Chronic Venous Insufficiency Treatment

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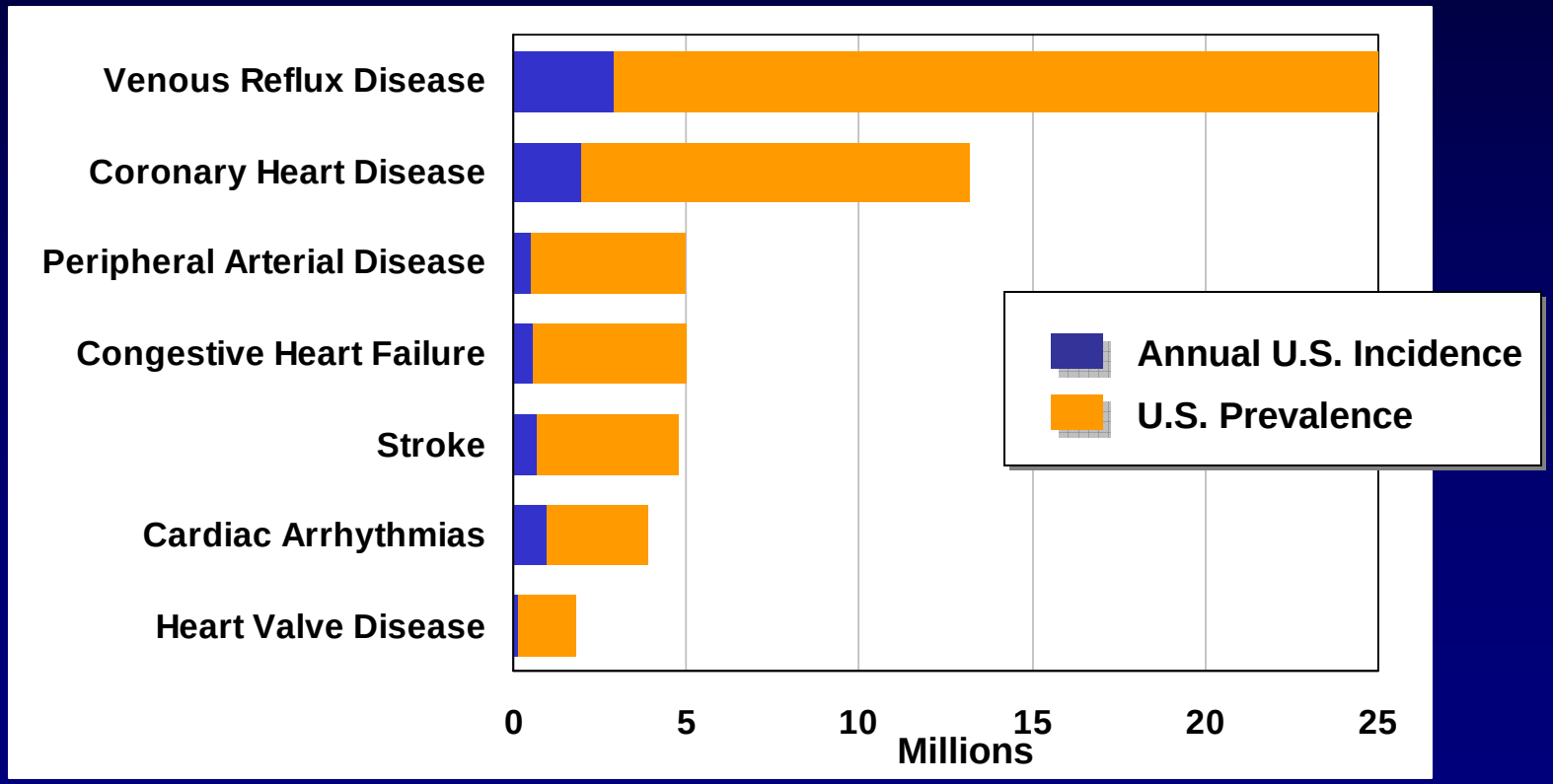
Relevant Conflict of Interest

- Research and Educational grants to the Midwest Cardiovascular Research Foundation from Covidien
- www.mcrfmd.com

Prevalence and Etiology of Venous Insufficiency

Venous reflux disease is 2x more prevalent than coronary heart disease (CHD) and 5x more prevalent than peripheral arterial disease (PAD)



Prevalence and Etiology of Venous Insufficiency

Of the estimated 25 million people with symptomatic superficial venous reflux[1] :

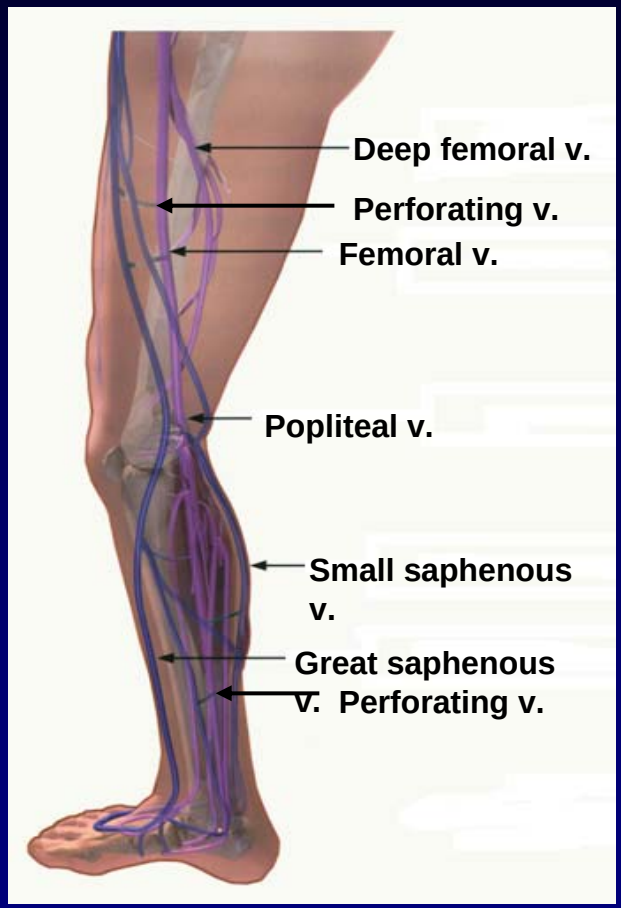
- Only 1.7 million seek treatment annually[2]
- Over 23 million go untreated

Prevalence by Age and Gender[3,4]

Age	Female	Male
20 - 29	8%	1%
40 - 49	41%	24%
60 - 69	72%	43%

Venous System

- Venous blood flows from the capillaries to the heart
- Flow occurs against gravity
  - Muscular compression of the veins
  - Negative intrathoracic pressure
  - Calf muscle pump
- Low flow, low pressure system



Superficial Venous System

Dominant superficial collecting veins

- Great saphenous vein (GSV)
- Small saphenous vein (SSV)
- Vein of Giacomini
  - Intersaphenous communicating vein connecting GSV to SSV
- Lateral subdermic venous plexus
  - Superficial veins of lateral leg

Superficial Venous System - GSV

- Often runs a superficial subcutaneous course from mid thigh-knee
- May enter and exit the saphenous sheath at various locations
- Closely associated with saphenous nerve below mid-calf


