Venous leg ulcers

Treat the source,

not just the symptom

Topics

- What causes venous ulcers (VU)
- Treating the source, not just the symptom
- Diagnosis with venous duplex ultrasound scan
- Treatment with the VNUS Closure® procedure
- Reimbursement
- Getting started

Chronic Venous Insufficiency (CVI)

A Serious Progressive Condition

Varicose Veins

CEAP 2

Leg Swelling

Skin Damage

CEAP 3 & 4

Skin Ulcers

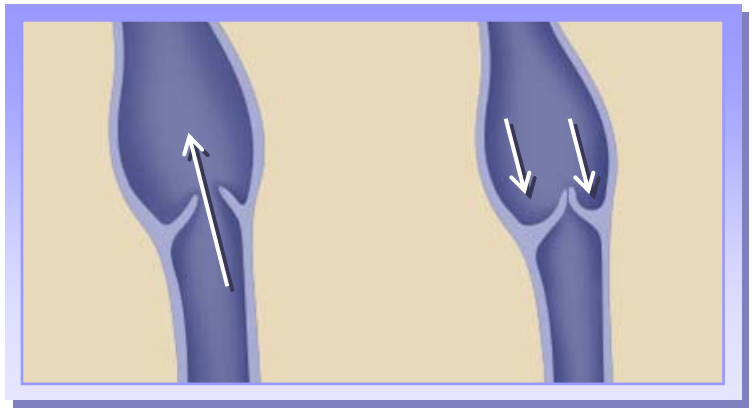
CEAP 6

Increased pain, reduced quality of life

CVI Cause

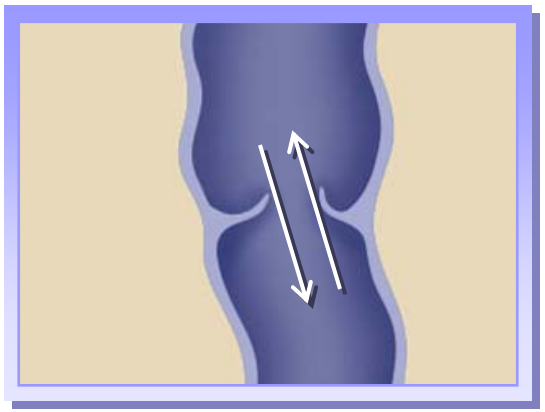
Vein wall dilation and valve dysfunction allow blood to reflux, causing hypertension

