

# Is Varithena Endovenous Ablation or Physician Compounded Foam The Answer

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EDWARD G. MACKAY MD

No Disclosures

Forgot to ask what the question  
was

Definitions PEM and PCF

Varithena is more than just foam

- ▶ It's a canister that makes a very consistent foam
- ▶ It's a procedure
- ▶ It's aimed primarily at axial veins and their tributaries
- ▶ In its current form it is only one concentration

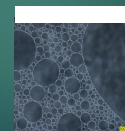
## A Microfoam UDSS™ Procedure

Microfoam generation

- ▶ Proprietary microfoam-generating device produces a microfoam that has:
  - ▶ Uniform density, size, and stability.
  - ▶ Median bubble diameter is <100 µm
  - ▶ No bubbles are greater than 500 µm



Foams with smaller and more uniform bubble size (red) are more cohesive and stable. <sup>1</sup>

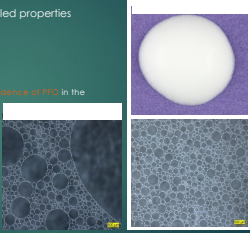


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### A Microfoam UDSS™ Procedure

Gas makeup

- Low-nitrogen foam with controlled properties
  - 65:35 O<sub>2</sub>:CO<sub>2</sub> Ratio
  - <0.8% N<sub>2</sub>
  - Highly absorbable in blood
- A 1984 autopsy study found a 34% incidence of PFO in the general population<sup>1</sup>
- A 2010 study of CEAP C3-5 patients found an R-L shunt was detected at more than twice the anticipated rate, 46.6% (95% CI, 32.3-60.1)<sup>2</sup>

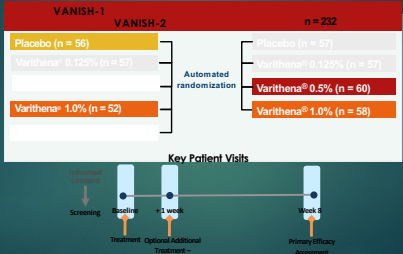


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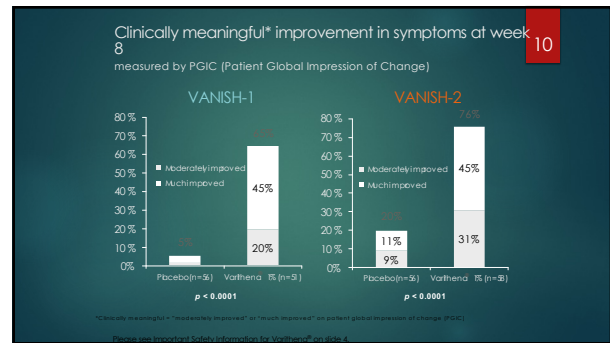
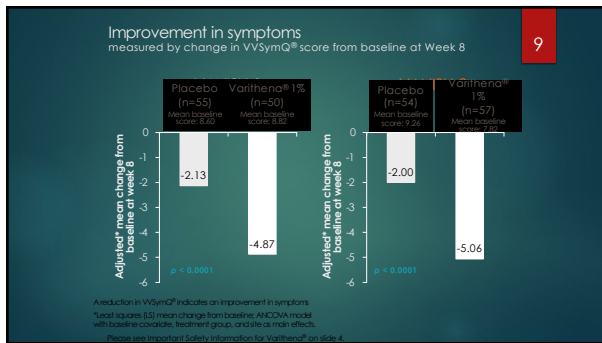
### VANISH-1/VANISH-2 study design

randomized, blinded, parallel-group, multicenter

n = 279



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### Summary of Peer-reviewed publications

Publication	Findings
King et al. Eur J Vasc Endovasc Surg 50(6): 784-793, 2015	VANISH-1 Study; 8-week outcome data Improvement in PRCs/VVSymQ
Todd et al. Phlebology 29(9): 608-618, 2014	VANISH-2 Study; 8-week outcome data Improvement in PRCs/VVSymQ
Todd et al. J Vasc Surg Venous Lymphat Disord 3(3): 258-264, 2015	VANISH-2 Study; 1 Year Durability Continued Improvement in PRCs/VVSymQ
Carugo et al. J Mater Sci Mater Med 26(11): 258, 2015	Review of ideal foam properties to optimize ablation
Carugo et al. Phlebology 31(4): 283-295, 2016	Varithena® properties (cohesiveness, vein wall contact, dwell time) are superior to compounded foam
Vasquez et al. Phlebology 32: 272-281, 2017	Improved outcomes when Varithena® is combined with thermal ablation
Gibson et al. Phlebology 32: 185-193, 2017	Improved symptoms and appearance
Regan et al. J Vasc Surg 53:131-138, 2011	Use of low nitrogen microfoam in patients with known PFO is safe

### The official definition of PCF

- ????????
- A sclerosant mixed with a gas
- Any foamable sclerosant
- Any gas
- Any ratio
- Any method
- Volume?