WL: 127 WW: 255
PCCV-0488851
L8-4/Vasc Ven
20100917.075227
FR 48Hz
RS
2D
52%
C 54
P Low
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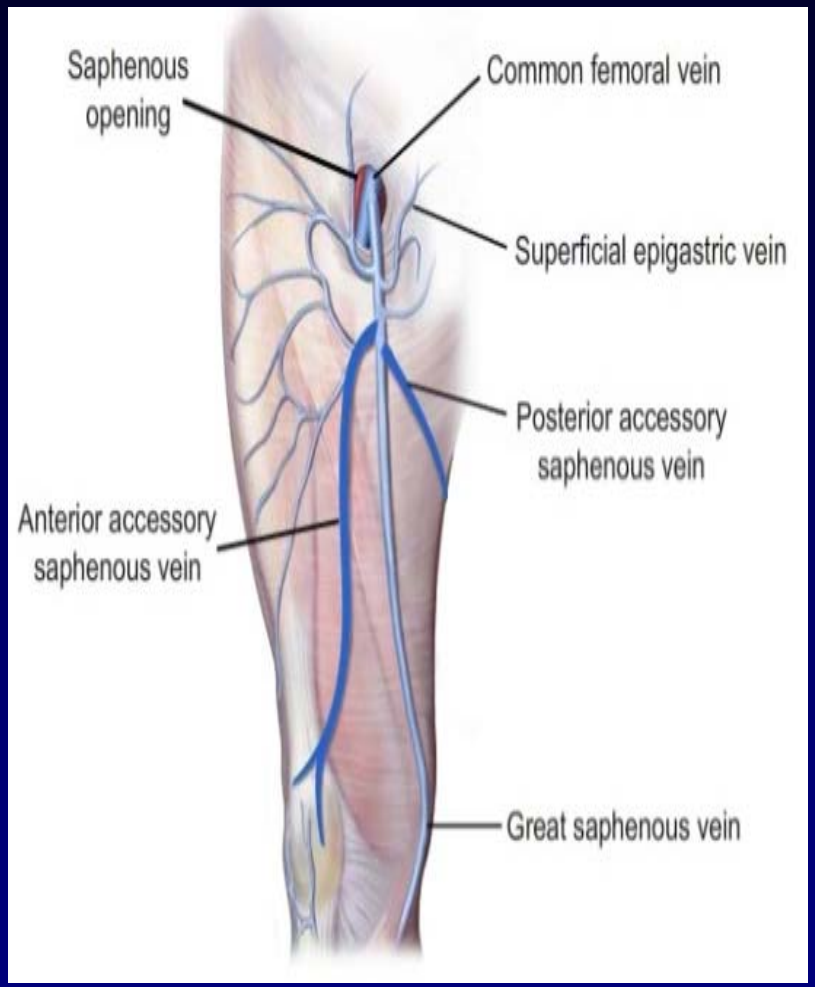
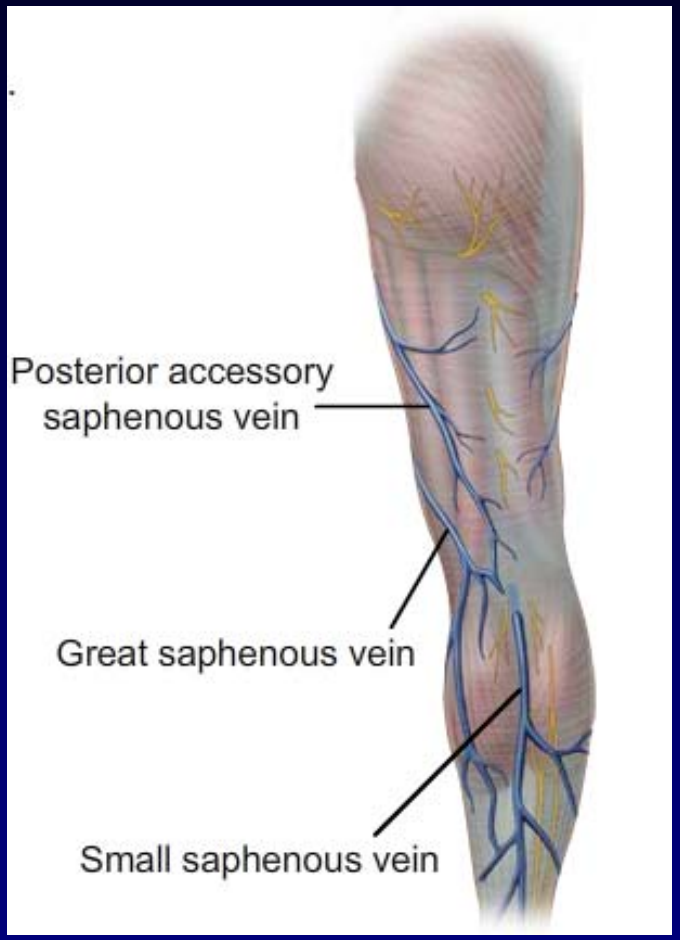
M2
0
255
1
128
2
0
3

Accessory Veins of GSV





Superficial Venous System – SSV

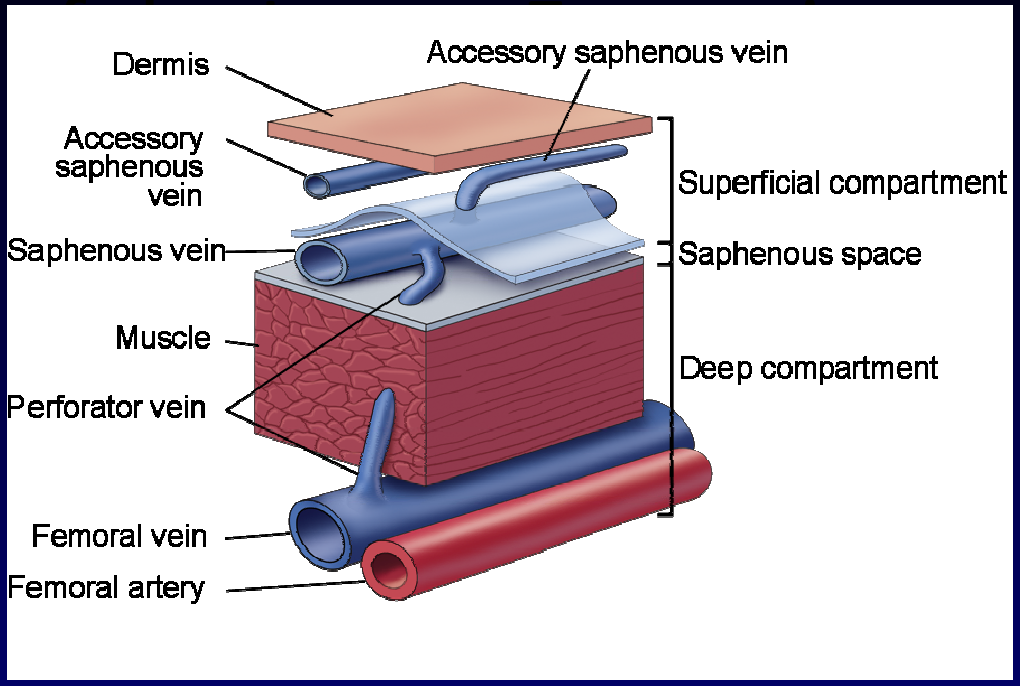
- Within the fascial space (saphenous sheath)
- Begins posterior to the lateral malleolus
- Travels up calf between two heads of gastrocnemius muscle

SSV Termination Variations

Communicating Veins and Perforating Veins

- Communicating veins (tributaries/branches) connect veins in the same fascial plane
- Perforator veins connect a superficial vein to a deep vein (crossing fascial plane)
  - Variable appearance: linear, oblique, tortuous
  - ‘Rungs on a ladder’

The Relationship Between the Fascia and Veins

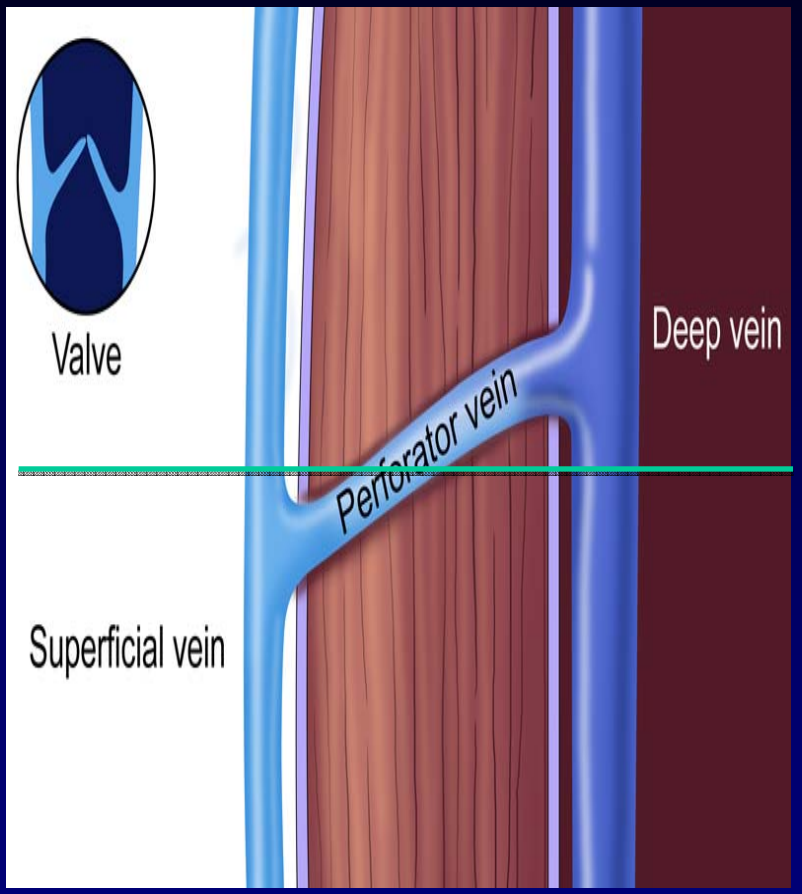


- Fascia covers muscle and separates deep from superficial compartment
- Saphenous fascia invests saphenous vein
- Saphenous compartment is sub compartment of superficial compartment

