Non-Thermal Options for Saphenous Ablation: When to Consider them and Why

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LAKE WASHINGTON
VASCULAR

DISCLOSURE

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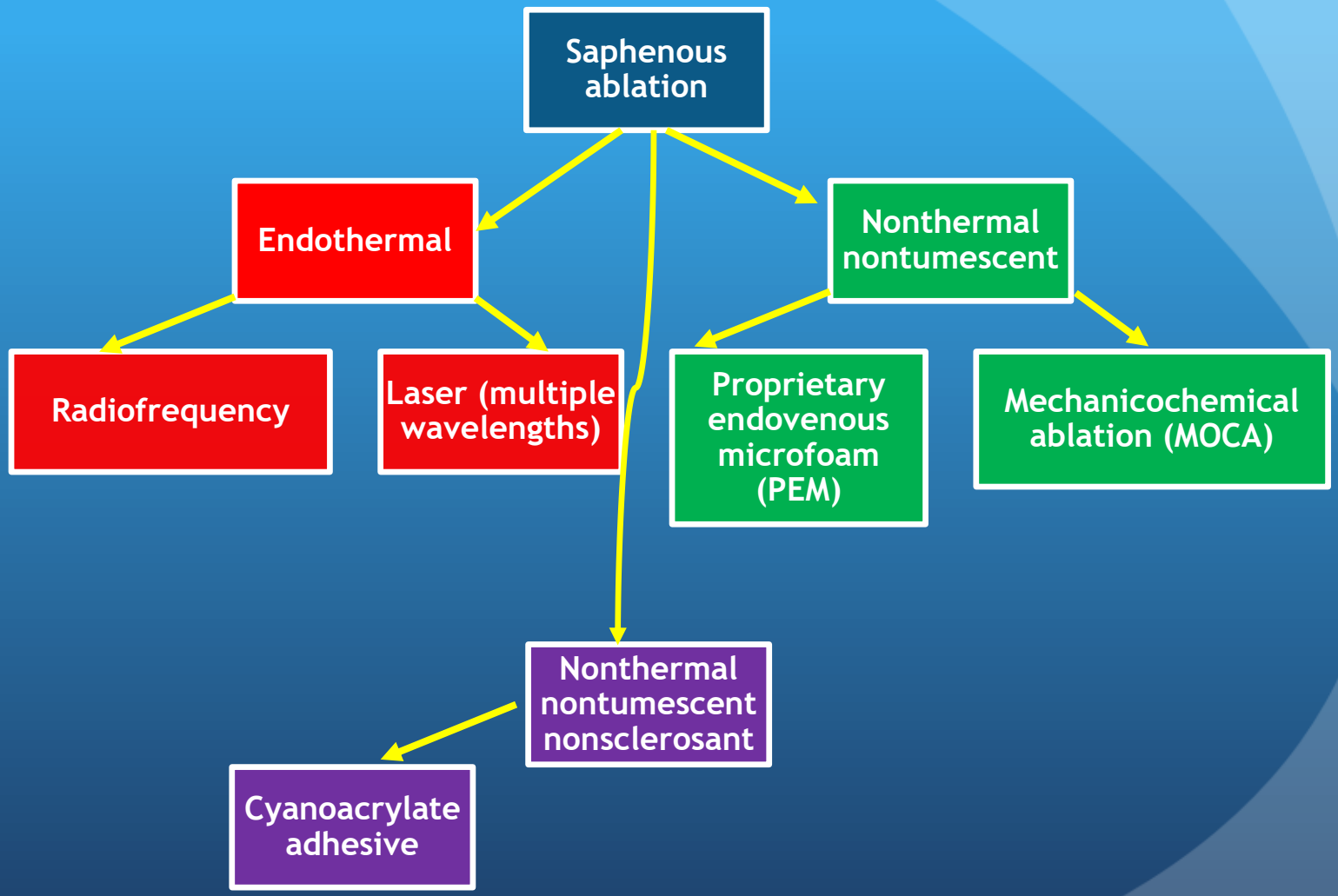
Consulting Fee: Medtronic, BTG, Vascular Insights, Vesper Medical

Speakers Bureau: Medtronic, BMS

Research Grants: Medtronic, BTG, Vascular Insights, Bayer, AngioDynamics


Saphenous ablation
Endothermal
Nonthermal nontumescent
Radiofrequency
Laser (multiple wavelengths)
Proprietary endovenous microfoam (PEM)
Mechanicochemical ablation (MOCA)
Nonthermal nontumescent nonsclerosant
Cyanoacrylate adhesive

