)</td>
<td>230</td>
</tr>
<tr>
<td>Healed Ulcer (C5)</td>
<td>50</td>
</tr>
<tr>
<td>Active Ulcer (C6)</td>
<td>73 (79 patients)</td>
</tr>
</tbody>
</table>
Results: Post RFA

• Successful saphenous closure-98.6%
  – GSV: n=942/955 (98.6%)
  – SSV: n=44/45 (97.8%)
• Mean length of follow up: 9 ± 5 months
• 14 veins (1.4%) remained patent on initial postoperative duplex
• Late GSV Recanalization: 13 patients (1.8%)
• No SSV recanalization

Results: Relief of Symptoms by CEAP Class Following RFA

<table>
<thead>
<tr>
<th>Clinical Severity</th>
<th>Relief of Symptoms (Mean=9 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic varicose veins (C2)</td>
<td>92%</td>
</tr>
<tr>
<td>Limb Swelling (C3)</td>
<td>91%</td>
</tr>
<tr>
<td>Hyperpigmentation and/or lipodermatosclerosis (C4)</td>
<td>81%</td>
</tr>
<tr>
<td>Healed Ulcer (C5)</td>
<td>84%</td>
</tr>
<tr>
<td>Active Ulcer Healed (C6)</td>
<td>73%</td>
</tr>
</tbody>
</table>

Results: Venous Ulcers

• 69 patients, 79 active ulcers
• Mean time of ulceration prior to RFA: 22 ± 5 months
• 73% of ulcers healed following saphenous vein closure + compression (n=58/79)
• Mean healing time: 6 months
• 11% of patients with persistent ulcers underwent subsequent perforator RFA

Results: Complications

• One patient-Pulmonary Embolus (0.1%)
  – 20 mm GSV
  – Breast cancer s/p lumpectomy and radiation
  – Estrogen Replacement Therapy (NuvaRing)
  – Normal Level 1 Closure postop prior to PE
• No occlusive DVT in remainder of series
• No additional hospitalization
• No reoperations
• No skin necrosis
• 17 patients-LMWH-for levels 3,4, or 5 X 12 ± 2 days
Venous Ulcers Not Responsive to Compression and Superficial Vein Ablation

- Incompetent perforating veins are implicated in the development and difficulty healing recalcitrant venous ulcers
- Reports on endovenous perforator ablation have focused on ablation success, rather than ulcer healing

Central Role of Perforators

| Table 2. Number of competent and incompetent perforator veins in patients with CVD. |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| CVD Class | Number of limbs | Number of competent | Number per limb | Number of incompetent | Number per limb | Range |
| 1          | 8               | 31               | 3.8             | 1.4             | 3               | 0.4   |
| 2          | 37              | 125              | 4.2             | 1.5             | 26              | 0.7   |
| 3          | 16              | 62               | 3.8             | 1.5             | 17              | 1.1   |
| 4          | 20              | 68               | 3.4             | 1.5             | 48              | 2.4   |
| 5          | 5               | 35               | 4.3             | 1.6             | 24              | 3     |
| 6          | 14              | 67               | 4.7             | 1.7             | 45              | 3.2   |
| Total      | 105             | 408              | 3.8             | 1.7             | 163             | 4.0 |

Number of incompetent PVs per limb, CVD classes 1 or 2 vs. CVD classes 3 or 4 or 5, p=0.0001.

Labropoulos N et al. EJVES 1999;18:228-34

Patient Selection

- Patients evaluated for nonhealing ulcer
- Duplex ultrasound of the superficial, deep, and perforating veins
- CEAP classification
- All incompetent superficial veins (great saphenous, small saphenous, trib) >3 mm treated with surgery/ablation
- Patients managed with optimal wound care for > three months
- Persistent nonhealing ulcers underwent repeat duplex scan
- Incompetent perforating veins >3mm with reflux > 1.0 sec had endovenous ablation

Venous Ulcer Study

The impact of ablation of incompetent superficial and perforator veins on ulcer healing rates

Michael Hernando-Lorca, Nancy R. Lawrence, MD, Ali Askar, MD, Juan Carlos Jacobo, MD, Doris Kugler, MD, and Brian B. Robbins, MD, PhD, New York and Los Angeles, Calif.