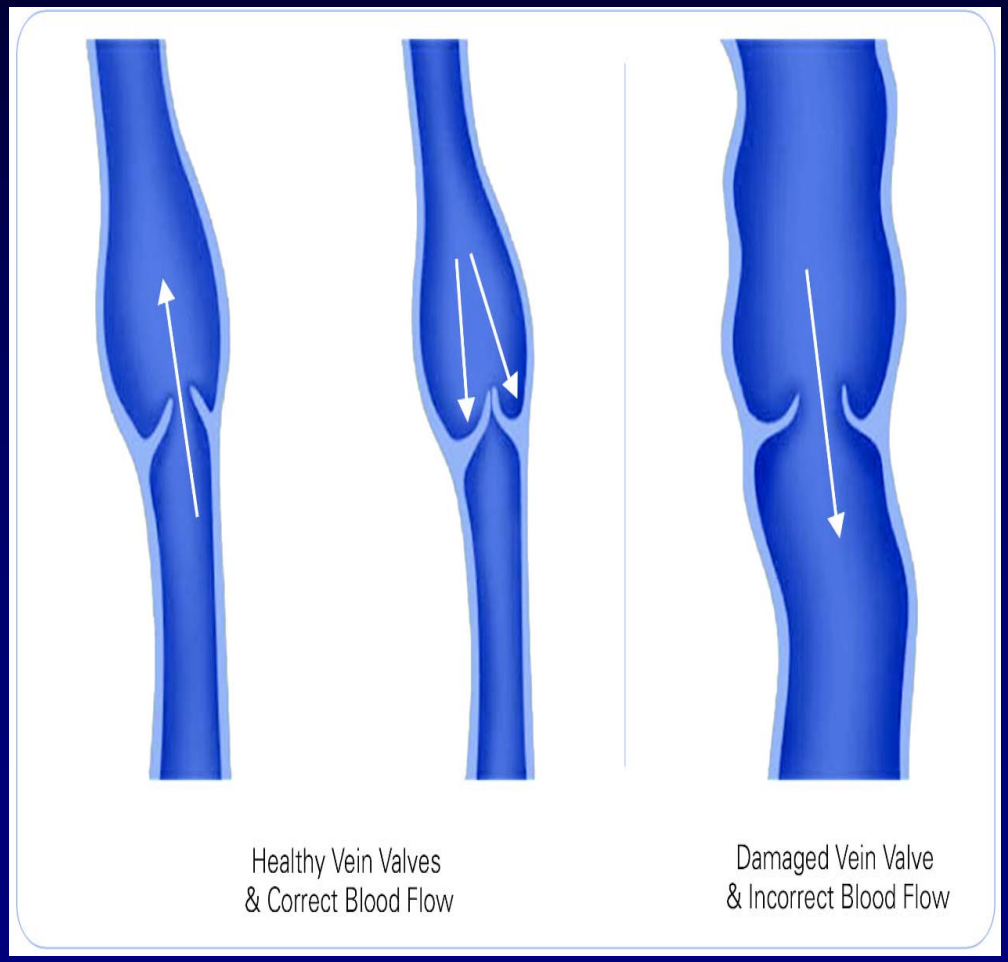
Mozes G, Gloviczki P.,(2004), Vasc Endovasc Surg;38

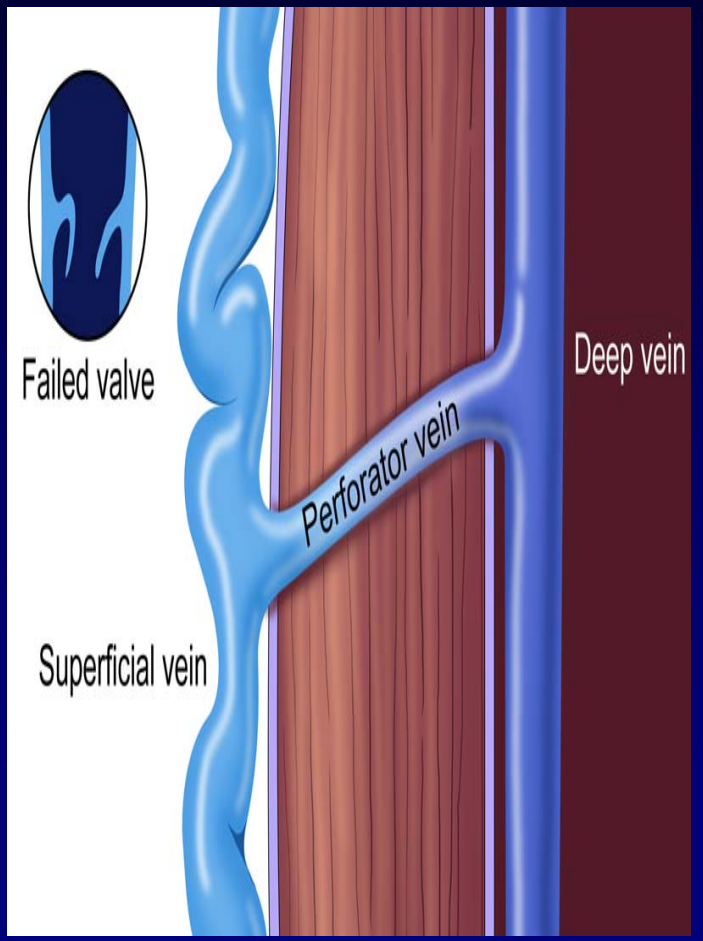
Valves

- Bicuspid and unidirectional
- More valves in lower legs than upper legs
- Valves near proximal end of major veins are stronger, more distinct than distal
- Valves are present even in smaller veins
  - Microscopic venous valves have been demonstrated even in post capillary venules (Caggiati, 2006)



Pathophysiology of Venous Insufficiency





Risk Factors and Symptoms of Venous Insufficiency

Risk factors of venous insufficiency:

- Gender
- Age
- Heredity
- Pregnancy
- Standing occupation
- Obesity
- Prior injury or surgery
- Sedentary lifestyle

Symptoms of venous insufficiency:

- Leg pain, aching, or cramping
- Burning or itching of the skin
- Leg or ankle swelling
- “Heavy” feeling in legs
- Skin discoloration or texture changes
- Open wounds or sores
- Restless legs
- Varicose Veins

History

- Thoroughly document:
  - How often symptoms occur and location
  - Location of signs and symptoms
  - Occupation and impact on symptoms
  - Use of analgesics for pain symptoms, how often and what type
  - Use of compression therapy

History

- Prior treatment
  - Medications, sclerotherapy injections, surgery, compression therapy
- Age of onset
- SVT/phlebitis
- DVT/PE
- Limb trauma, fracture

History

- Gynecologic and obstetric history
  - Pregnancy history and effects on venous complaints
  - Plan for future pregnancies
  - Hormone replacement therapy
  - Oral contraceptives
  - Menstrual cycle-related symptoms

History

- Family history
  - Venous disease
  - Peripheral vascular disease
  - Thrombosis
- Medications and allergies
  - Iron supplements
  - “Natural” remedies
    - Horse chestnut seed

Physical Inspection

- Look for:
  - Stasis changes
  - Palpate for venous tension and for evidence of thrombosis
  - Auscultation over veins: make sure no AV fistula present particularly prior to phlebectomy

Physical Exam

- General inspection
  - Swelling, asymmetry
  - Scars – GSV ligation/stripping vs. phlebectomy
  - CVI stigmata
    - Ulcers: measure size, photograph
    - Dermatitis
    - Hyperpigmentation
    - Atrophie blanche
    - Corona phebectasia (multiple telengectasia at or near the ankle)

Physical Exam

- Detailed inspection
  - Document findings from proximal thigh to distal leg
  - Drawing and photodocumentation of varicosity patterns, size, zones of influence
    - Great Saphenous Vein (GSV) pattern
    - Small Saphenous Vein (SSV) pattern
    - Lateral Venous Complex (LVC) pattern