Normal Vein



Valve Open **Valve Closed**

Dilated Vein

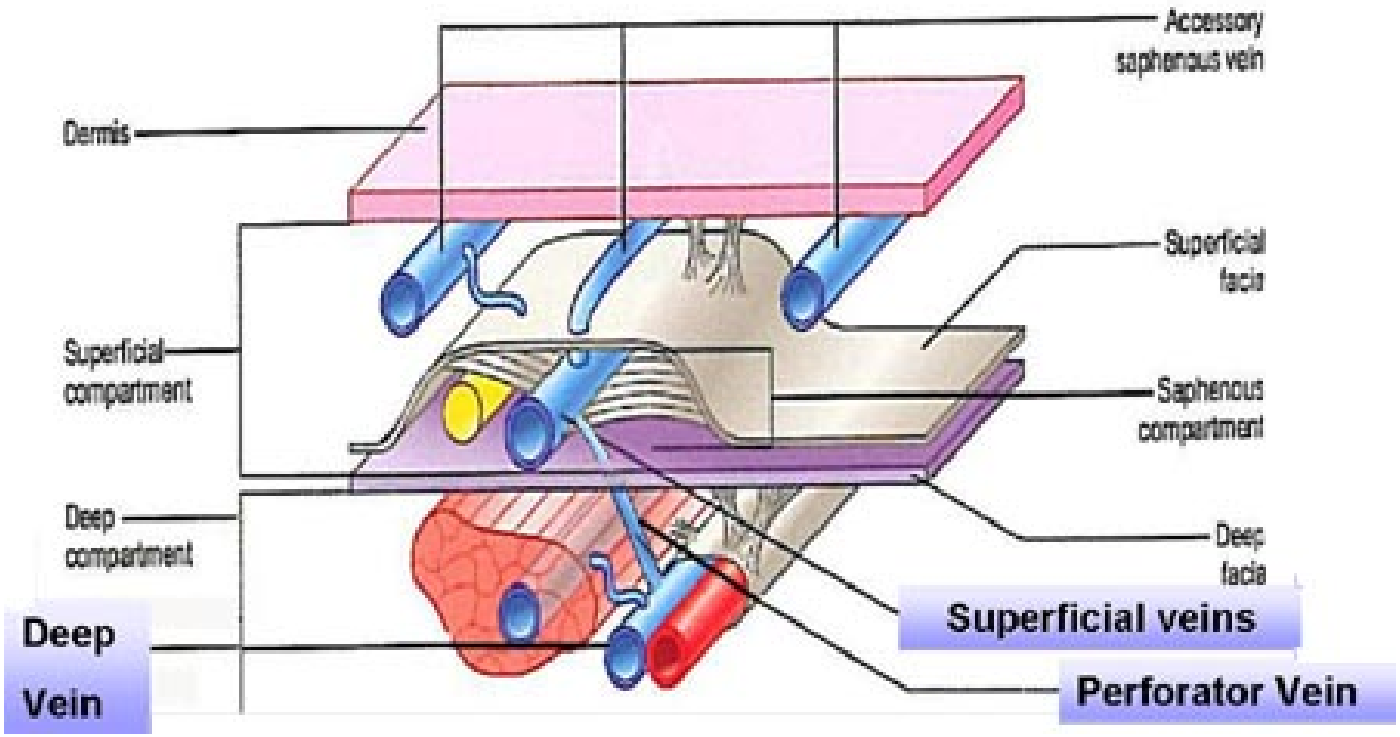


Incompetent Valve

- One-way valves direct venous blood upward
- Hypertension can be 3x normal at ankle when standing

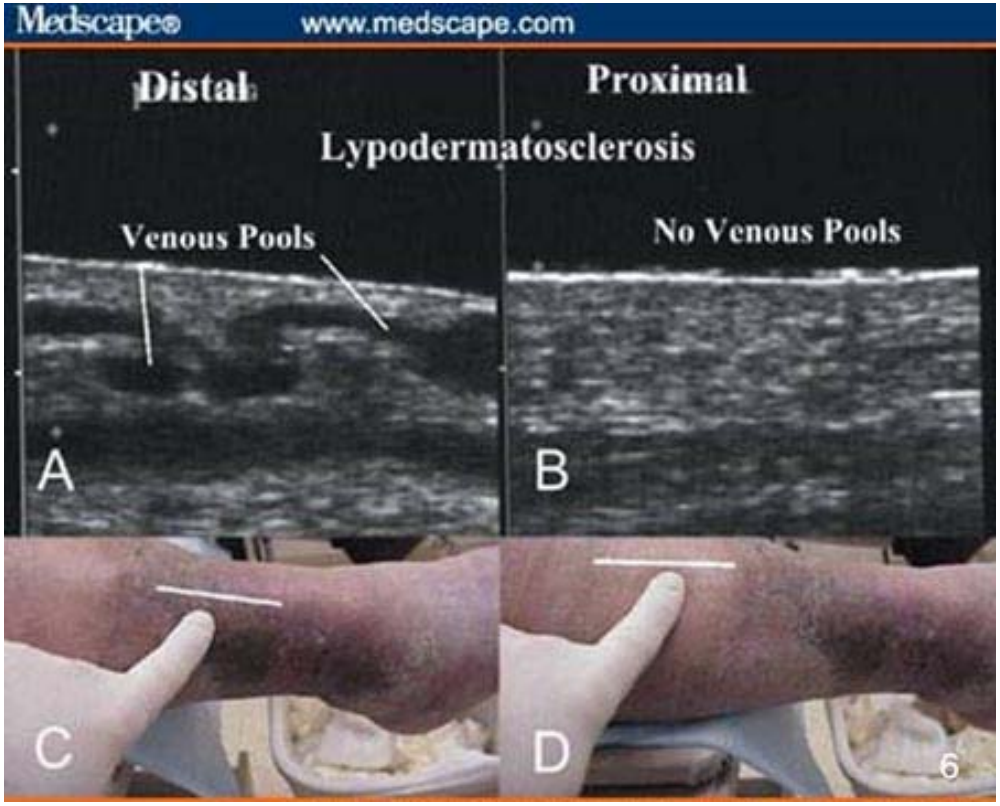
Source & Prevalence of VU Reflux

- Superficial (79%), Perforating (63%), Deep (49.5%)[1]

