2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018

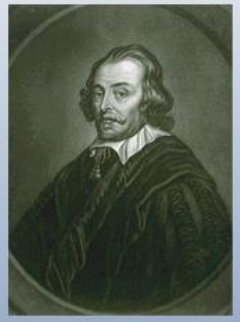
C SCOTT MCENROE

Medical Director
Vein Center of Virginia
Sentara Medical Group

April 27, 2018

Why Tumescent-Free Therapy Will Replace RF and Laser

History of Venous Surgery

Stripping and cauterization of varicose veins	Galen recommended tearing veins out with a hook	Paulus performed ligation and stripping of segments	William Harvey taught that treatment was worse than cure	Modern anesthesia introduced	Surgical vein stripping became common
30 BC - 30 AD	200 AD	660 AD	1600 AD	1850 AD	1950 AD
					
Celsus	Galen	Paulus of Aegina	William Harvey	Vein Stripping	Standard of Care

1950's GSV/SSV stripping became " Gold Standard " for management of SVI

-Elimination of axial reflux caused by venous valvular incompetency

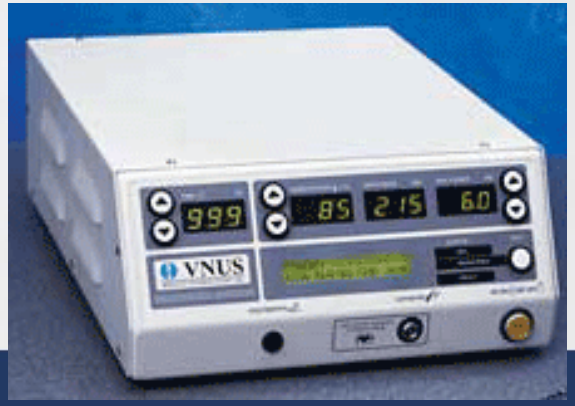
Surgical Vein Stripping

- **Blind procedure**
- **General/spinal anesthesia**
- **Painful recovery**
- **Suboptimal outcome**

Tumescent Thermal Ablation

New “ Gold Standard “ for management of axial reflux

- 1998 Radiofrequency
- 2002 Laser

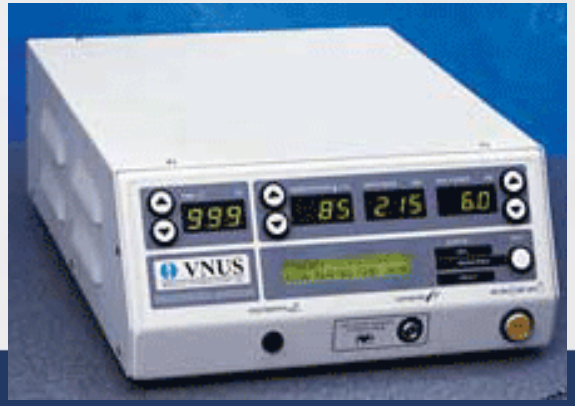


Tumescent Thermal Ablation

New “ Gold Standard “ for management of axial reflux

24 RCT’s

- **Saphenous vein closure rates: > 95 %, > 90 % at 1, 5 years**
- **DVT: Laser 3 %, RF 4 %, surgical stripping 2.5 %**
- **PE: 0.3 %**