Vessel Classification

- Large caliber veins: >4mm
- Venules: 1-4mm
- Reticular veins
- Spider veins

Physical Exam: Palpation

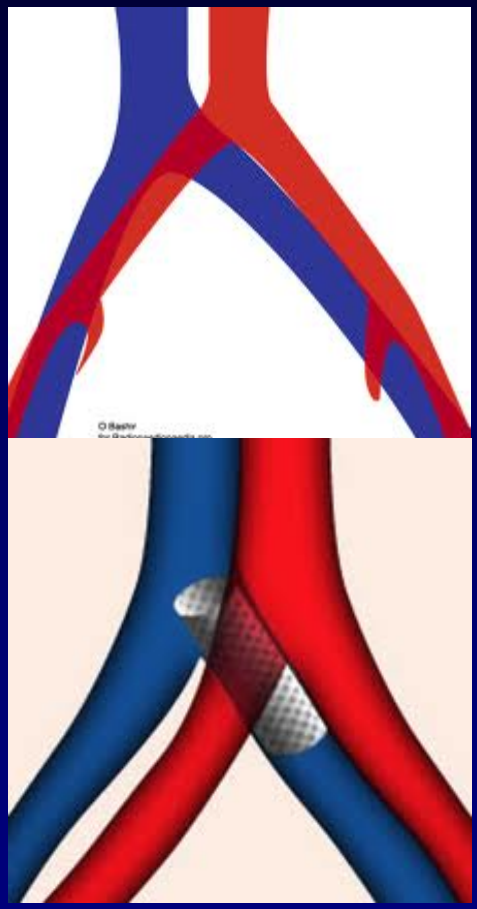
- Standing
  - Pitting edema – origin may not be venous disease
  - Compressibility differences between normal (soft) veins and varices (springy)
  - Cords – indicate thrombotic vessels
  - Lipodermatosclerosis

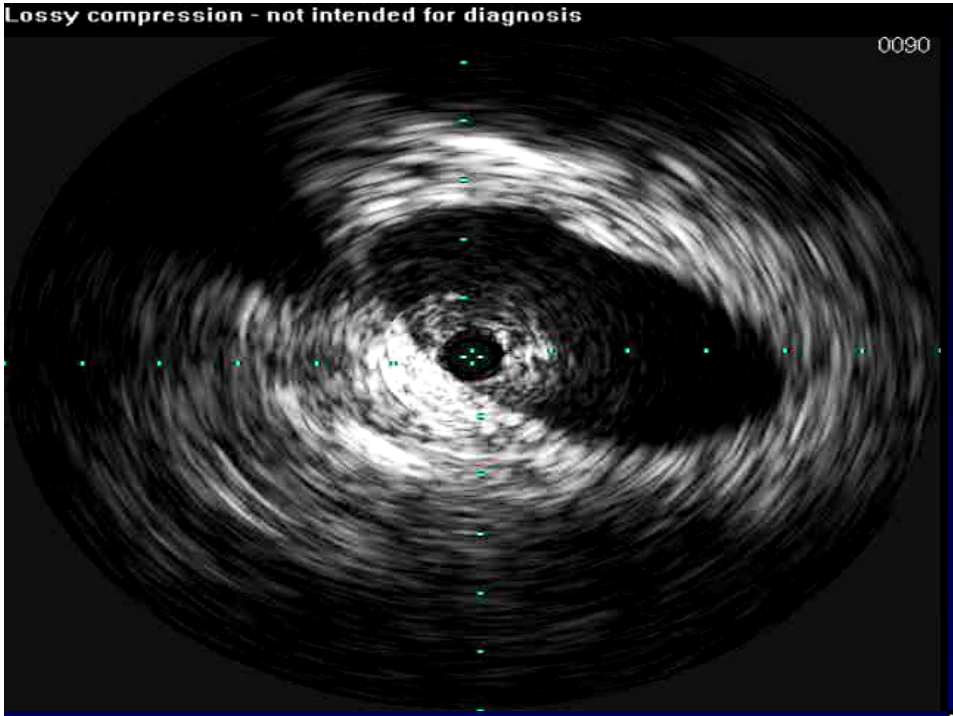
Physical Exam: Palpation

- Supine
  - Allows thorough inspection of feet and ankle
  - Palpate pulses, measure ABI if PVD suspected
  - Note areas with discrete swellings
    - Inguinal/femoral adenopathy

Left leg unilateral swelling

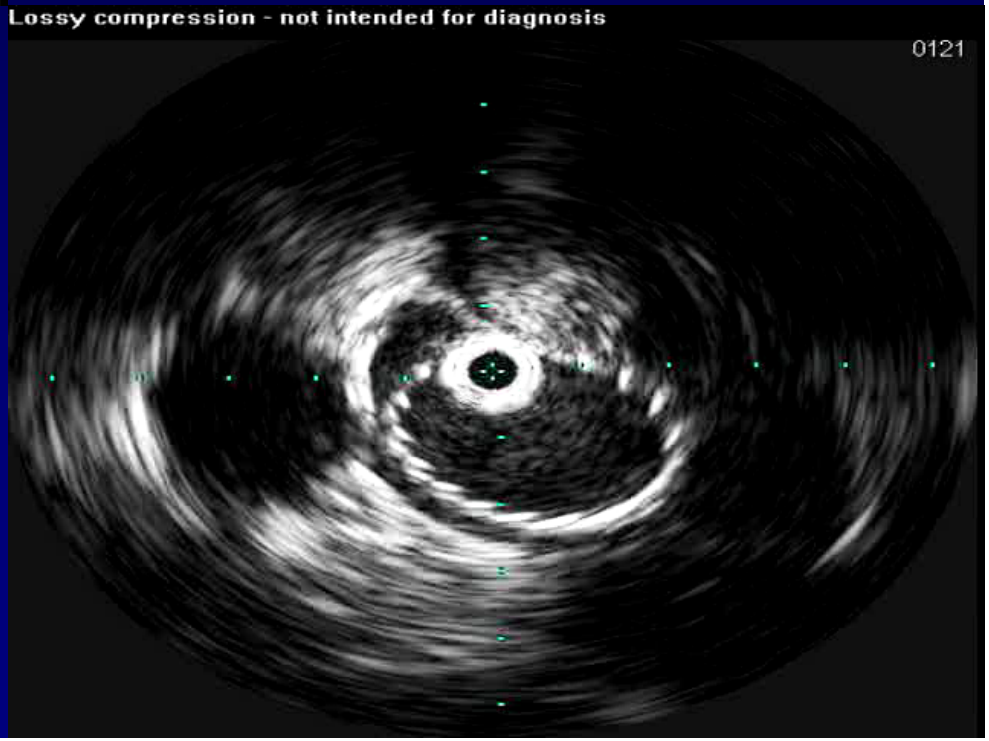
- May-Thurner Syndrome





Prestenting

Poststenting



Manifestations of Venous Insufficiency

Superficial venous reflux is progressive and if left untreated, may worsen over time.
Below are manifestations of the disease.

Varicose Veins	Swollen Legs	Skin Changes	Skin Ulcers
			
20+ million	2 to 6 million		500,000

CEAP Classifications
"snap shot of CVI"

Clinical Classifications of Venous Insufficiency (CEAP)

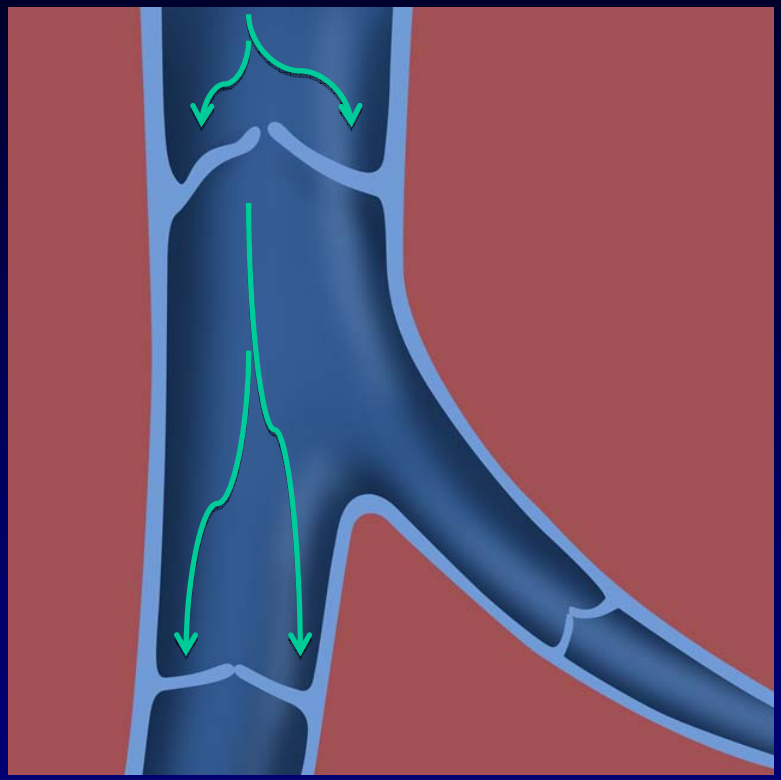
- Class 0 - No visible or palpable signs of venous disease
- Class 1 - Telangiectasias or reticular veins
- Class 2 - Varicose veins
- Class 3 - Edema
- Class 4 - Skin changes
    - (4a) Skin changes including pigmentation or venous eczema
    - (4b) Skin changes with lipodermatosclerosis
- Class 5 - Healed venous ulceration
- Class 6 - Active venous ulceration