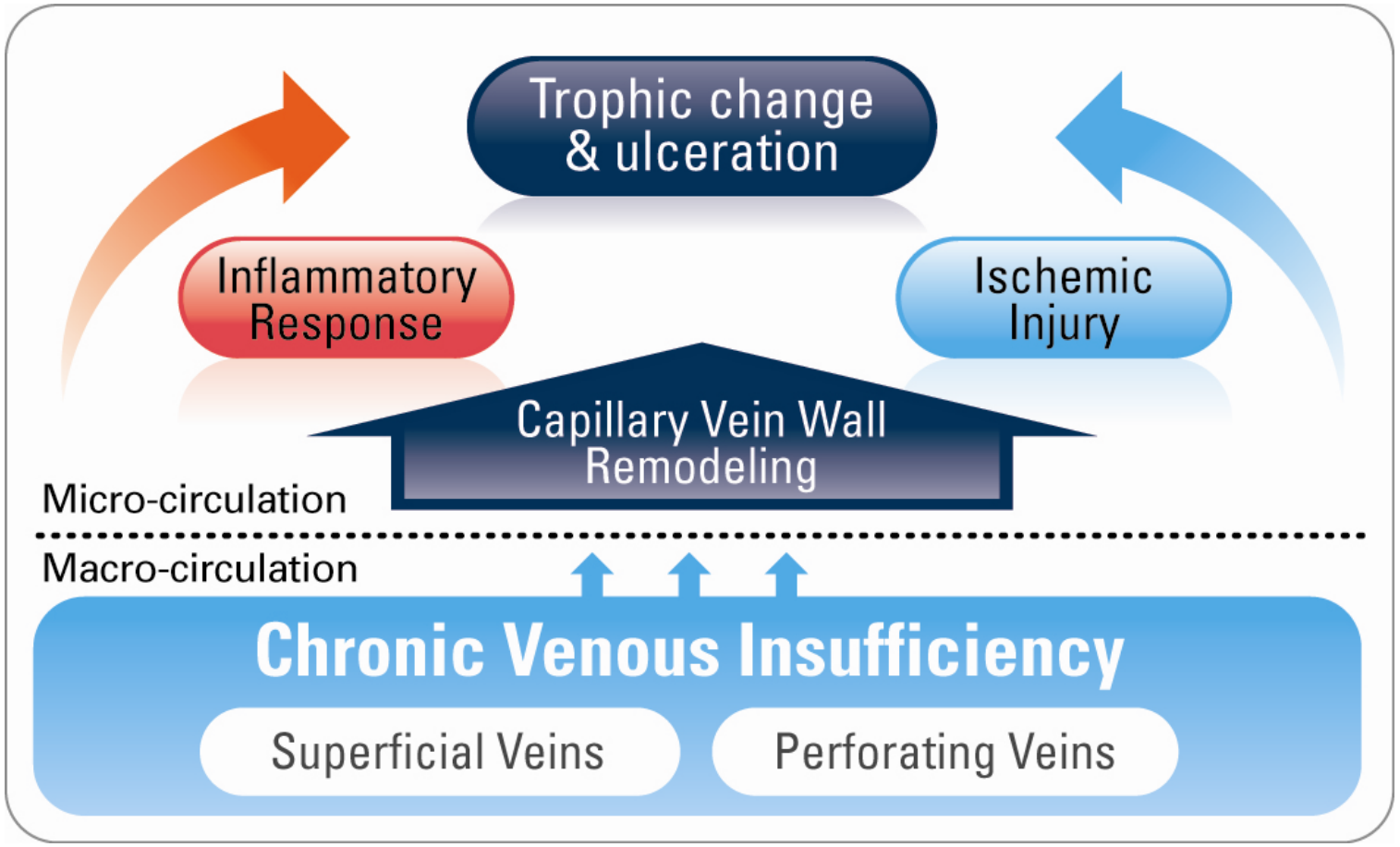


Tissue Changes Beneath Wound

- Ultrasound images (A, B):
  - Pathologic (C) vs.
  - Non-pathologic (D) areas



The Reason for the Lesion



Chronic hypertension in the macro-circulation cause micro-circulatory inflammatory and ischemic injury leading to VU