Tumescent Thermal Ablation

- **Advantages**

  Effective: equivalent to surgical stripping

  Low complication rate: DVT/PE

  Superior clinical outcome

  Office based/ambulatory

  Local/Tumescent anesthesia

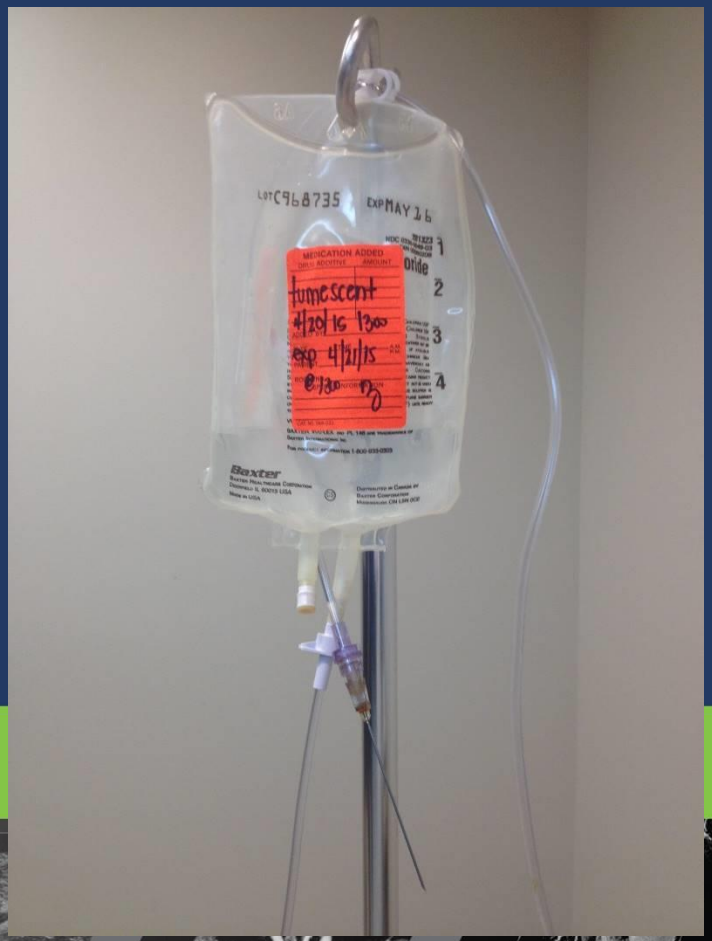
  Rapid recovery

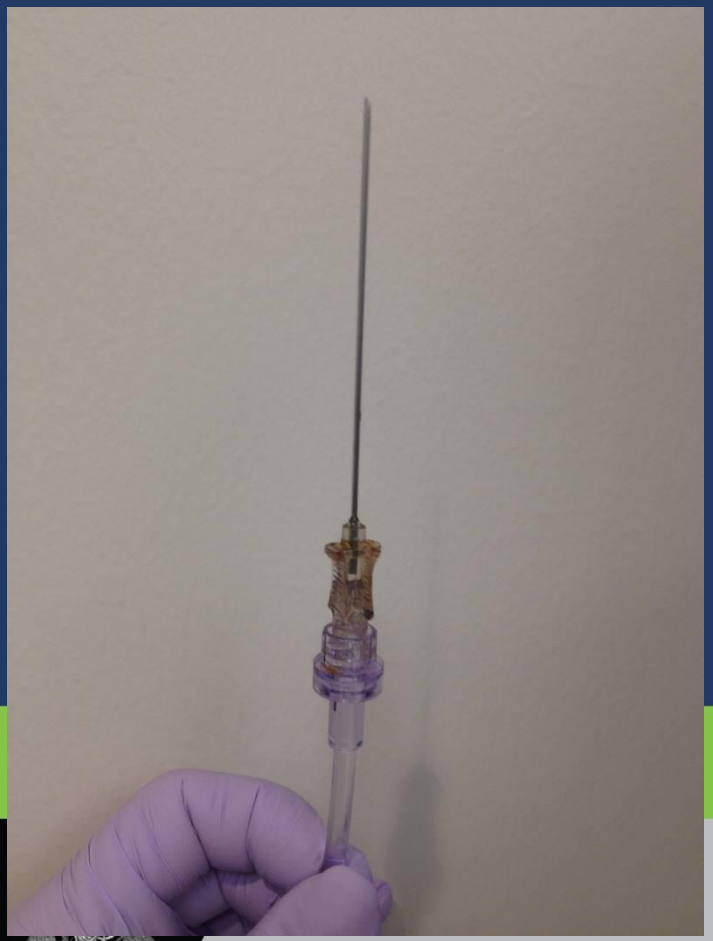
  Mild to moderate post-op pain

  High patient acceptance

Tumescent Thermal Ablation *Disadvantages*

***Tumescent anesthesia*: patient tolerance, lidocaine toxicity, single limb treatment**





Tumescent Thermal Ablation
Disadvantages

***Compression hose*: poorly tolerated**

- **inadequate proximal compression**
- **distal migration, tourniquet effect**
- **skin chaffing, blistering**