Quantitative Scoring

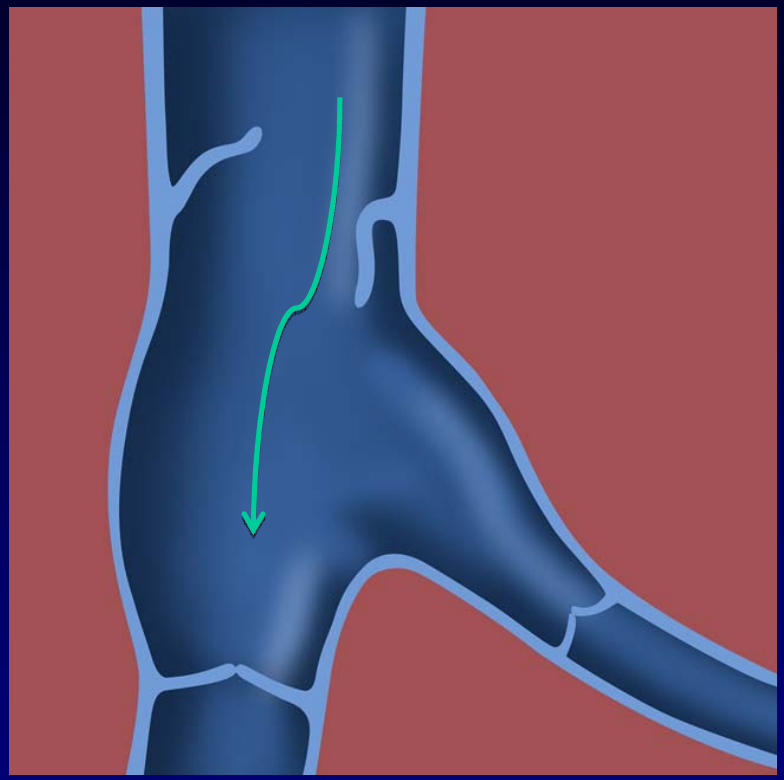
- Reflux
  - Venous Clinical Severity Score (VCSS)
  - Venous Disability Score (VDS)
  - Venous Segmental Disease Score (VSDS)
- Post Thrombotic Syndrome (PTS)
  - Villalte Score
- QOL scores
  - Chronic Venous Insufficiency QOL score (CVIQ)
  - VEINES-QOL questionnaire (acute and chronic)

Venous Pathophysiology

Valve Incompetence

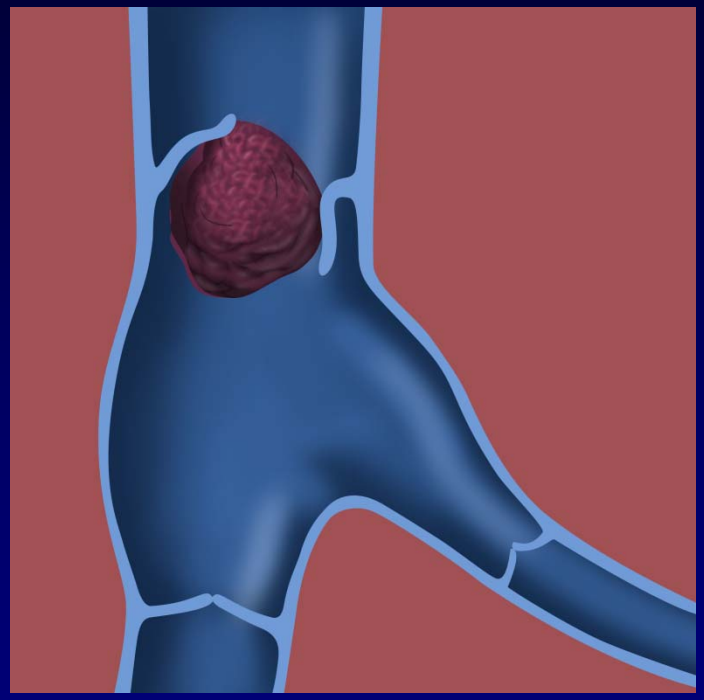


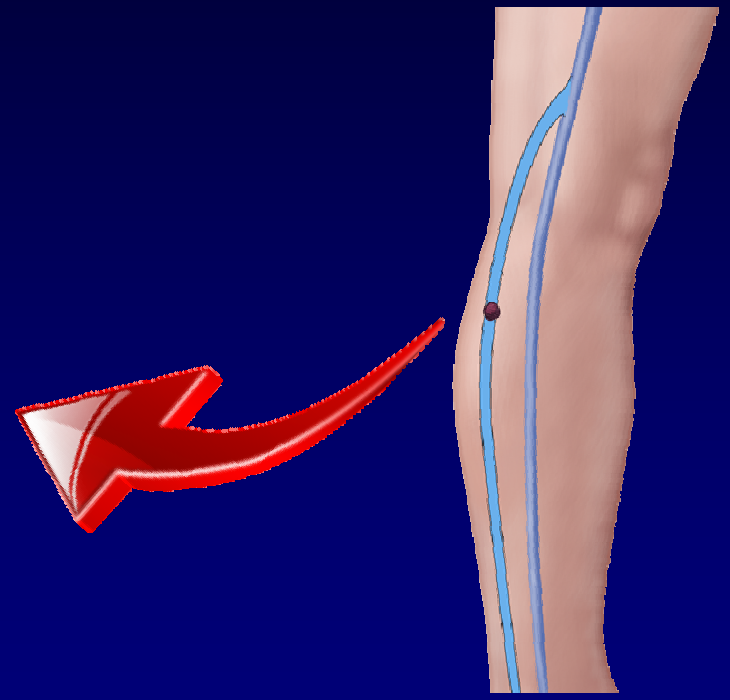
Normal Vein



Varicose Vein

Venous Obstruction





Thrombosis

Treatment Options

Conservative Therapies:

- Exercise
- Leg elevation
- Compression Stockings
- Unna Boot Bandage

These therapies treat the <u>symptoms</u>, not the ***<u>underlying cause</u>****…*

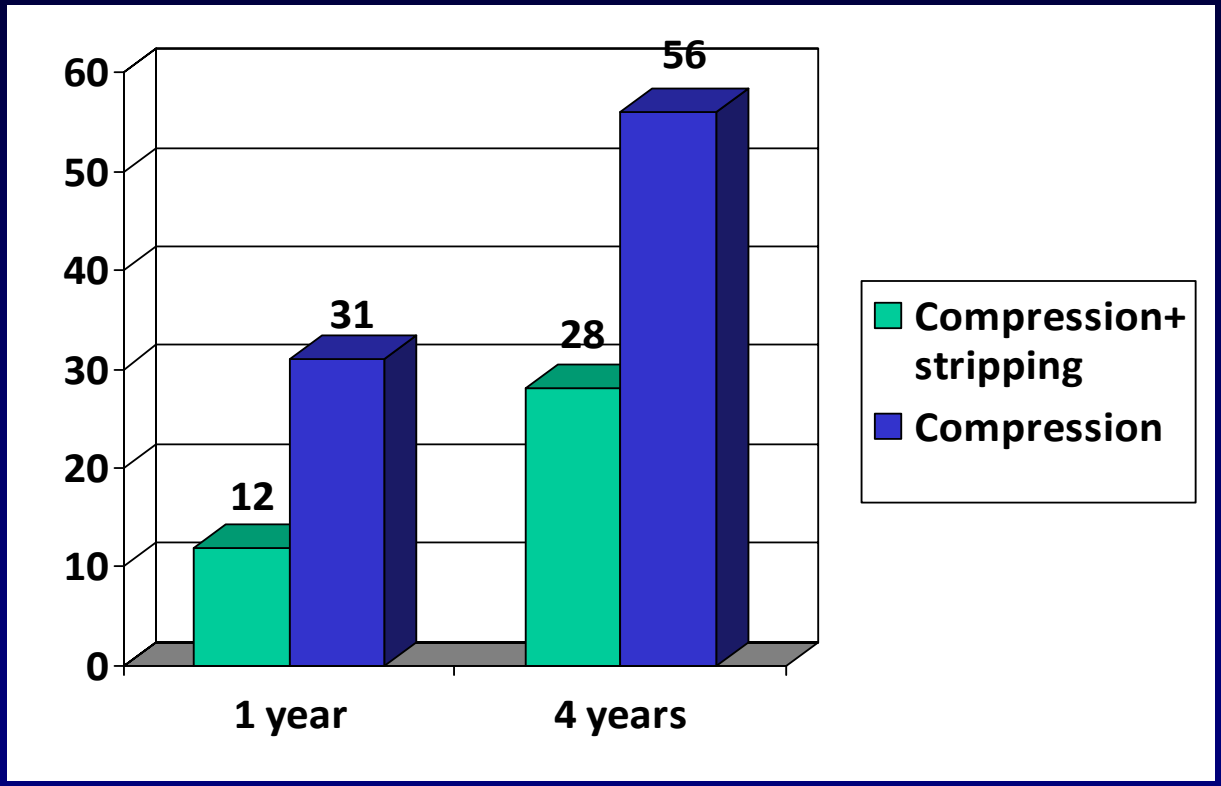
Conservative treatment

Mean healing time is 5.3 months

40% heal by 3 weeks

70% heal eventually

Venous Ulcer Recurrence (ESCHAR RCT)