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Treating the Source of Venous Ulcers

Not Just the Symptoms

Epidemiology of Venous Ulcers

	% Total Population	Affected US Population
Active or Healed VU	0.8%[1]	2.5 Million[1*]
Prevalence	0.29%[1]	870K[1*]
Incidence (1st time ulcer)	18 per[2] 100,000	172K[2*]

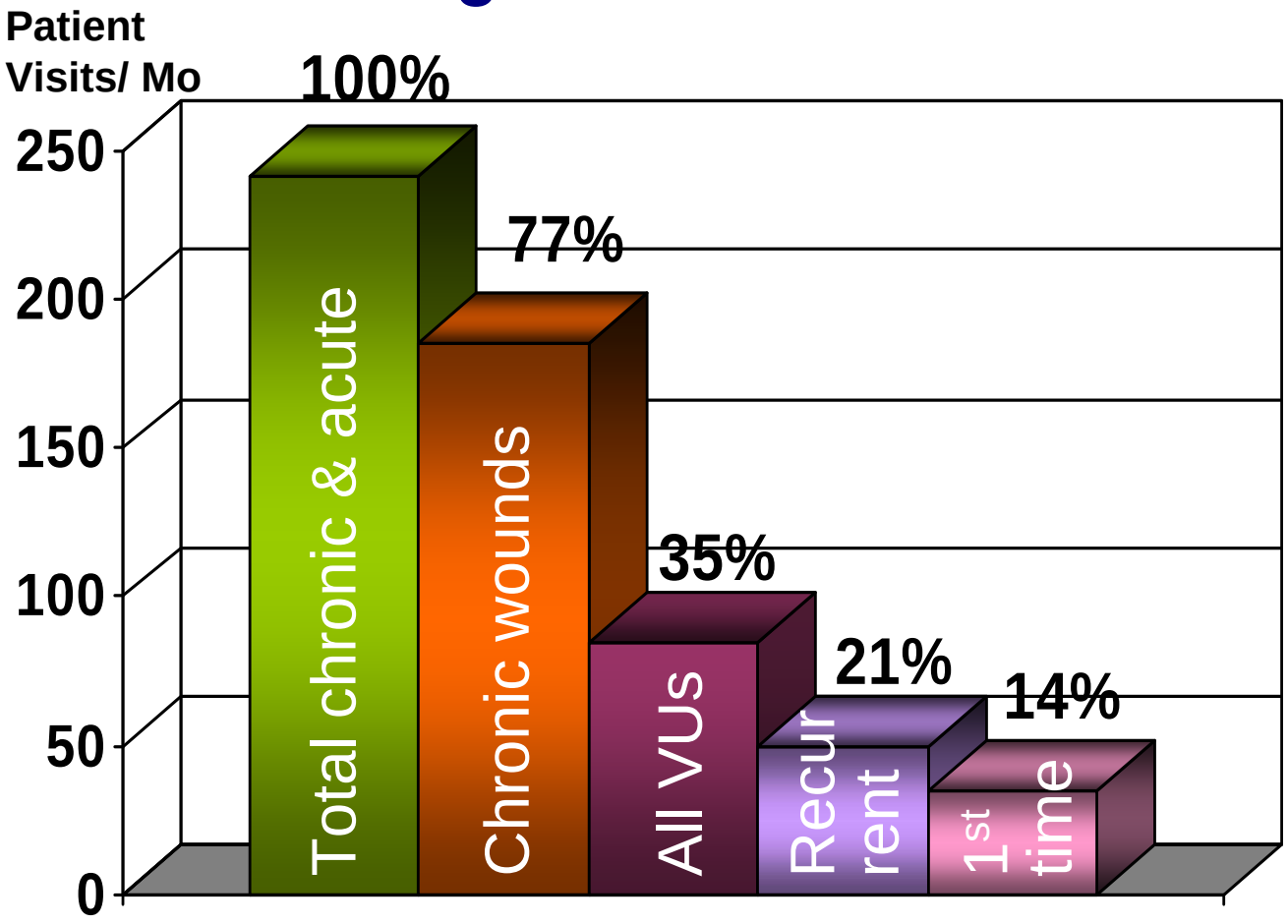
Aggressive vein surgery resulted in 46% reduction of VU prevalence from 0.16% in 1988 to 0.09% in Sweden[3]