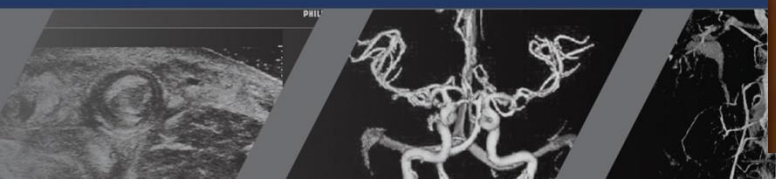
Tumescent Thermal Ablation
Disadvantages

***Limited post-op activity*: non-strenuous activity x 7 days**

Tumescent Thermal Ablation
Disadvantages

***Post-op phlebitis*: thermal injury, thrombus**

Pain: NSAIDS, narcotics

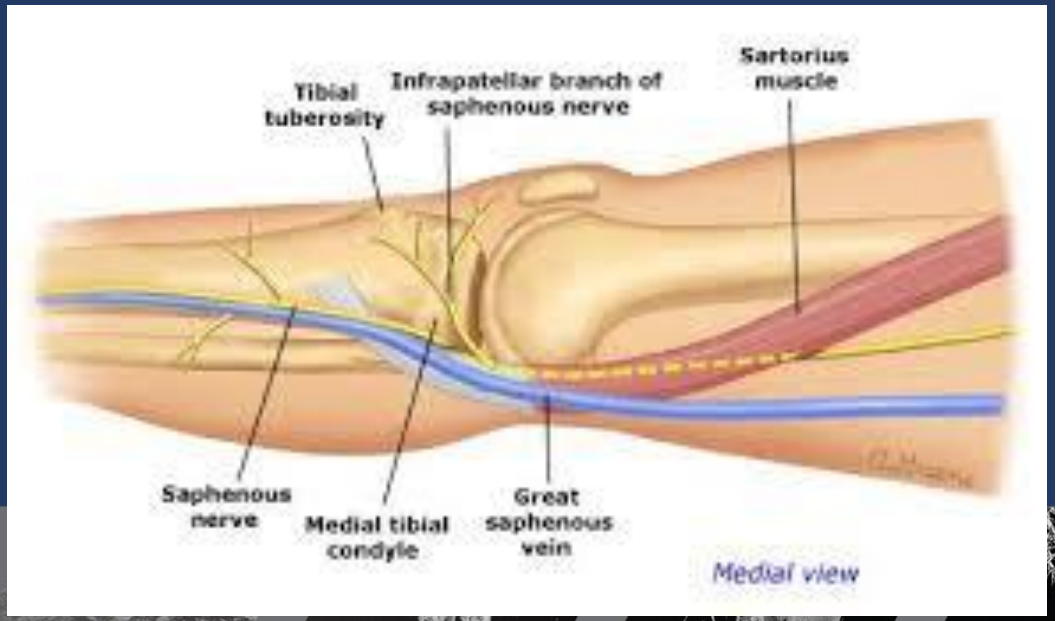


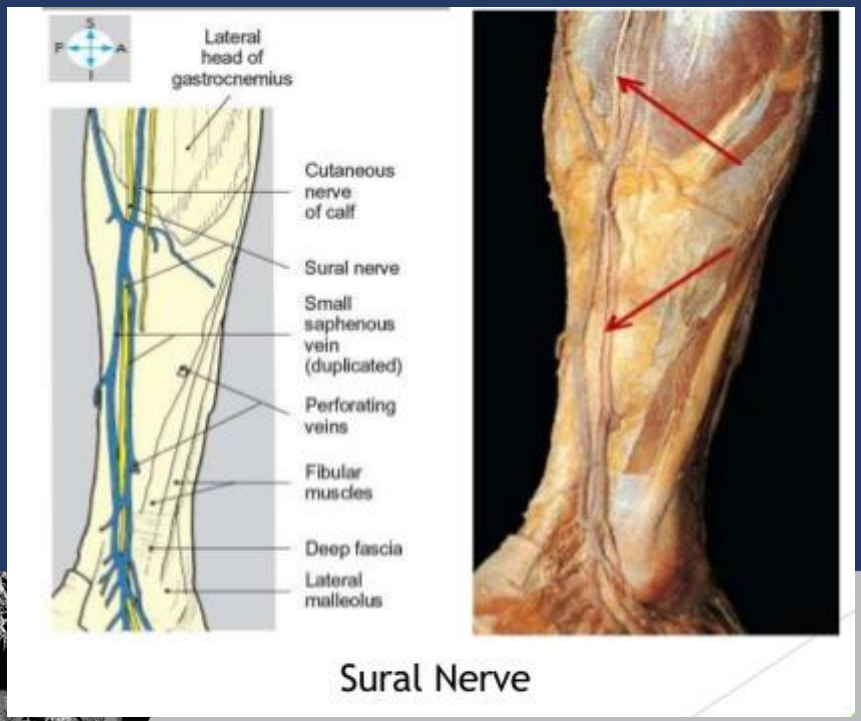
Tumescent Thermal Ablation
Disadvantages

Anatomic limitations: **saphenous/sural nerve injury**

-residual distal GSV/SSV

- RECURRENT VARICOSITIES!!!!!!!!!



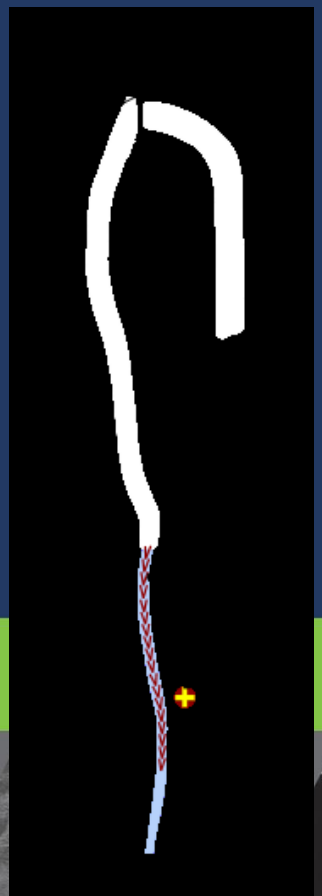


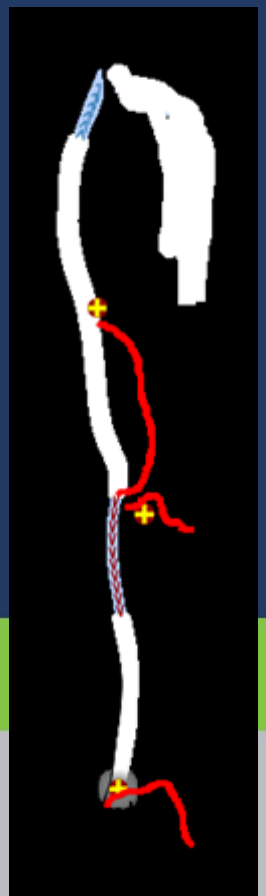
Tumescent Thermal Ablation
Disadvantages

Anatomic limitations: **saphenous/sural nerve injury**

-residual distal GSV/SSV

- RECURRENT VARICOSITIES!!!!!!!!!





Tumescent Thermal Ablation
2 Decades

Disadvantages

- **Varicose vein recurrence**
- **Pain: operative, post-operative**
- **Single limb treatment**
- **Limitations in immediate post-operative activity**

Next “ Gold Standard “ for Saphenous Ablation

Ideal Modality

- Meet or exceed results of Thermal Ablation
- No anatomic limitations
- Lower recurrence rate
- Permit bilateral limb treatment
- Less operative/post-operative pain
- More rapid return to full activity

What's Next After *Tumescent, Thermal* Ablation ??