## Physician Compounded Foam is...

- ▶ Safe
- ▶ Decades of Data
- ▶ Proven benefits in patients with C1 – C6 Disease
- ▶ Easy to use
- ▶ Cost-Effective

## Patients are just as happy with Foam

Table 2. Estimates of Treatment Effect on Primary Quality-of-Life Outcomes.\*

Measure	Laser Group (N=210)	Foam Group (N=206)	Surgery Group (N=209)	Surgery vs. Foam†	Surgery vs. Laser†	Laser vs. Foam‡
AVQoL score						
Baseline	17.8±9.1	17.6±9.9	18.2±9.1			
6 Mo after treatment	7.9±8.4	9.1±7.9	7.8±7.5	-1.7 (-3.0 to -0.5)	-0.6 (-2.2 to 0.9)	-1.1 (-2.6 to 0.4)
EQ-5D™						
Baseline	0.78±0.168	0.80±0.177	0.78±0.175			
6 Mo after treatment	0.90±0.171	0.89±0.174	0.88±0.202	0.005 (-0.025 to 0.035)	-0.015 (-0.051 to 0.021)	0.025 (-0.010 to 0.059)
SF-36 physical component††						
Baseline	48.6±7.8	48.9±8.0	48.2±8.6			
6 Mo after treatment	52.6±7.3	52.3±8.5	52.4±8.9	1.0 (-0.2 to 2.3)	0.1 (-1.4 to 1.6)	0.7 (-0.8 to 2.1)
SF-36 mental component††						
Baseline	51.9±9.0	52.4±8.7	51.2±9.4			
6 Mo after treatment	53.3±7.7	52.2±9.1	52.1±8.6	0.2 (-1.1 to 1.6)	-1.1 (-2.9 to 0.2)	1.5 (0.0 to 3.1)‡‡

\* P-values minus values are means ±SD.

†† P-values minus values are means ±SD.

## Patients are just as happy with PCF and it is more cost effective than Thermal

Table 4. Model-based incremental cost-effectiveness analysis (over a 2-year time horizon)

	Cost (€)	Incremental cost (€)	QALYs	Incremental QALYs	Incremental cost per QALY (€)
UGFS	864	-	4.000	-	-
EVLA	1995	431	4.119	0.118	3640
Surgery	1200	208	4.640	0.078	Dominate

QALY, quality-adjusted life-year; IC, ceiling ratio of willingness to pay per QALY gained; UGFS, ultrasound-guided radiofrequency laser ablation.

## Proven benefits in Patients with C1 – C6 disease

Author	Ulcer Healing in Compression-only Group	Ulcer Healing in Sclerotherapy + Compression Group
O'Hare et al. 2010	17/20 (85%)	12/13 (92%) (ns)
Rojas et al. 2009	23/37 (62%)	28/33 (85%) (p=0.06)
Galimberti et al. 1988	72/72 (100%)	46/46 (100%) (ns)
Galimberti et al. 1988	Recurrence: 21/72 (29%)	0/46 (0%) (p<0.01)

Pre-Sclerotherapy vs Post-Sclerotherapy (8mo)

## List of all the randomized double blinded studies comparing PEM to PCF

## Easy to use

- No machines
- No tumescence
- No catheters
- Simple stick with butterfly
- Anyone in the office can make the foam

**Phlebology**

Physicochemical properties and reproducibility of air-based sodium tetradecyl sulphate foam using the Tessari method

Mike B Watkins and Richard J Oliver

## Costs

- ▶ STS 1% 10 cc's \$289
- ▶ PDL 1% 10 cc's \$128
- ▶ PEM is a lot

## Reimbursement

- ▶ 36470 single vein sclerotherapy \$115.17
- ▶ 36471 multi vein sclerotherapy \$192.49
- ▶ 76942 ultrasound guidance \$48.01
- ▶ 36465 single vein PEM \$1208.68
- ▶ 36466 multi vein PEM \$1258.03

## One big difference

- ▶ FDA has approved Varithena®

## When to use PEM vs PCF

- ▶ PEM is used when 1% PDL foam is the appropriate concentration and when it can be reimbursed
- ▶ PCF for all other circumstances

## Conclusions

- ▶ PEM is well defined
- ▶ PCF is more nebulous
- ▶ Plenty of data to support PCF and PEM
- ▶ Advantage goes to PEM with a more well defined product and better reimbursement