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

Leg Swelling

Skin Damage

Skin Ulcers

CEAP 2

CEAP 3 & 4

CEAP 6

Increased pain, reduced quality of life
CVI Cause

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

- 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%)\textsuperscript{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.
References

**Image sources**
1. Paul McNeill, MD
2. Rajabrata Sarkar, MD
3. missinglink.ucsf.edu/.../stasis_dermatitis.html

**Citations**
Treating the Source of Venous Ulcers
Not Just the Symptoms
Epidemiology of Venous Ulcers

<table>
<thead>
<tr>
<th></th>
<th>% Total Population</th>
<th>Affected US Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active or Healed VU</td>
<td>0.8%(^1)</td>
<td>2.5 Million(^1*)</td>
</tr>
<tr>
<td>Prevalence</td>
<td>0.29%(^1)</td>
<td>870K(^1*)</td>
</tr>
<tr>
<td>Incidence (1(^{st}) time ulcer)</td>
<td>18 per(^2)</td>
<td>172K(^2*)</td>
</tr>
</tbody>
</table>

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

**Average WCC Patient Mix**

- **VU is largest patient segment**
- **VU as % all leg ulcers**
  - 50% below knee
  - 70% excluding foot
Current WCC treatment methods

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

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

Apligraf is a registered trademark of Organogenesis Inc.
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

Venous Ulcer Recurrence (ESCHAR RCT)\textsuperscript{5,6}

<table>
<thead>
<tr>
<th></th>
<th>1 Yr</th>
<th>4 Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression</td>
<td>28%</td>
<td>56%</td>
</tr>
<tr>
<td>Compression + Surgery</td>
<td>12% (P&lt;0.001)</td>
<td>31% (P&lt;0.01)</td>
</tr>
</tbody>
</table>
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

- “superficial venous ablation … can be useful in decreasing the recurrence of venous leg ulcers”\textsuperscript{9}
- “We recommend superficial venous surgery to decrease ulcer recurrence in patients with superficial venous reflux”\textsuperscript{10}
- “Endovenous thermal ablation is the new standard of care”\textsuperscript{11}
References

Image Source
1. Images courtesy of R. Basile, MD
2. Family Health Media: www.familyhealthmedia.com/VLU.htm

Citation
4. Data on file from VNUS survey of wound care centers
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
The VNUS Closure® Procedure

- Minimally invasive alternative to traditional surgery
  - Faster recovery$^{1-3}$
  - Fewer complications$^{3-6}$
  - High efficacy$^{3,7-9}$
ClosureFAST™ 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
ClosureRFS™ 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 ClosureFAST catheter**
- **Indication:** The ClosureFAST™ 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 ClosureRFS 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

ClosureFAST Catheter histology at 12 weeks

Collagen triple helix molecule
Closure Procedure Efficacy and Complications

- **ClosureFAST**: 97.4% occlusion @ 1 year

<table>
<thead>
<tr>
<th>ClosureFAST Complications</th>
<th>N=396</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecchymosis</td>
<td>21 (5.3%)</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>16 (4.0%)</td>
</tr>
<tr>
<td>Skin Pigmentation</td>
<td>10 (2.5%)</td>
</tr>
<tr>
<td>Erythema</td>
<td>9 (2.3%)</td>
</tr>
<tr>
<td>Thrombus Extension / DVT</td>
<td>7 (1.8%)</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>6 (1.5%)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>4 (1.0%)</td>
</tr>
<tr>
<td>Thermal Skin Injury</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Pulmonary Embolism</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

- **ClosureRFS**: 80% to 90% success @ 1 year

ClosureFAST: 97.4% occlusion @ 1 year

ClosureRFS: 80% to 90% success @ 1 year
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\textsuperscript{11,12}

- Improve quality of life
  - Quality of life significantly improves by treating the venous disease over compression therapy alone\textsuperscript{13}
References

Image sources
2. Image courtesy of Dr. Steven Elias, MD

Citations
1. Lurie F., Creton D. et al. Prospective randomized study of endovenous radiofrequency obliteration (Closure procedure) versus ligation and stripping in a selected patient population (EVLVeS Study), JVS 2003; 38:220-214
7. Dietzek A, ClosureFAST is better than first generation radiofrequency ablation – a quantum leap forward, 34th Vein Symposium. Nov 2008 New York, NY
8. Jones L., Braithwaite B.D. et. al. Neovascularisation is the Principal Cause of Varicose Vein Recurrence : Results of a Randomised Trial of Stripping the Long Saphenous Vein, Eur J Vasc Endovasc Surg 1996 Vol 12
10. Murphy E, Two year experience with endoluminal ablation of incompetent perforator veins, American College of Phlebology annual meeting presentation #73, November 2007, Scottsdale AZ