Non-Thermal, Non-Tumescent Ablation

- Non-thermal technology
- Tumescent anesthesia unnecessary

Non-Thermal, Non-Tumescent Ablation

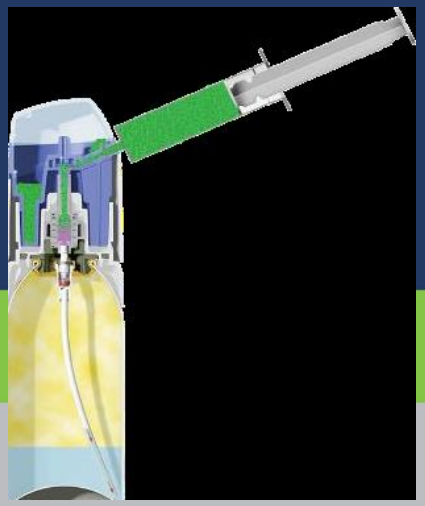
- **FDA approved, office based, percutaneous, duplex guided, non-thermal devices**
  - **Chemical(UGFS): *Varithena*™**
  - **Mechanochemical(MOCA): *ClariVein*™**
  - **Chemical adhesive(CAE)*: VenaSeal*™**

No head to head comparison studies

Non-Thermal, Non-Tumescent Ablation

VARITHENA™

- **Polidocanol injectable foam(UGFS)**
  - **Proprietary gas composition: O2/CO2 65:35**
    - **Uniform bubbles <100 um**
    - **Pre-mixed canister**
  - **Duplex guided injection**
  - **Incompetent GSV, SSV, accessory vein, and associated tributary veins**
  - **No sedation**
  - **No tumescent anesthesia**
  - **Compression hose 2 weeks**
  - **No strenuous activity 1 week**
  - **No prolonged inactivity 4 weeks**