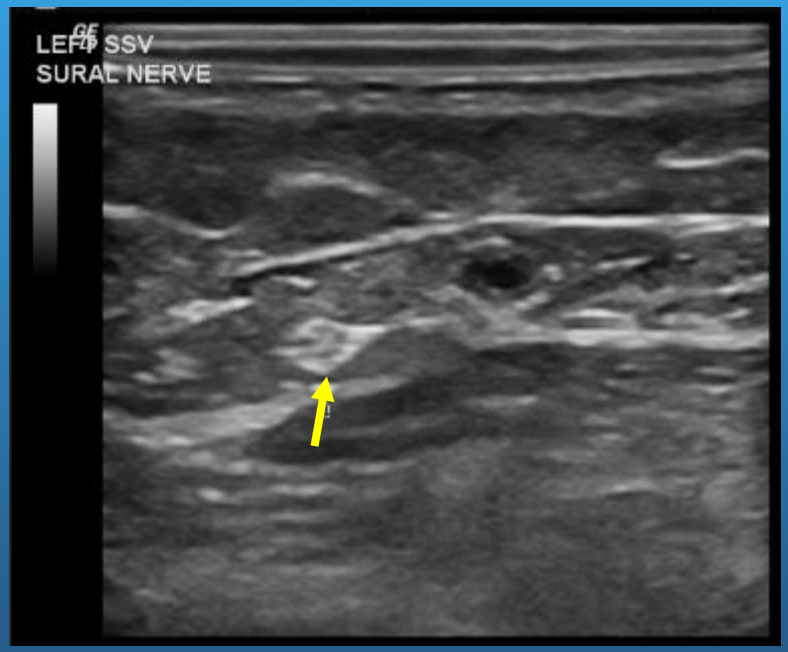
Endothermal ablation

- Durable, excellent efficacy-15 years
- Safety profile well established
- Disposables can be expensive
- Capital equipment outlay for generator
- Requires tumescent anesthesia
- Doesn’t address large side branches
- Sedation optimal in some patients

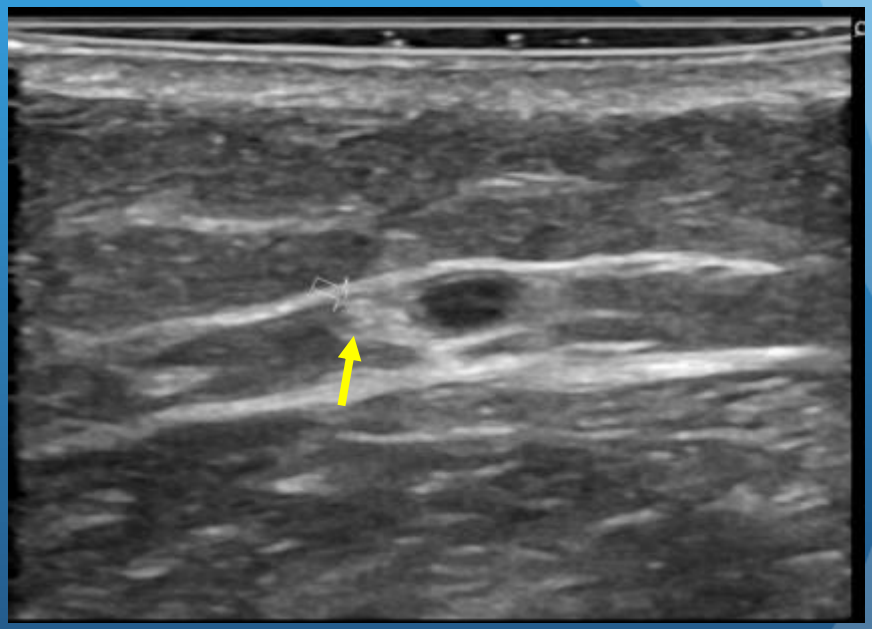
Nonendothermal ablation

- Short term efficacy variable, but comparable to endothermal
- Safety profile well established
- Disposables can be expensive
- No capital equipment outlay for generator
- No tumescent anesthesia
- All but PEM do not address large side branches
- Sedation almost never needed
- Post compression not needed with cyanoacrylate
- No risk of burns, nerve injury

Nerve proximity!