*Data extrapolated from source

US Wound Care Center (WCC) Patients

- VU is largest patient segment
- VU as % all leg ulcers[1]
  - 50% below knee
  - 70% excluding foot

Average WCC Patient Mix[2]



Current WCC treatment methods

- Conservative treatment is standard of care, even for recurrent or non-healing VUs

Leg Elevation

Unna Boot

Compression Stockings

Apligraf®

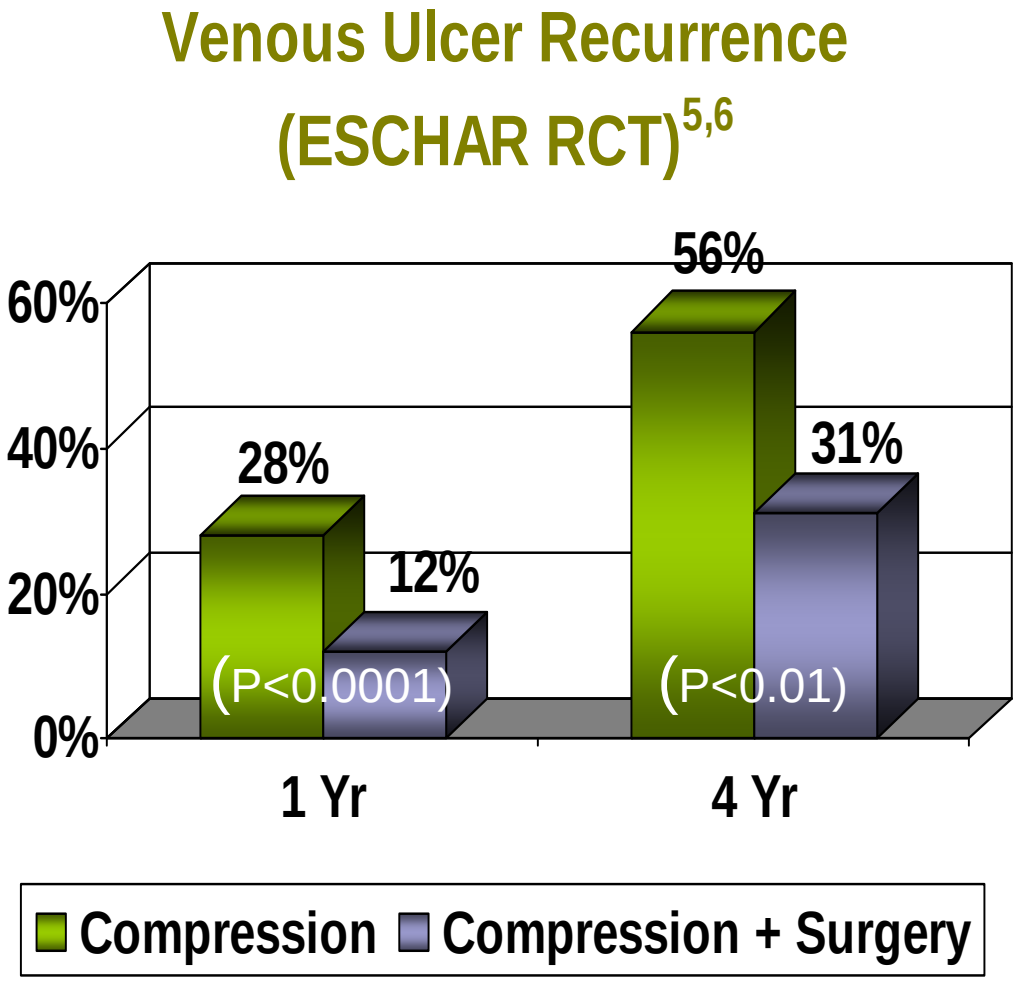
Compression & wound care treat the symptom, not the underlying cause of venous ulcers

Benefits of Conservative Treatment

- Successful at healing VU
  - Mean healing time 5.3 months[3]
  - 40% heal by 3 weeks, 70% heal eventually[4]