Non-Thermal, Non-Tumescent Ablation

VARITHENA™

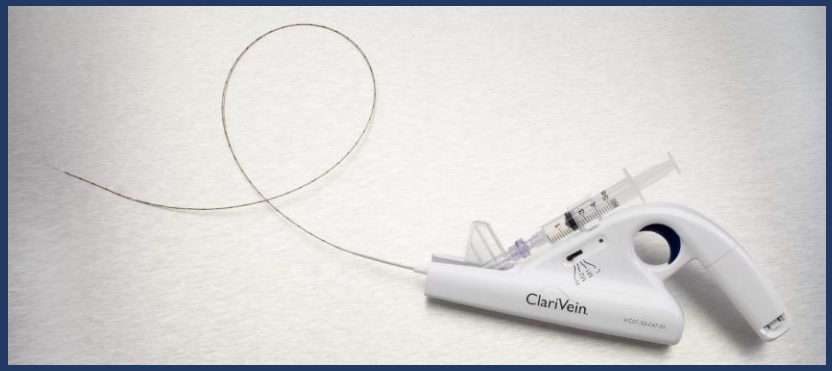
- **Clinical Data(UGFS)**

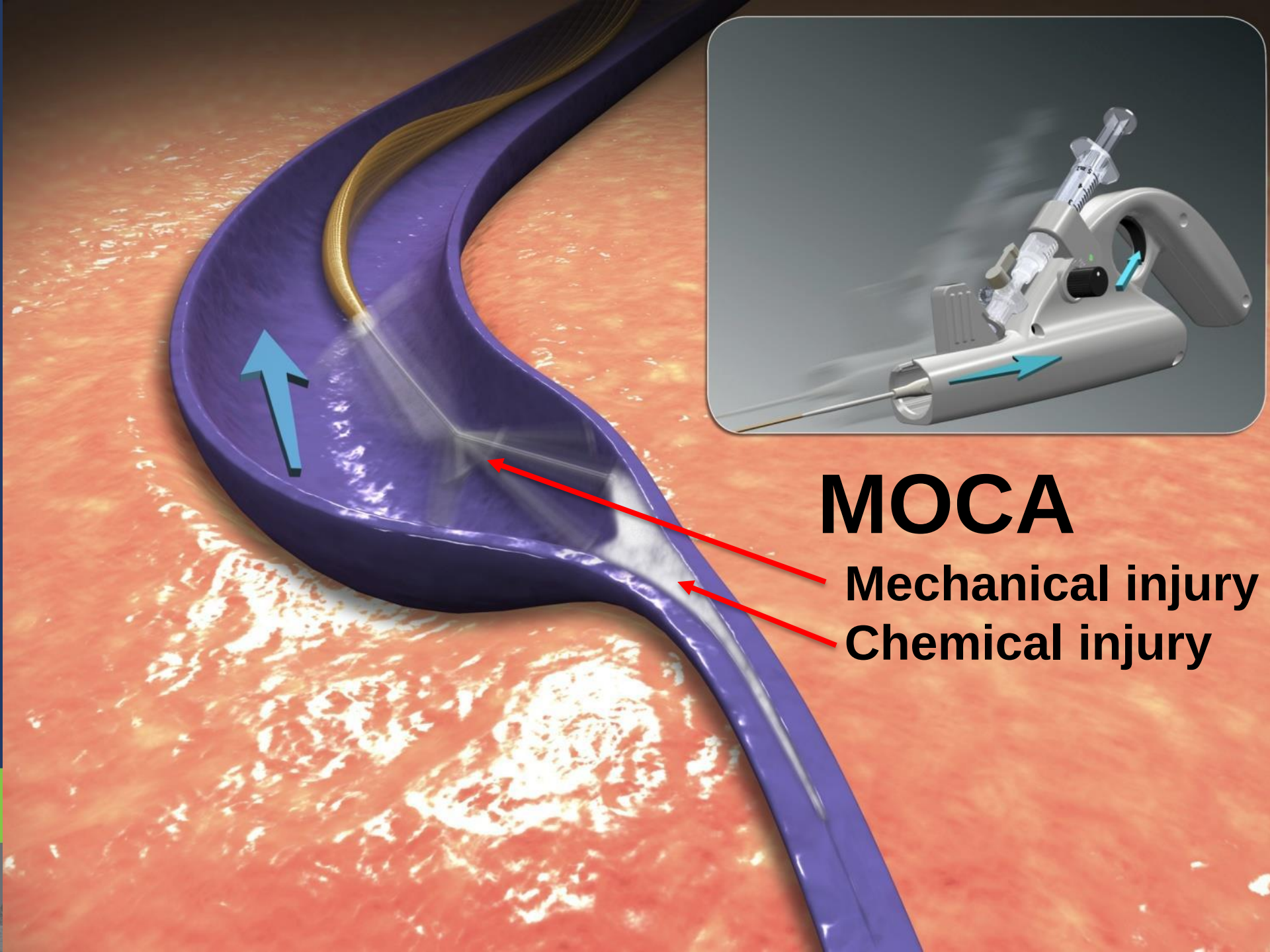
  - GSV reflux: 85 % @ 2 years
  - Full length GSV/SSV, no reported nerve injury
  - Phlebitis 5 – 15 %
  - Improved QOL, VCSS compared with RF
  - DVT 1.5 – 4.5 %
  - PE none reported

Non-Thermal, Non-Tumescent Ablation

ClariVein™

- **Mechanochemical Tumescentless Ablation(MOCA)**
  - **Duplex guided, catheter based**
  - **Great, Small, Accessory Saphenous incompetency**
  - **No sedation**
  - **No tumescent anesthesia**
  - **No post-op compression hose**
  - **Immediate return to all activity**