Objective: To examine the impact of endovenous ablation of incompetent superficial (great saphenous [GSV] and small saphenous, SSV) and perforator veins (PVE) on healing rates of venous ulcers in patients who had failed conventional compression therapy.

Methods: Patients with CVD with ulcers were treated with a microphlebectomy in a dedicated wound care center. Ulcers were treated using a standardized protocol. We aimed to achieve an absence of pain and improvement in wound size after 3 months of treatment.

Results: We performed 14 consecutive endovenous ablation procedures (1 superficial and 13 perforator) in 135 venous ulcers in 98 limbs. Ulcers had been present for 71.5 ± 53.9 months with an initial ulcer area of 22.4 ± 18.9 cm². Following initial treatment with endovenous ablation of incompetent PVEs, ulcers were treated with a compression bandage during 2 hours per day for 12 hours (P < .001). Ulcer healing rate was higher after the first application of compression bandages and continued for 2 weeks (P < .001) and then until the next application (P < .001).

Conclusions: Our study shows that endovenous ablation of incompetent perforator veins can improve ulcer healing rates, and patients should be followed up with duplex ultrasound.


From the Society for Vascular Surgery

See the Society for Vascular Surgery
Demographic Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>74 (35-93)</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>31 (19-45)</td>
</tr>
<tr>
<td>Sex (Male: Female)</td>
<td>26:19</td>
</tr>
<tr>
<td>ABI (&lt;0.9)</td>
<td>29%</td>
</tr>
<tr>
<td>Anticoagulation therapy</td>
<td>33%</td>
</tr>
<tr>
<td>Previous DVT</td>
<td>31%</td>
</tr>
<tr>
<td>Deep venous reflux</td>
<td>46%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>18%</td>
</tr>
</tbody>
</table>

RF Ablation Stylet

For Incompetent Perforators

Endovenous Perforator Ablation Technique

- Reversed Trendelenberg position on an electronic tilt table
- A GE Logiq e portable duplex scanner used for imaging
- The incompetent vein adjacent to the ulcer with both reflux and a diameter above 3 mm selected for Rx

Endovenous Perforator Ablation Technique

- RFS catheter placed at a 45 degree angle- transverse and longitudinal transducer
- Confirmed stylet in vein at the level of the fascia
- Vein treated with radiofrequency energy for 1 minute in each quadrant; repeated above the fascia if possible
- Attempt to confirm ablation post procedure
Endovenous Perforator Ablation Technique

- The leg dressed with a four layer compression dressing
- Confirmation of closure of the perforating vein at next clinic visit
- Independent vascular lab technician

Methods of Ulcer Tracking

Ulcer decreasing in size after vein ablation

Methods of Ulcer Evaluation

Green: Treatment with compression therapy alone
Orange: Ongoing compression after vein ablation

Results

- 45 patients; 51 limbs; 75 ulcers
- CEAP 6 (open venous ulcer) classification in all patients
- Etiology of the venous ulcer was post-phlebitic in 31%; unknown in 69% (probably primary incompetence)
- Incompetent perforating veins ranged from 1 to 5 per leg
- Ulcer age mean = 93 months (range 3-300 months)
- Concomitant diseases that interfere with wound healing
  - 3 patients with chronic liver disease, 2 undergoing chemotherapy for a neoplasm, 1 immunosuppressed for SLE, 1 with leg edema due to CHF, 1 dialysis dependent, 1 with sickle cell disease
Healed Ulcers
N=84

Healing Ulcers
N=26

Results: Healing Rates

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-ablation healing rate (cm²/mo) ± SEM</th>
<th>Post-ablation healing rate (cm²/mo) ± SEM</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healed Ulcers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL VEINS</td>
<td>+ 1.02 ± .11</td>
<td>- 4.35 ± .13</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Axial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GSV</td>
<td>+ 1.18 ± .12</td>
<td>- 6.44 ± .17</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SSV</td>
<td>+ 1.06 ± .13</td>
<td>- 4.82 ± .14</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Perforators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTV</td>
<td>+ .89 ± .09</td>
<td>- 2.92 ± .10</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Unhealed Ulcers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL VEINS</td>
<td>+ .96 ± .07</td>
<td>- 4.60 ± .11</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>GSV</td>
<td>+ .99 ± .08</td>
<td>- 4.57 ± .11</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SSV</td>
<td>+ .89 ± .06</td>
<td>- 2.79 ± .06</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Learning Curve of Successful Ablation by Single Surgeon