Limitations of Conservative Treatment

- Compression + surgery (vein stripping) more effective than compression alone



Benefits of Surgically Correcting CVI

- Reduce recurrence
  - 4 year recurrence rate 56% compression group, 31% compression plus surgery (P<0.01)[6]
  - 3 and 5 year recurrence with perforator surgery 8% and 18% respectively[7]
- Faster healing
  - Median heal time: 63 day compression group, 31 days surgical group, (P<.005)[8]
- Improve quality of life
  - SFJ 36 questionnaire: surgical group better than compression group (P<.05)[8]

Consensus Guidelines

Wound Healing Society

- “superficial venous ablation … can be useful in decreasing the recurrence of venous leg ulcers”[9]

American Venous Forum

- “We recommend superficial venous surgery to decrease ulcer recurrence in patients with superficial venous reflux”[10]

American College of PHLEBOLOGY

- “Endovenous thermal ablation is the new standard of care”[11]

References

Image Source

1. Images courtesy of R. Basile, MD
2. Family Health Media: www.famil...media.com/VLU.htm

Citation

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Treatment Options

VU Treatment Options

Conservative therapy

- Compression
- Wound dressing
- Leg elevation
- Exercise

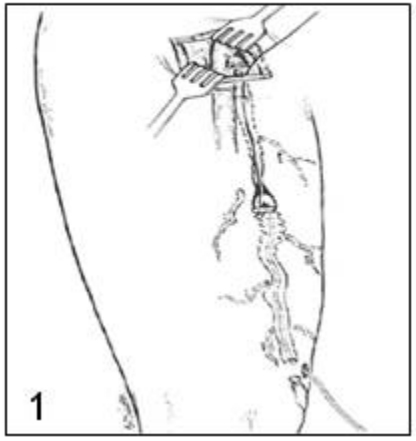
Surgical interventions

- Vein stripping
- SEPS
- VNUS Closure® RF Ablation
- Ultrasound guided sclerotherapy
- Linton procedure
- Deep vein reconstruction

Historical Perspective

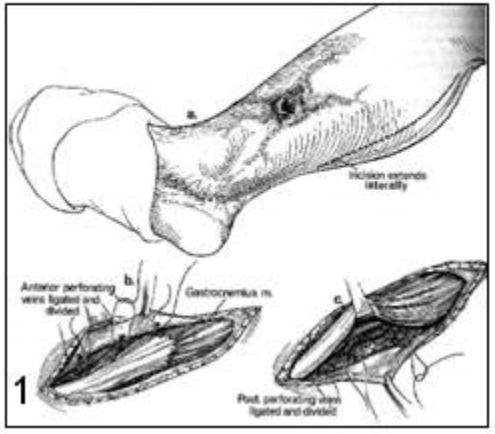
- Little importance on venous disease
  - Traditional treatment: high morbidity
  - Surgeon attitude: surgery last resort
    - Not inclined to perform

