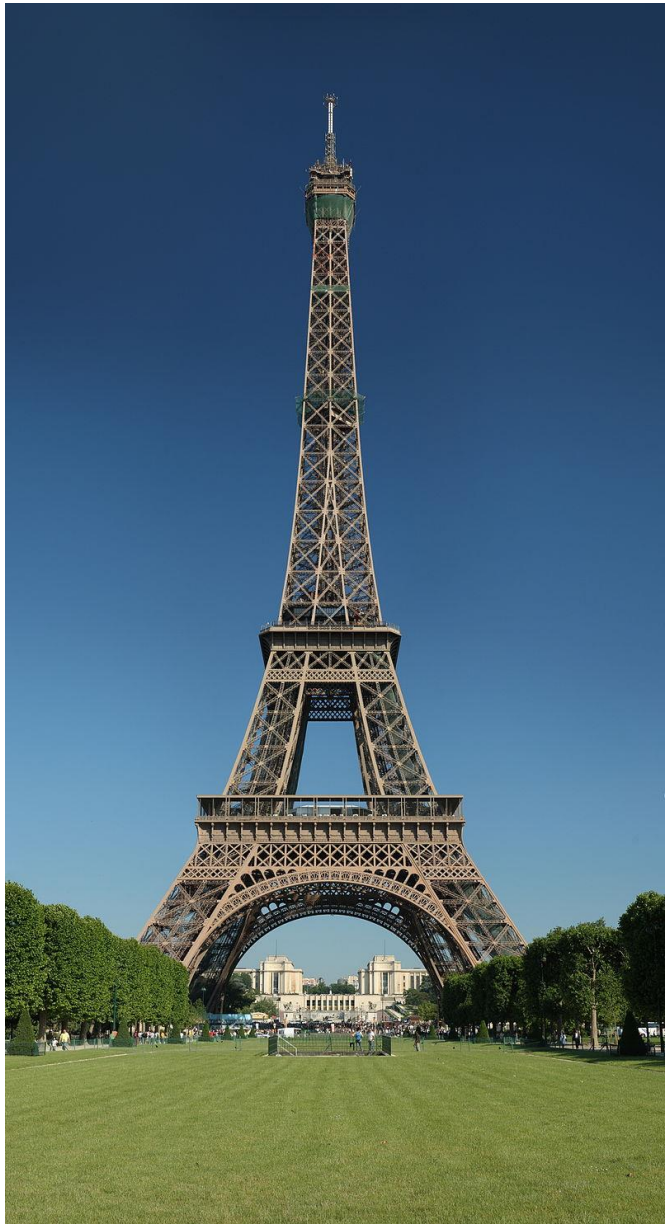


US and Turkish Glue for varicose vein: is there a difference?

CACVS meeting 2016

Ian J Franklin

Consultant Vascular Surgeon

London, UK

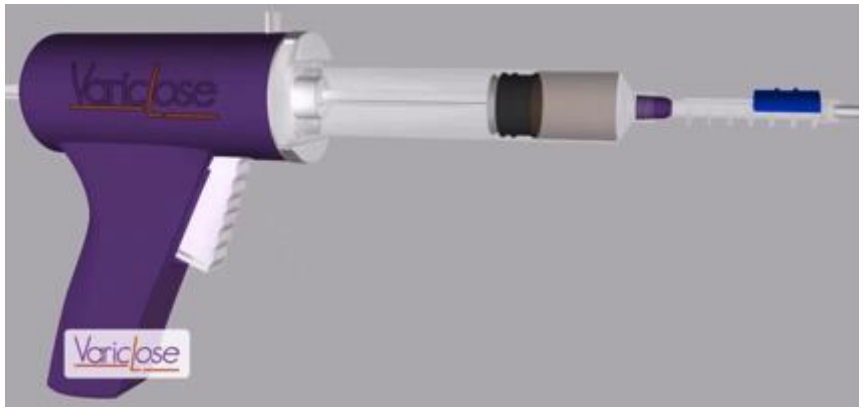
Conflict of interest: none
Disclosures: none

Two glues

“Non-thermal-non-tumescent”

- VenaSeal (Medtronic)

- Variclose (Biolas)