Not scary



Scary

PEM

- A combination device to generate pharmaceutical-grade microfoam
- Delivers reproducible microfoam with small bubble size and narrow bubble size distribution
- Highly stable, similar to air-based sclerosing foams
- Benefits *in vivo* of an ultra-low N_2, CO_2-O_2 based gas formulation

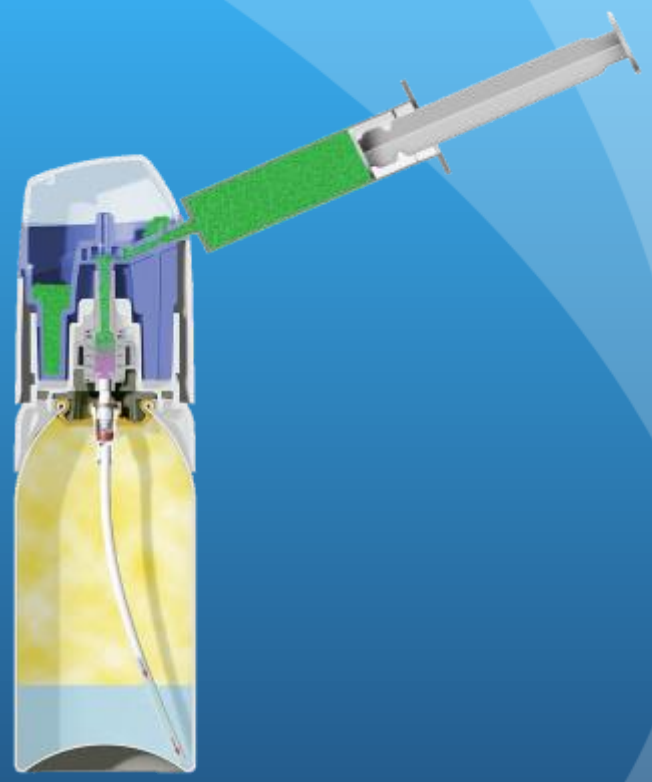


Image courtesy of BTG International

Proprietary Endovenous Microfoam

BTG Announces Positive Data from First US Phase III Trial of

- Two pivotal Phase III trials completed-
- Primary endpoints- change in patient symptoms
- Secondary endpoints-improvement in appearance (pt and blinded assessor)
- Tertiary endpoints-Duplex elim. of reflux, change in VCSS and VEINES SYM/QOL
- All endpts highly statistically significant compared to placebo

Pivotal Phase III Trial of Varisolve®

London, UK, 23 April 2012: BTG plc (LSE: BGC), the specialist healthcare company, today

Elimination of reflux

Placebo	PEM 0.125% Control	PEM 0.5%	PEM 1%	Pooled PEM (0.5% + 1.0%)
2%	60%	83%	86%	85%
	Comparison vs. PEM 0.125%	p=0.0043	p=0.0009	p=0.0002

PEM: Recent Literature

Author/Journal	Year	N	Follow up	Closure rates	Comment
Gibson, Phlebology	2016	77	4, 8, 12 weeks	90% at 4 weeks (Varithena)	Randomized to Varithena v. Placebo. Significant improvement in pt symptoms and appearance in Varithena group
Todd, JVS Venous Lymphat Disord	2015	56	1 year	73%	Significant and maintained improvement in pt symptoms and appearance

When do I like to use PEM?