Stripping



SEPS

Linton

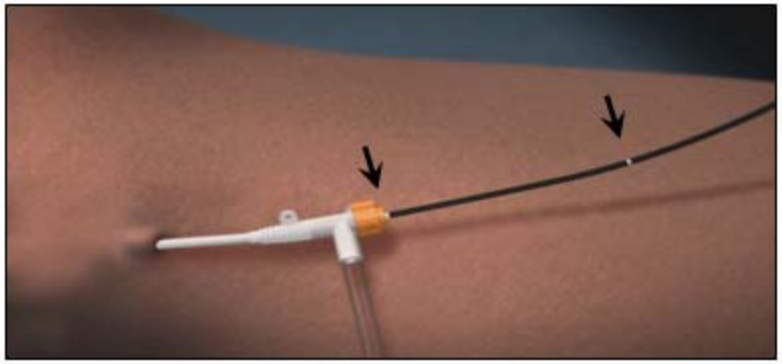


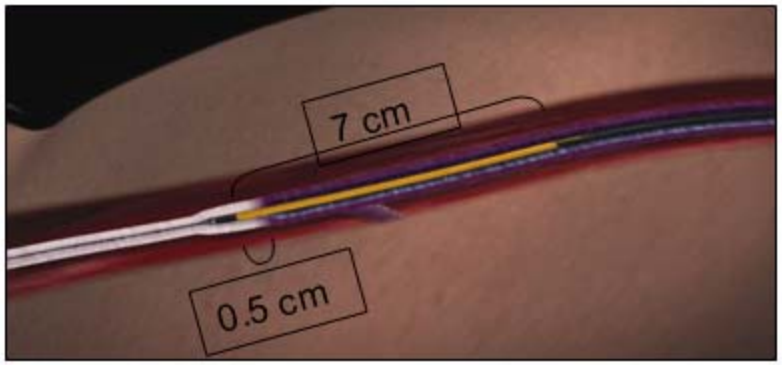
The VNUS Closure® Procedure

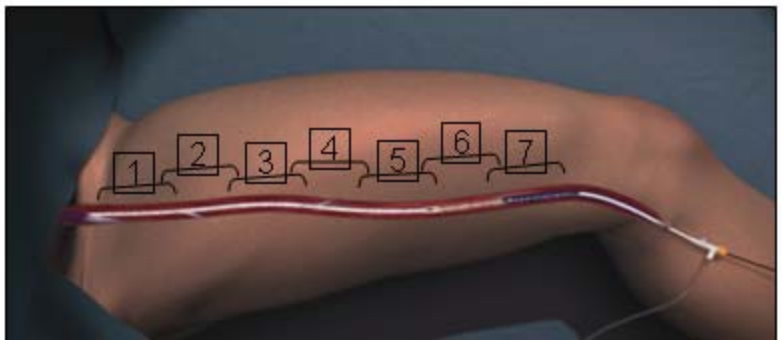
- Minimally invasive alternative to traditional surgery
  - Faster recovery[1-3]
  - Fewer complications[3-6]
  - High efficacy[3,7-9]

Closure*FAST*™ *Catheter*
for superficial system reflux

- Percutaneous access under ultrasound guidance
- Stationary, temperature controlled 20 second heating cycles
- Stepwise treatment cycles along length of vein in 3 to 5 minutes





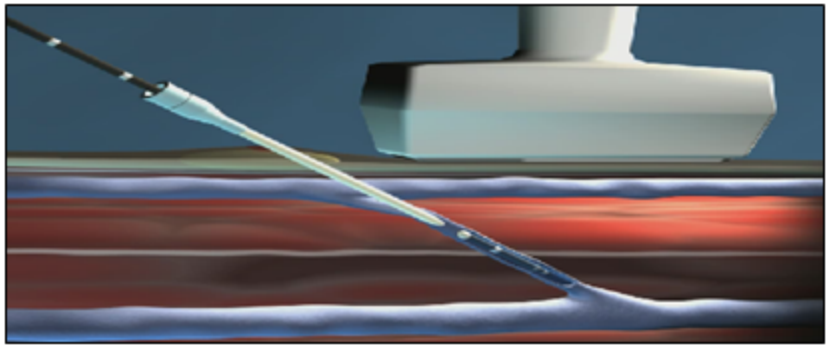


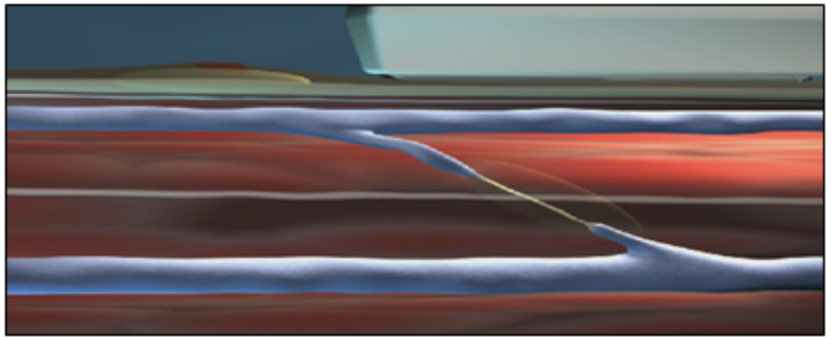
Closure*RFS*™ Stylet
for perforating vein reflux