MOCA
Mechanical injury
Chemical injury

Non-Thermal, Non-Tumescent Ablation

ClariVein™

- **Clinical Data(MOCA)**

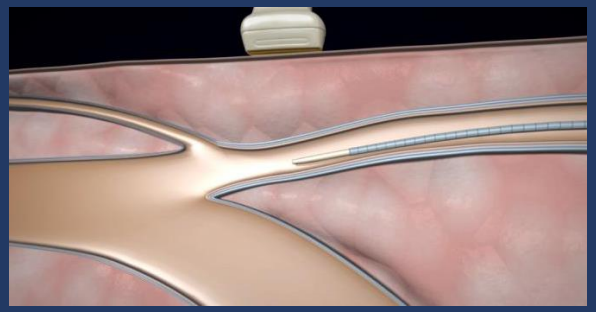
  - GSV reflux: 90 % @ 2 years (non-inferior to RF)
  - Full length GSV/SSV, no reported nerve injury
  - Phlebitis 12-14 %
  - Improved QOL, VCSS compared with RF
  - Post op pain levels and return to work superior to RF
  - DVT 0.5 %
  - PE none reported

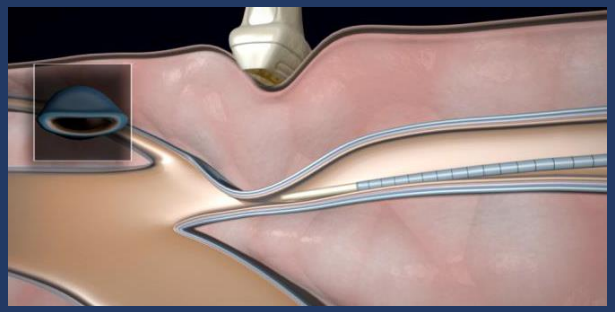
Non-Thermal, Non-Tumescent Ablation

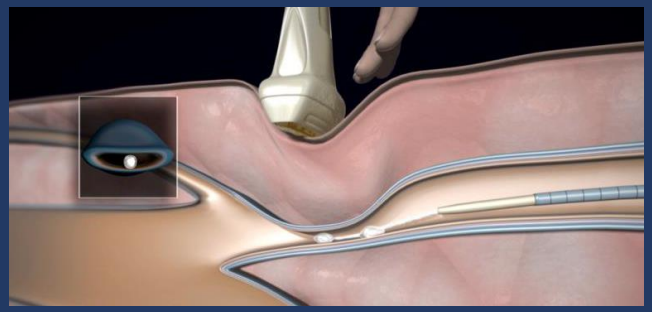
VenaSeal™

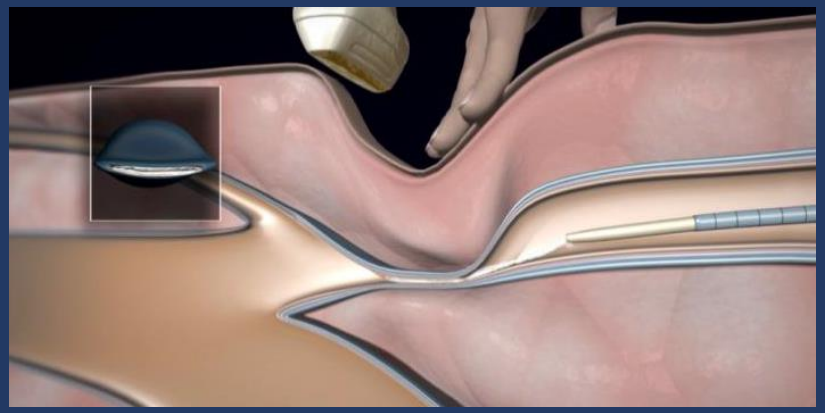
- Proprietary cyanoacrylate adhesive(CAE): high density, water activated
- Duplex guided, catheter based delivery system
- Great, Small, Accessory Saphenous incompetency
- No sedation
- No tumescent anesthesia
- No post-op compression hose
- Immediate return to all activity

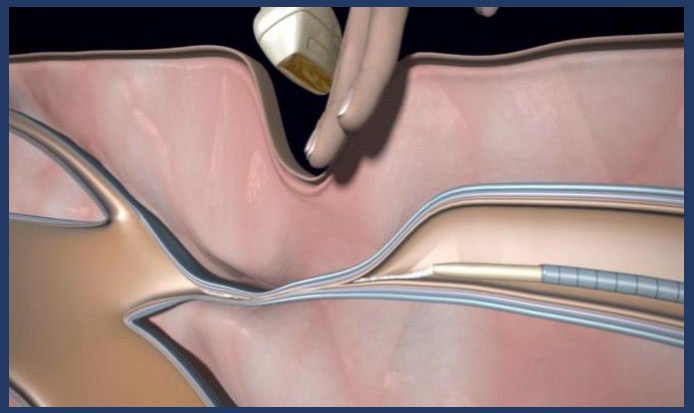
VenaSeal™ (CAE)