Gloviczki et al. J Vasc Surg 1997; 25:94-105

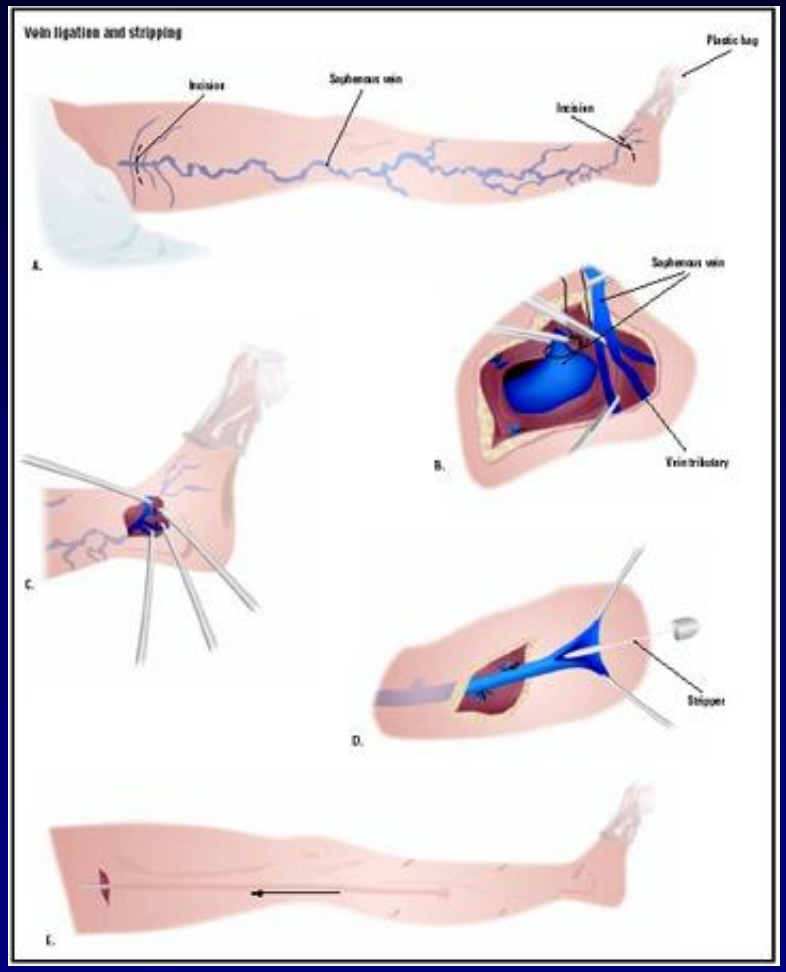
Consensus Guidelines

- American Venous Forum
  - We recommend superficial venous surgery to decrease ulcer recurrence in patients with superficial venous reflux
- American College of Phlebology
  - Endovenous thermal ablation is the new standard of care
- Wound Healing Society
  - “Superficial venous ablation …can be useful in decreasing the recurrence of venous leg ulcers”

Treatment Options (continued)

Surgical Treatments:

- Vein Stripping & Ligation



Treatment Options (continued)

Non-Surgical Treatments:

- Endovenous ablation
  - RF ablation
  - Laser ablation

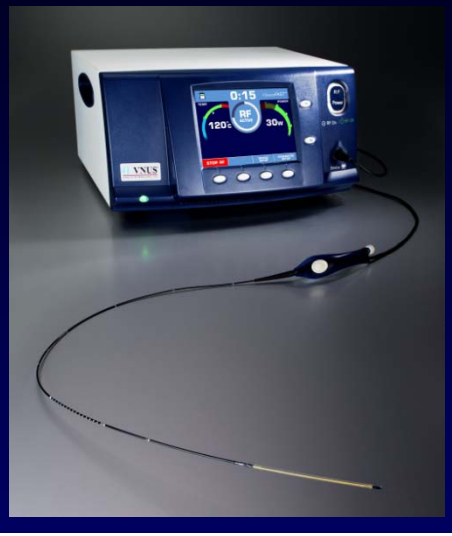
Ultrasound Diagnostic Study

- Required in order to determine the source of reflux
- Evaluate for venous occlusion or thrombus
- Map the course of the incompetent superficial veins

Venefit Targeted Endovascular therapy

(previously known asThe VNUS Closure™ Procedure)

- The Venefit Targeted Endovascular Therapy is a minimally invasive treatment alternative for patients with symptomatic superficial venous reflux and varicose veins
- Using a catheter-based approach, the VNUS RFG Plus™ generator delivers radiofrequency (RF) energy to the ClosureFAST™ catheter
- The catheter heats the vein wall and contracts the vein wall collagen, thereby occluding the vein



Disposable catheter inserted into vein

Vein heats and collapses

Catheter withdrawn, closing vein

Venefit Targeted Endovascular therapy

Systemic Reflux in Venous Ulceration

Photos courtesy of Steven A. Kaufman, MD.

Sources of Reflux in Venous Ulcer Patients[8]		
Superficial	Perforating	Deep
79%	63%	50%

Incompetent perforators found in 63% of venous ulcer patients

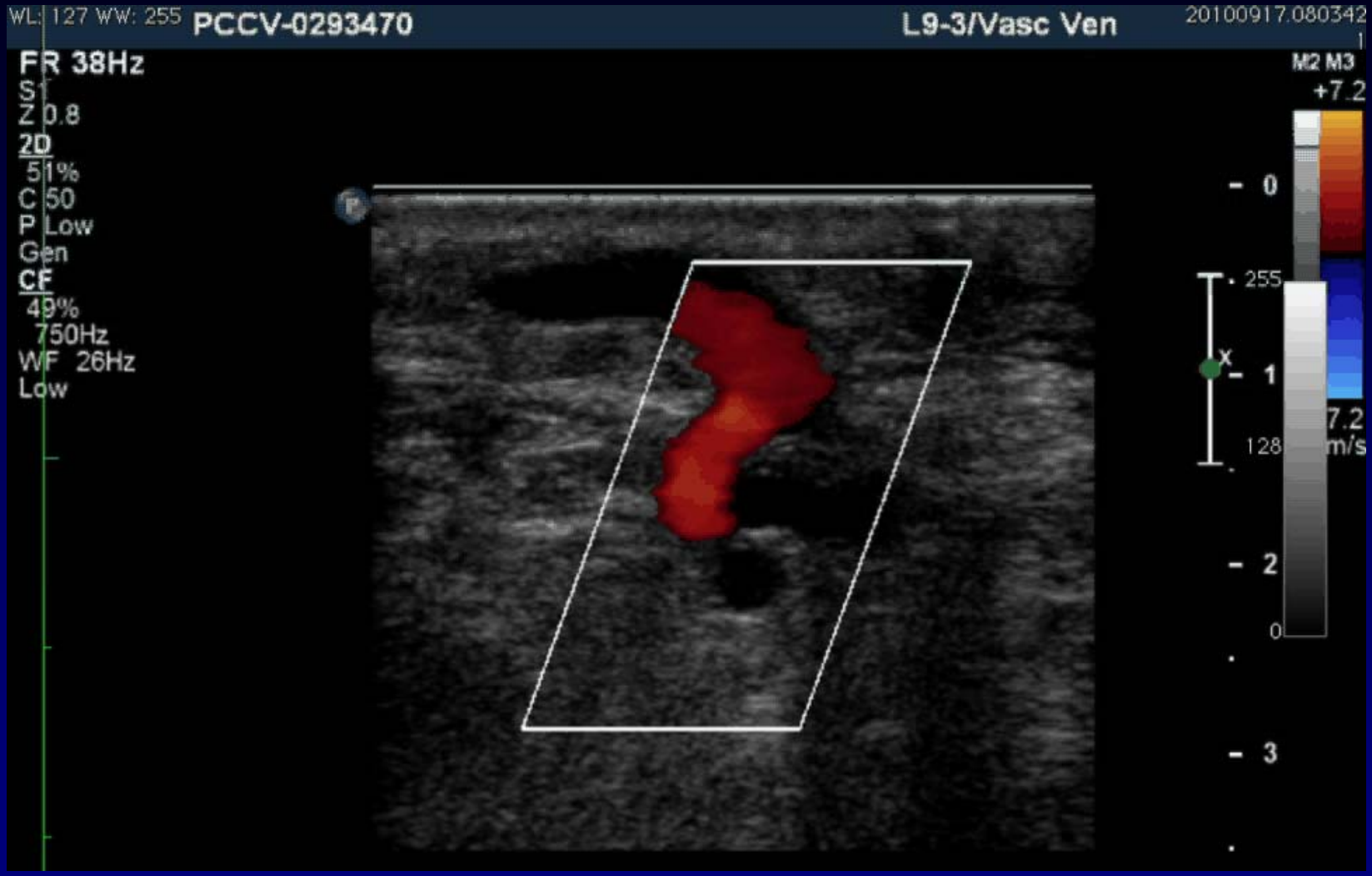
Comprehensive care treats all sources of reflux