Overall Success of Perforator Closure
Location of Venous Ulcers Prior to Endovenous Perforator Ablation

Location of Incompetent Perforators

Location of Ablated Perforators Following Initial Procedure

Location of Ablated Perforators Following Second Procedure
Remaining Venous Ulcers

• 46/75 venous ulcers healed
• 28/29 with residual ulcers did not complete ablation procedures
  — Death
  — Insurance changes
  — Intercurrent disease (breast and colon cancer)

Endovenous Perforator Outcome Analysis

• Ablation initially successful in 58%; additional procedures in 16%
• 10/11 repeat procedures successful; final closure rate was 71%
• Mean healing time ~4 months (60-365 days)
• 90% of ulcers healed when at least 1 perforator was closed
• No ulcer healed without at least 1 perforator being ablated
• No complications from the procedure — Skin necrosis, infection, or nerve injury

Combined treatment with compression therapy and ablation of incompetent superficial and perforating veins reduces ulcer recurrence in patients with CEAP 5 venous disease

STUDY | PATIENTS (N or %) | THERAPY | 1 YR RR | 2 YR RR | 3 YR RR
---|---|---|---|---|---
Gohel et al. | 500 | Compression | 28% | N/A | 56% |
Erickson et al. | 71 | Compression | 35% | 42% | 49% |

Several studies have reported ulcer recurrence rates from (28-56%) of CEAP 5 (healed) venous ulcers with compression alone
A recent JVS supplement cited the need for reducing venous ulcers by 50% in the next 10 years
No studies have evaluated the impact of ablation of incompetent axial and/or perforating veins on CE5 (healed venous ulcer) recurrence

To examine the effect of endovenous ablation of incompetent axial and perforating veins on patients with CEAP 5 healed venous ulcers who have progressive symptoms with impending ulceration in spite of compliant compression therapy
To compare recurrence rate in these patients with historic studies using compression therapy alone
From 2006-2010, 76 patients were evaluated for CEAP 5 CVI
56 patients were compliant with compression, had prior surgery or prior ablation of incompetent veins
20 consecutive patients; 21 limbs; 21 healed ulcers
- Mean time of initial ulcer prior to healing = 40 months
- Ablation procedures:
  - 19 axial (GSV, AASV)
  - 9 perforator
- Final successful ablation rates of 100% (axial) and 89% (perf)

### Healed Ulcer Locations and Procedures

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>20 (100%)</td>
</tr>
<tr>
<td>Etiology</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>17 (85%)</td>
</tr>
<tr>
<td>Secondary (documented prior DVT)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Anatomy</td>
<td></td>
</tr>
<tr>
<td>Superficial (Saph + AASV)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Perforator</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Superficial + Deep</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Superficial + Perforator</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Superficial + Deep + Perforator</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Pathophysiology</td>
<td></td>
</tr>
<tr>
<td>Reflux</td>
<td>20 (100%)</td>
</tr>
</tbody>
</table>

### Ulcer Recurrence Rates

- Shortest follow-up = 25 mo, mean = 31.8 mo, longest = 59 mo
- 2 Ulcers recurred at 8 and 21 months post saphenous ablation
  - (Ulcer #1) Second incompetent perforator vein ablated, re-healed 5 months later
  - (Ulcer #2) Still actively healing