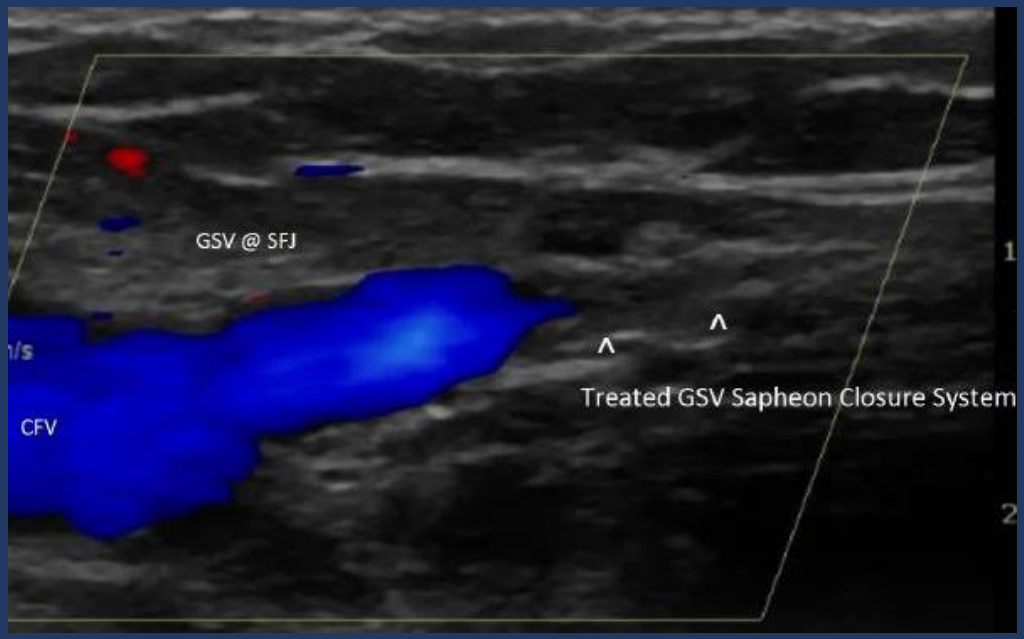








VenaSeal™ (CAE)



Non-Thermal, Non-Tumescent Ablation

VenaSeal™

- **Clinical Data(CAE)**

  - GSV reflux: 95 % @ 3 years (non-inferior to RF)
  - Full length GSV, no reported nerve injury
  - Phlebitis 11-20 %
  - Improved QOL, VCSS compared with RF
  - Post op pain levels and return to work superior to RF
  - DVT/PE none reported (feasibility trials, eScope, VeClose)

Why Tumescent-Free Therapy Will Replace RF and Laser

SUMMARY

- Non-tumescent, non-thermal modalities for the treatment of saphenous reflux are available which avoid many of the problems encountered with thermal ablation over the last 20 years.
- MOCA, CAE non-inferior to RFA, have lower rates of post-operative DVT/PE, and do not always require post-operative application of compression hose
- UGFS, MOCA, CAE result in improved QOL, VCSS, lower post-operative pain levels, and more rapid return to work compared with RFA
- Bilateral LE ablation is feasible with UGFS, MOCA, CAE: convenience, lower cost
- Full length ablation with USGF, MOCA, CAE can be performed without risk of nerve injury: ? Lower incidence of recurrence ?

Why Tumescent-Free Therapy Will Replace RF and Laser

The Honeymoon with Thermal Tumescent Ablation is over…time to move on to better things

“ THE FUTURE OF NON-THERMAL ABLATION *IS* THE FUTURE OF ENDOVENOUS ABLATION “

Steve Elias