Perforating Veins

Grade 2b recommendation to treat perforators:

- Pathologic = ≥3.5mm in size, outward flow ≥500 ms duration and located beneath chronic venous stasis skin changes/ulcer, CEAP 5 & 6

Gloviczki. P., Comerota, A.J., Dalsing, M.C., Eklof, Bo. G., Gillespie, D.L., Gloviczki, M, et al. (2011). *J Vasc Surg; 53, Number 16S, page 38S.*


WL: 127 WW: 255
PCCV-0293470
L9-3/Vasc Ven
20100917.080342
FR 38Hz
S1
Z 0.8
2D
51%
C 50
P Low
Gen
CF
49%
750Hz
WF 26Hz
Low
M2 M3
+7.2
0
255
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128
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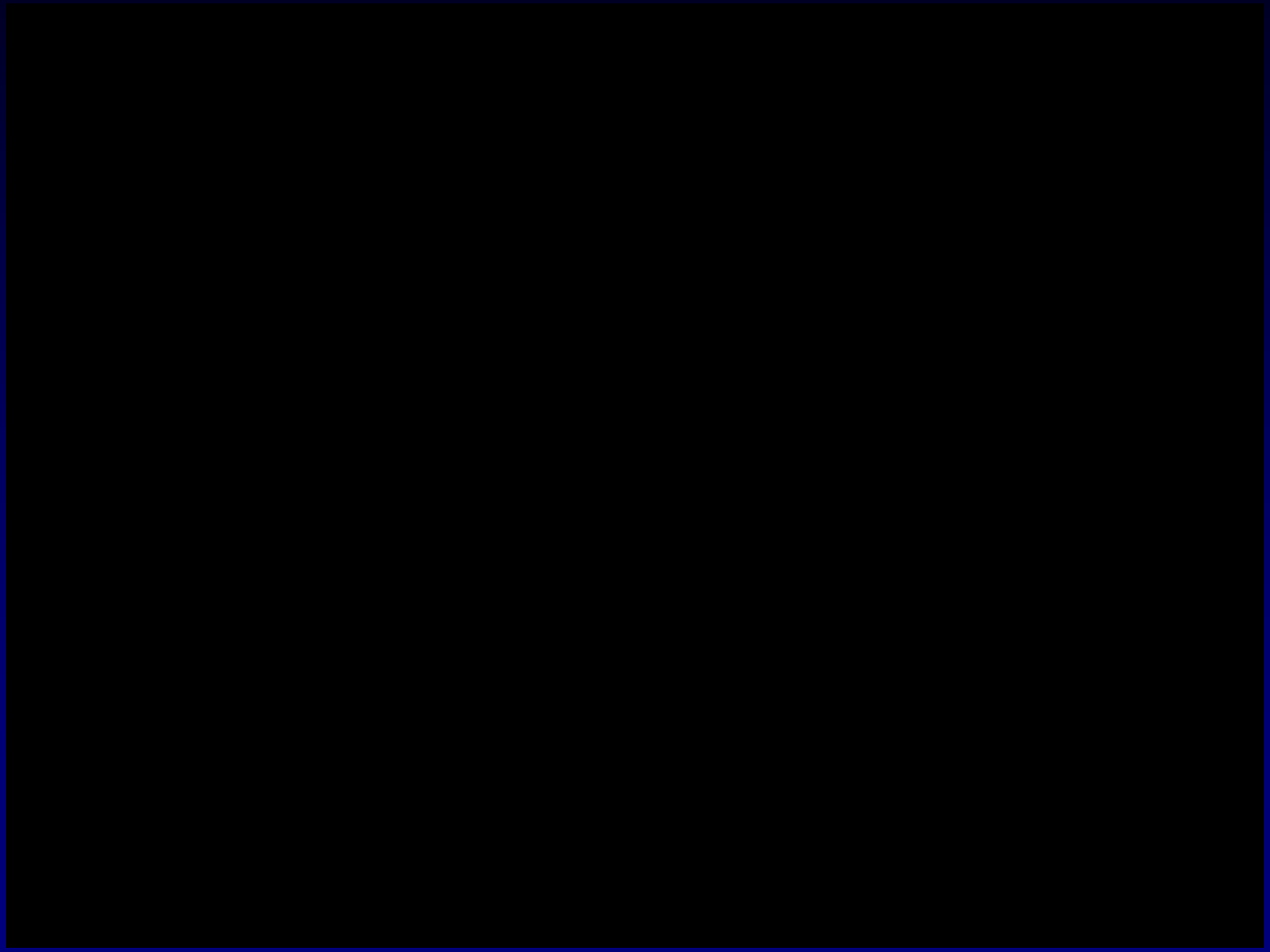
3
7.2
m/s

Perforator Vein Ablation



How does RF ablation works?

- Temperature controlled heating to the vessel wall
  - Endothelial destruction
  - Collagen contraction
  - New collagen synthesis
  - Further vein wall thickening
  - Eventual fibrotic sealing

Post-Procedure Instructions

- Ambulate frequently, a minimum of 30 minutes daily
- Avoid heavy/strenuous exercise for a few days
- Avoid prolonged sitting or standing
- Wear compression stockings for up to 2 weeks
- Patient should return for duplex scan within 72 hours

Venefit Targeted Endovascular therapy

Pre-treatment

One week post-treatment*

*Individual results may vary

RECOVERY Trial[7]

A Prospective, Multi-Center, Randomized Study

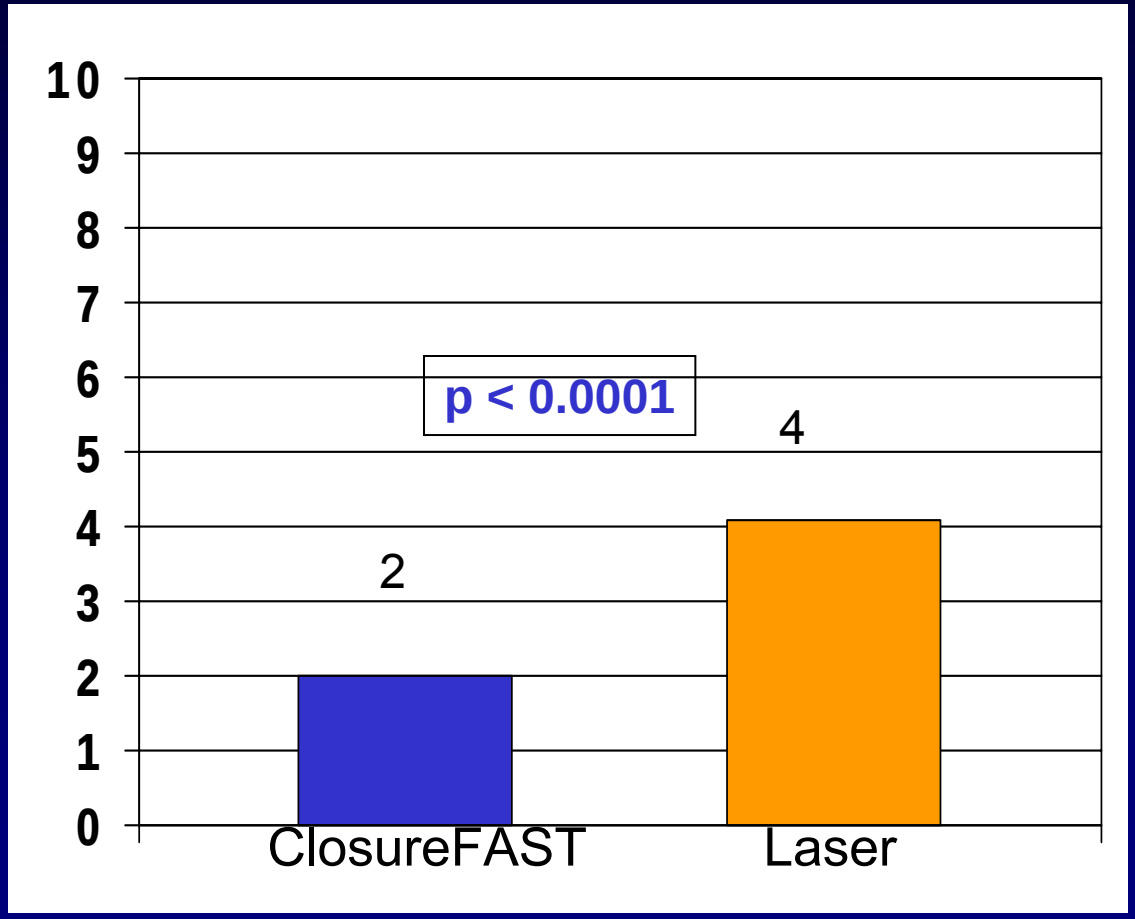
Purpose - Determine if patient recovery and other short term outcomes are different between radiofrequency and laser treatment