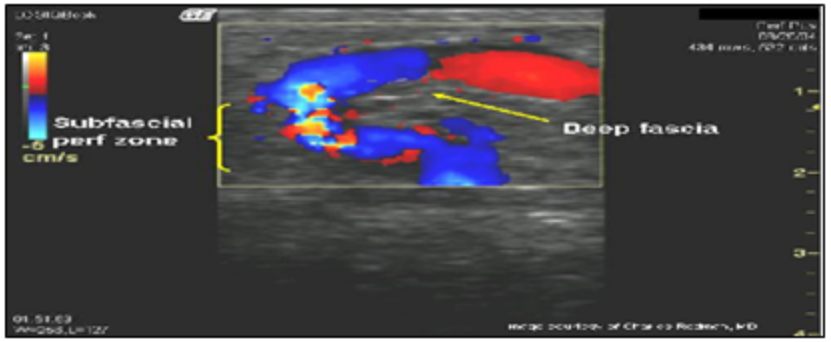
- Percutaneous access under ultrasound guidance

- Temperature controlled 90°C heating at or below deep fascia

- Only endovenous ablation method specifically cleared by FDA to treat incompetent perforator veins







Indication, Contraindications, and Potential Complications

VNUS Closure*FAST* catheter

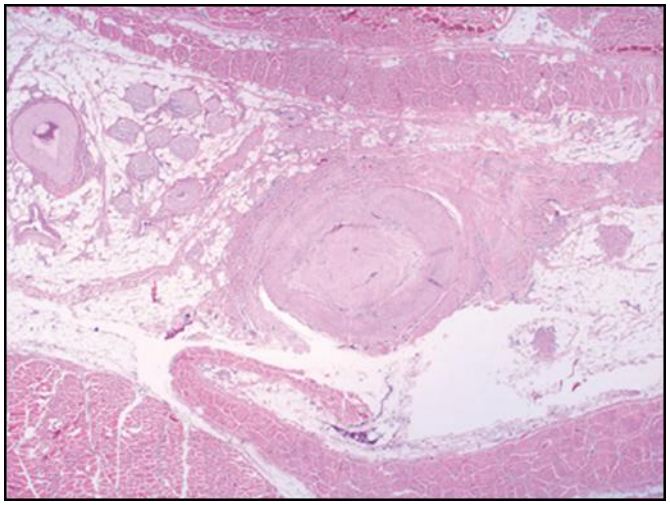
- **Indication:** The Closure*FAST* ™ catheter is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux.
- **Contraindications:** Patients with thrombus in the vein segment to be treated.
- **Potential Complications:** include, but are not limited to: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, adjacent nerve injury, skin burns, and deep vein thrombosis.

VNUS Closure*RFS* stylet

- **Indication:** The VNUS ClosureRFS stylet is intended for use in vessel and tissue coagulation including: Treatment of incompetent (i.e., refluxing) perforator and tributary veins.
- **Contraindications:** Patients with thrombus in the vein segment to be treated.
- **Potential Complications:** include, but are not limited to: arteriovenous fistula, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, nerve damage, and skin burns.

Closure Method of Action

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



Closure*FAST* Catheter
histology at 12 weeks

Collagen triple helix molecule

Closure Procedure Efficacy and Complications

- **Closure*FAST*** 97.4% occlusion @ 1 year[7]

- **Closure*RFS*:** 80% to 90% success @ 1 year[10]

Closure*FAST* Complications[7]	**N=396**
Ecchymosis	21 (5.3%)
Paresthesia	16 (4.0%)
Skin Pigmentation	10 (2.5%)
Erythema	9 (2.3%)
Thrombus Extension / DVT	7 (1.8%)
Phlebitis	6 (1.5%)
Hematoma	4 (1.0%)
Thermal Skin Injury	0 (0.0%)
Pulmonary Embolism	0 (0.0%)

Closure Procedure Benefits

- Office/outpatient procedure
- Minimally invasive
- Can be performed under local anesthesia
- Return to normal activities next day
- High efficacy rate

Reduce Recurrence, Improve Quality of Life

- Compress the wound and treat the disease
  - High ulcer recurrence rates with compression alone
  - Surgical intervention significantly reduces ulcer recurrence[11,12]

- Improve quality of life
  - Quality of life significantly improves by treating the venous disease over compression therapy alone[13]

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Image sources

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2. Image courtesy of Dr. Steven Elias, MD

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