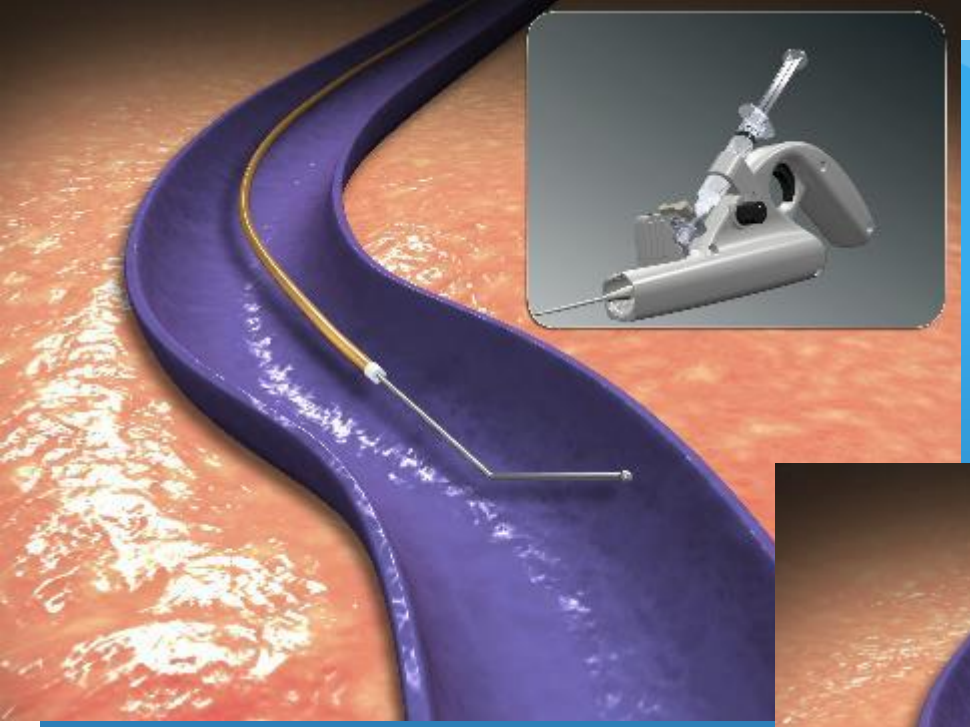
- Recurrent varicose veins
- Post-phlebitic veins with webbing
- Truncal veins that are not large
- Accessory saphenous veins
- Tributaries/pelvic source veins
- Above if insurance covering!

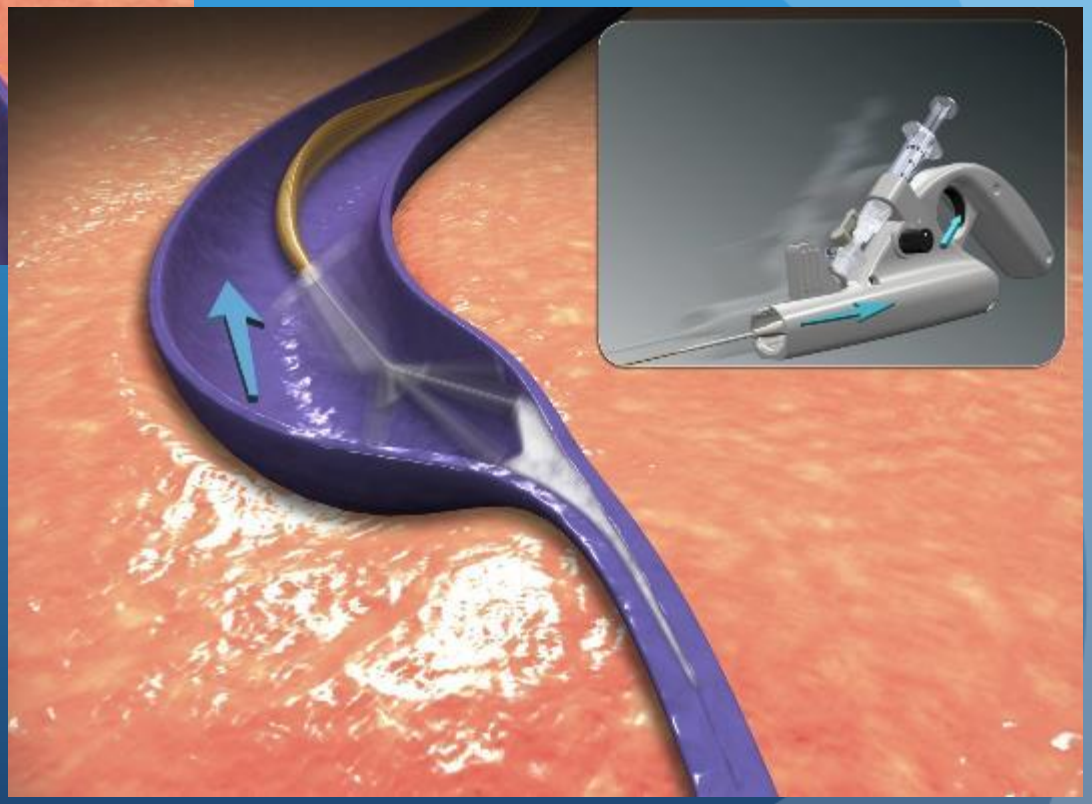
PEM in recurrent vvs

Mechanico-chemical ablation (Clarivein®)-MOCA

- Combination – endovenous mechanical and chemical
- Mechanical – wire > rotates > intimal damage
- Chemical – liquid > penetrates > scar
- End result – venous occlusion