- Six center, single-blinded randomized trial of ClosureFAST vs. Endovenous Laser
- 69 patients; 87 limbs treated (46 CLF; 41 EVL)
- Patient follow up at 2, 7, 14, and 30 days after treatment

RECOVERY Trial: Pain

A Prospective, Multi-Center, Randomized Study

Overall Maximum Pain Score (0 none to 10 max)

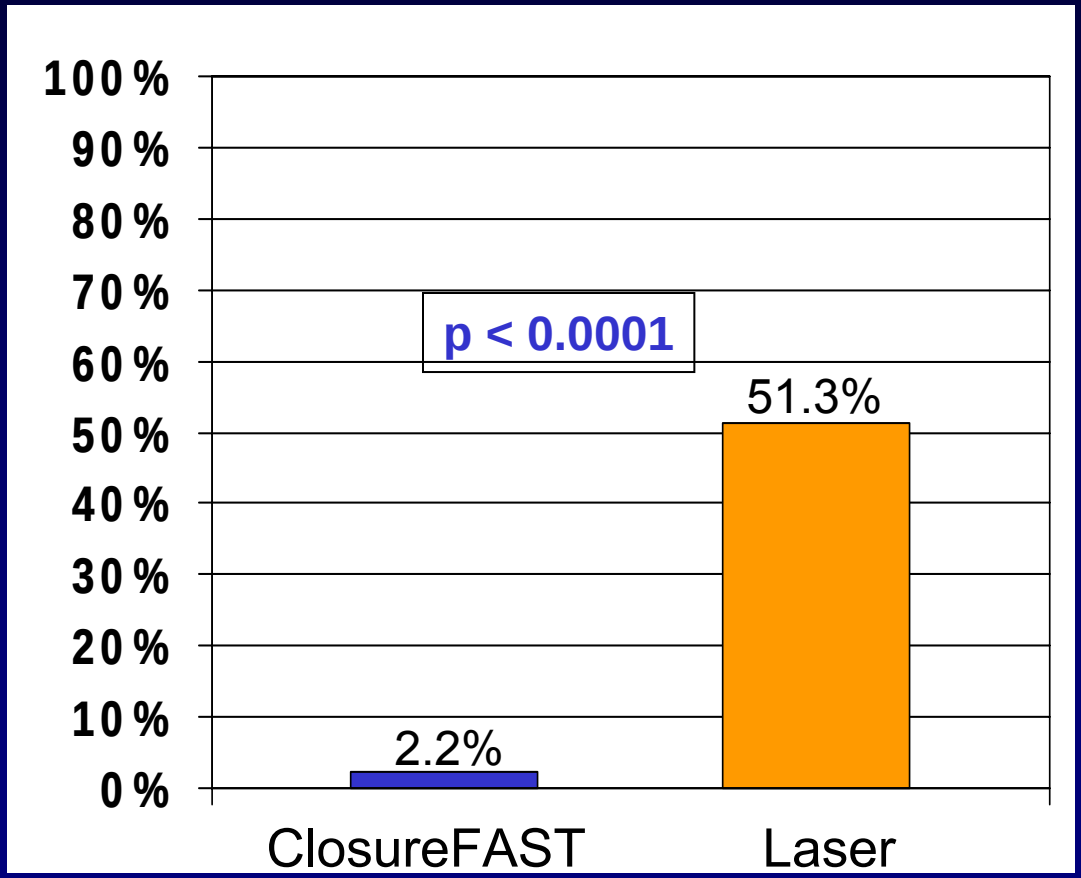


RECOVERY Trial: Ecchymosis

A Prospective, Multi-Center, Randomized Study

Moderate to Severe Ecchymosis (Bruising) After Treatment

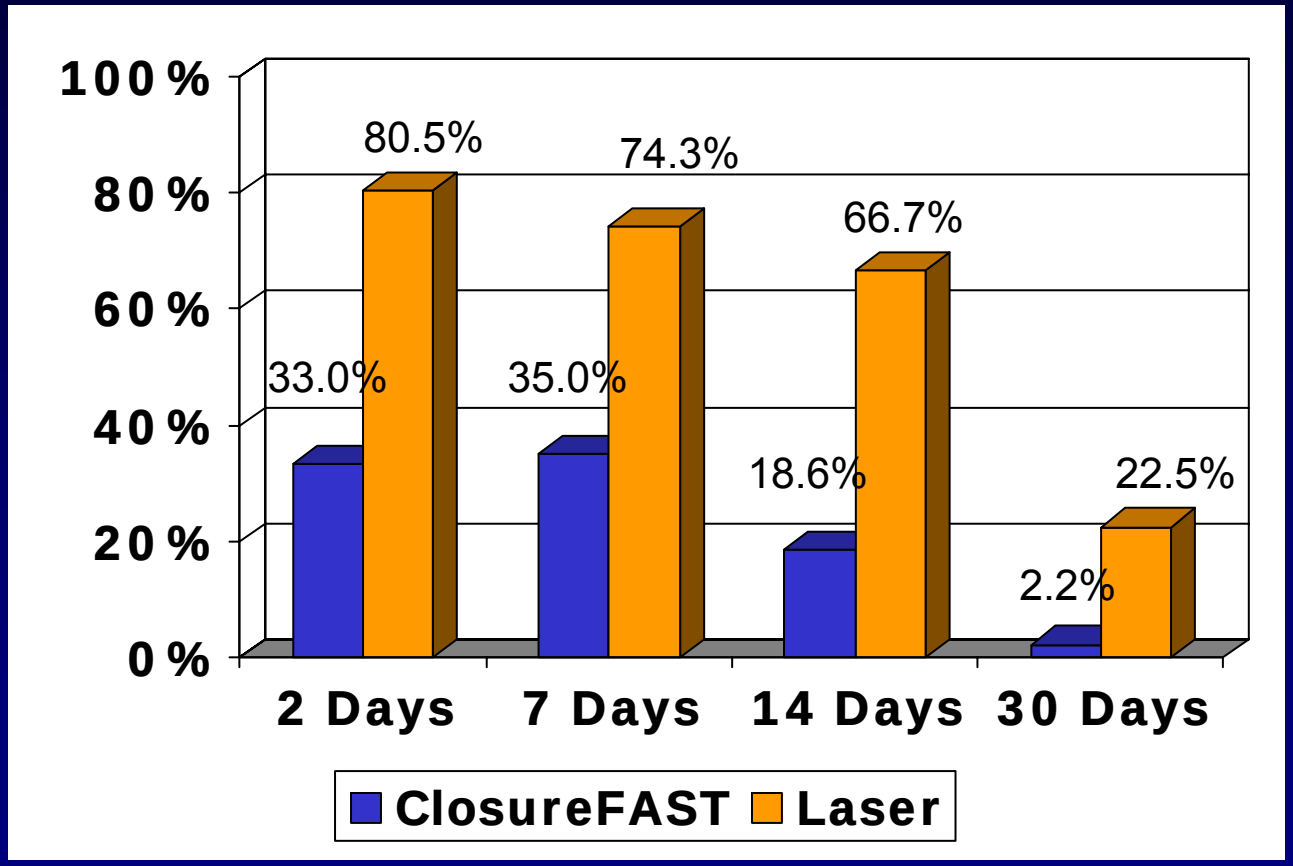
Moderate to severe ecchymosis is defined as bruising over greater than 25% of the treated surface area



RECOVERY Trial: Ecchymosis

A Prospective, Multi-Center, Randomized Study

Presence of Any Ecchymosis (Post Procedure)



RECOVERY Trial: Conclusion

A Prospective, Multi-Center, Randomized Study

Compared to laser, RF treatment with ClosureFAST produced significantly

- Less pain $p < 0.0001$
- Less tenderness $p = 0.0008$
- Less bruising $p < 0.0001$
- Fewer adverse events $p = 0.021$

THANK YOU