### Comparison to Historic Controls

<table>
<thead>
<tr>
<th>STUDY</th>
<th>PATIENTS (n =)</th>
<th>THERAPY</th>
<th>1 YR RR</th>
<th>2 YR RR</th>
<th>3 YR RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gohel et al1</td>
<td>500</td>
<td>Compression</td>
<td>28%</td>
<td>N/A</td>
<td>56%</td>
</tr>
<tr>
<td>Erickson et al2</td>
<td>71</td>
<td>Compression</td>
<td>35%</td>
<td>42%</td>
<td>49%</td>
</tr>
<tr>
<td>UCLA3</td>
<td>20</td>
<td>Compression + Ablation</td>
<td>5%</td>
<td>10%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- Our patients with C5 healed venous ulcers who have ablation of incompetent axial and perforators had a 10% recurrence rate at 2 years with a combination of both compression therapy and elimination of all axial and perforator vein reflux
- Historic controls had a 17-49% recurrence rate within 3 years

1BMJ 2007  2JVS 1995  3JVS 2012
May-Thurner Syndrome

- 25% of patients with venous ulcers have proximal obstruction
- M-T is the most common cause of proximal venous obstruction
- Occurs primarily in the left iliac vein
- Best diagnosed by duplex ultrasound, followed by MRV and IVUS
- Treated with thrombolysis, mechanical thrombectomy, and iliac vein stenting

Marston JVS 2011
May-Thurner Post Iliac Vein Stent

- 28 patients with acute and chronic left leg swelling
- Several with limb threatening ischemia
- Diagnosed with venogram and IVUS
- Treated with mechanical thrombectomy, thrombolysis, and self-expanding stent
- No complications
- Patency 28 long term, but 2 had early thrombosis and were reopened

Conclusions

- Patients with nonhealing venous ulcers heal after superficial axial vein ablation and/or perforator ablation
  - 99% of superficial veins are successfully ablated and ~70% of perforating veins are ablated; repeat ablation is as successful as the initial ablation
  - Significant learning curve for endovenous perforator ablation
- Complications are rare with perforator ablation
- 90% of venous ulcers heal when one incompetent perforator is ablated
- Recurrence of a venous ulcer in a compression compliant CEAP 5 patient should suggest incompetent axial or perforating veins
- CEAP 5 patients who undergo ablation of axial and perforator veins had a 10% ulcer recurrence rate with 95% healing at 2 years
- Look for proximal iliac venous occlusive disease when CVI progresses after superficial and perforator ablation

UCLA Experience with May-Thurner

- 28 patients with acute and chronic left leg swelling
- Several with limb threatening ischemia
- Diagnosed with venogram and IVUS
- Treated with mechanical thrombectomy, thrombolysis, and self-expanding stent
- No complications
- Patency 28 long term, but 2 had early thrombosis and were reopened
Why Should All Surgeons Know About Chronic Venous Disease?

- Most common disease in the US
  - 40% of Americans have venous disease
  - 15-25% of the adult population have saphenous or branch incompetence
  - 40% of adults have telangiectasias (spider veins)
  - 6% have a venous ulcer during their lifetime

Results: Vein Diameters by CEAP Class

<table>
<thead>
<tr>
<th>Level of Closure</th>
<th>Number</th>
<th>Vein Diameter + SEM (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>18</td>
<td>10.6 + 1.0</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
<td>7.7 + 0.8</td>
</tr>
<tr>
<td>3</td>
<td>27</td>
<td>7.9 + 0.8</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>8.1 + 0.6</td>
</tr>
<tr>
<td>1</td>
<td>872</td>
<td>7.6 + 0.1</td>
</tr>
<tr>
<td>SSV</td>
<td>44</td>
<td>4.3 + 0.3</td>
</tr>
<tr>
<td>Unsuccessful Closure</td>
<td>14</td>
<td>8.8 + 0.6</td>
</tr>
</tbody>
</table>

Segmental Ablation

- Infiltration of tumescent solution with spinal needle (Normal saline, lidocaine with epi, bicarbonate)
- 7cm length treated-20 seconds per treatment
- No energy delivery during repositioning
- Energy delivery does not vary by pullback speed
- 40 Watts maximum power at 120 C
Methods

- Patients with healed venous ulcers were evaluated for increasing lipodermatosclerosis and/or progressive malleolar pain
- Duplex ultrasound of the superficial, deep, and perforating veins in standing position-CEAP classification
- Required use of compression therapy to relieve symptoms for $\geq 3$ months
- Endovenous radiofrequency ablation of incompetent superficial axial and perforator veins
- Continued use of compression therapy