MOCA: Mechanism of action





slide courtesy of Steve Elias, MD

Elias-Completed Trial *

- 30 limbs, GSV only, no tumescence or sedation
- C2 – 24 C3 – 2 C4 – 4
- All closed except 1st patient – btw 3-6mos
- 6 month – 29/30 **(96%)**
- 12 month – 29/30 **(96%)**
- 24 month – 27/28 **(96%)** (1 died,1 no US yet)

*Elias S, Raines JK. Mechanochemical tumescentless endovenous Endovenous ablation: final results of the initial clinical trial. Phlebology;27:67-72.

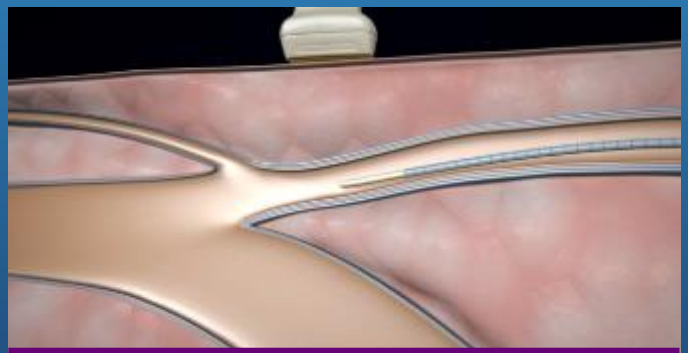
MOCA: Recent Literature

Author/Journal	Year	N	Follow up	Closure rates	Comment
Witte, J Endovasc Ther	2016	85	1, 2, 3 yrs	92%, 90%, 87%	AVVQ, VCSS improvement, but deteriorate from 2 to 3 yrs
Deijen, Phlebology	2016	570	6,12 wks	90%	Failures assoc. with SFJ incompetence
van Eekeren , JVS	2014	106	1 yr	88.2%	Significant improvement in QOL

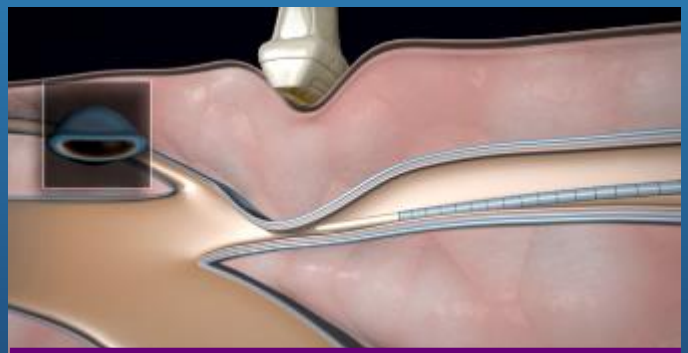
Cyanoacrylate Closure System

VenaSeal Sapheon Closure System

1) Access GSV using catheter technique



2) Position 5 cm from SFJ



3) Compress cephalad to catheter

slide courtesy of Medtronic

VeClose Primary Endpoint – Complete Closure

Timepoint	VenaSeal	RFA
Day 3	100% (108)	99.1% (114)
Month 1	100% (105)	87.3% (110)
Month 3*	99% (104)	95.4% (108)
Month 6	99% (101)	96.2% (105)
Month 12	96.8% (95)	95.9% (97)
Month 24	95.3% (86)	94% (84)
Month 36	94.4% (72)	91.9% (74)

94.4% closure rates, demonstrating long term durability at 36 months; and continued, non-inferiority results to RFA (P=0.005) through 36 months.

CAC*: Recent Literature

Author/Journal	Year	N	Follow up	Closure rates	Comment
Kolluri, JVS Venous Lymphat Disord	2016	20	3 months	100%	Roll-in patients from VeClose, significant QOL and VCSS improvement
Gibson, Vascular	2016	50	1 mo, 3 mos, 1 year	100%, 99%, 98%	WAVES trial: included SSV, AASV, and large veins up to 20 mm. Significant QOL and VCSS improvement

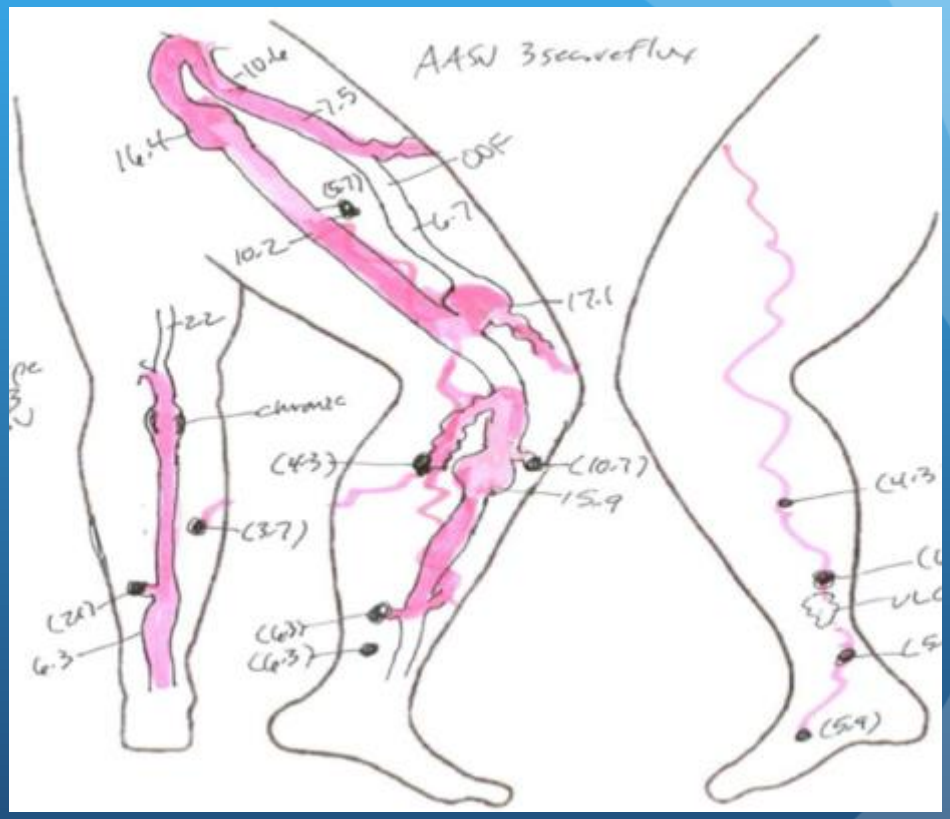
*Other CAC systems are available outside US, and are not FDA approved

Closure literature

	ClosureFast Study, Veclose study	Rasmussen Study	VANISH 2 Study	Elias Study, Witte Study	Veclose study
Modality	RFA	EVLT	PEM	MOCA	CAC
Short term	96.6% one year	94.2% one year	87.9% 8 weeks	96% one year	96.8% one year
Long term	91.9% at 3 years and at 5 years	81.2% at 5 years	73% at one year	87% at 3 years	94.4% at 3 years

EDS patient with nonhealing ulcer

- IVC and iliac veins patent
- Deep venous reflux, but no obstruction
- On left (ulcer side) GSV, AASV, SSV reflux
- Several pathologic perforator veins near lateral ulcer
- Plan-CAC ablation truncal veins, sclerotherapy ulcer bed



Limb before treatment

Patient course

August 2018

Which technique is superior?

Modality	RFA	EVLT	PEM	MOCA	CAC
Standard GSV	✓	✓	✓	✓	✓
Tortuous	✗	✗	✓	✗	✗
Below knee	✗	✗	✓	✓	✓
SSV	+/-	+/-	✗	✓	✓
> 12 mm vein	✓	✓	✗	✗	✓ (modified IFU)

Where do I see an NT/NT advantage?

- The elderly
  - Less fluid shifts
  - Less bruising (especially in anticoagulated patients)
  - Compression not mandatory
- Below the knee
- Advanced disease with damaged skin
- Short trunk with multiple branches amenable to PEM
- Patient choice-either insurance covers, or cash pay

Summary

- Lots of excellent choices for treatment of the saphenous veins
- In order to *replace* existing technologies, the new technologies must have:
  - Good safety profile (yes)
  - Close, better, or acceptable efficacy (yes)
  - $ outlay to get started must be reasonable (mixed)
  - Must have FDA approval (yes)
  - Ideally, will have own reimbursement codes or ability to use existing ablation codes (yes)
  - If insurance coverage tightens, the technology most economical to the patient may win!