VenaSeal (Medtronic) and Variclose (Biolas) similarities

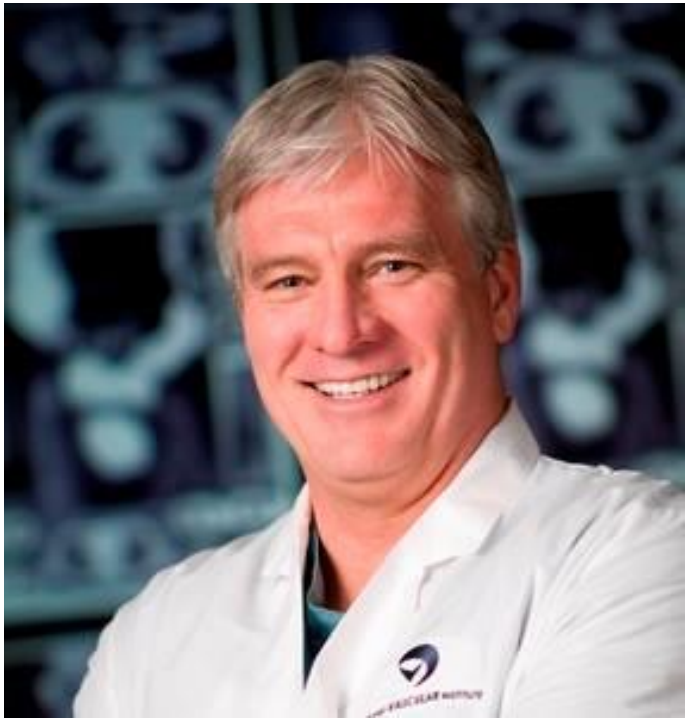
- Both acrylocyanate glue
- Appear to have same mechanism of action
- Identical delivery systems

VenaSeal (Medtronic) and Variclose (Biolas) differences

- Viscosity and feel
- Technique
- Evidence

VenaSeal

- Sapheon
- Covidien
- Medtronic



Rod Raabe

VariClose

Vein Sealing Systems by biolas®

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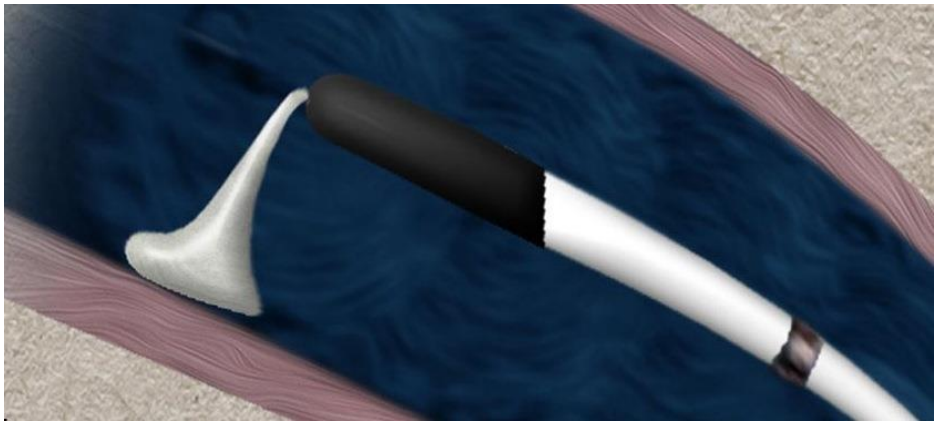
We're producing for the world

biolas®

SURGICAL CLOSURE CATHETER

Variclose glue

- N-butyl acrylocyanate glue
- Formulated for intravascular use
- CE mark awarded



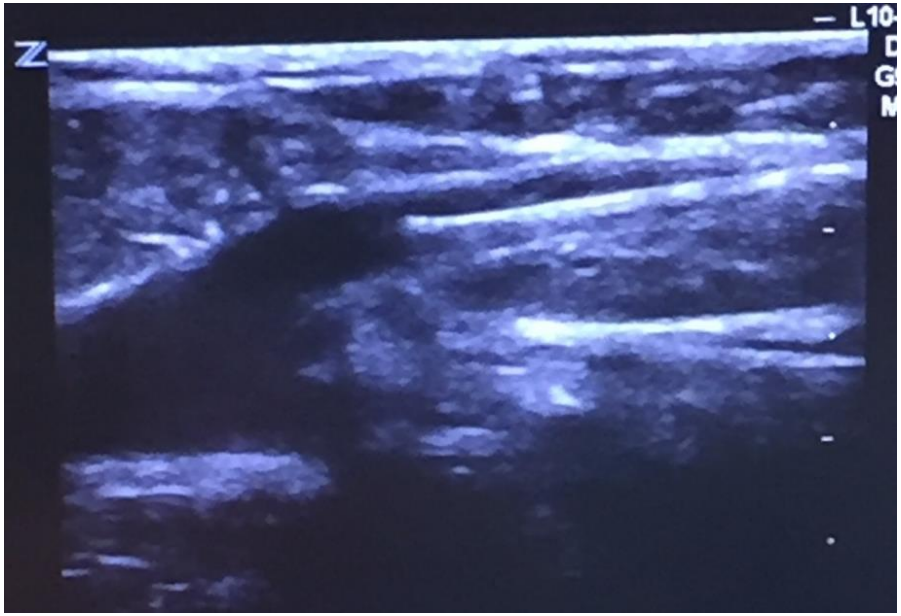
Viscosity

- VenaSeal (Medtronic)
  - Like honey
  - Soft after polymerisation
- Variclose (Biolas)
  - More like water
  - Harder after polymerisation

Endovenous glue: technique

Positioning

- VenaSeal (Medtronic)
  - 5cm back from junction
- Variclose (Biolas)
  - 3cm back from junction

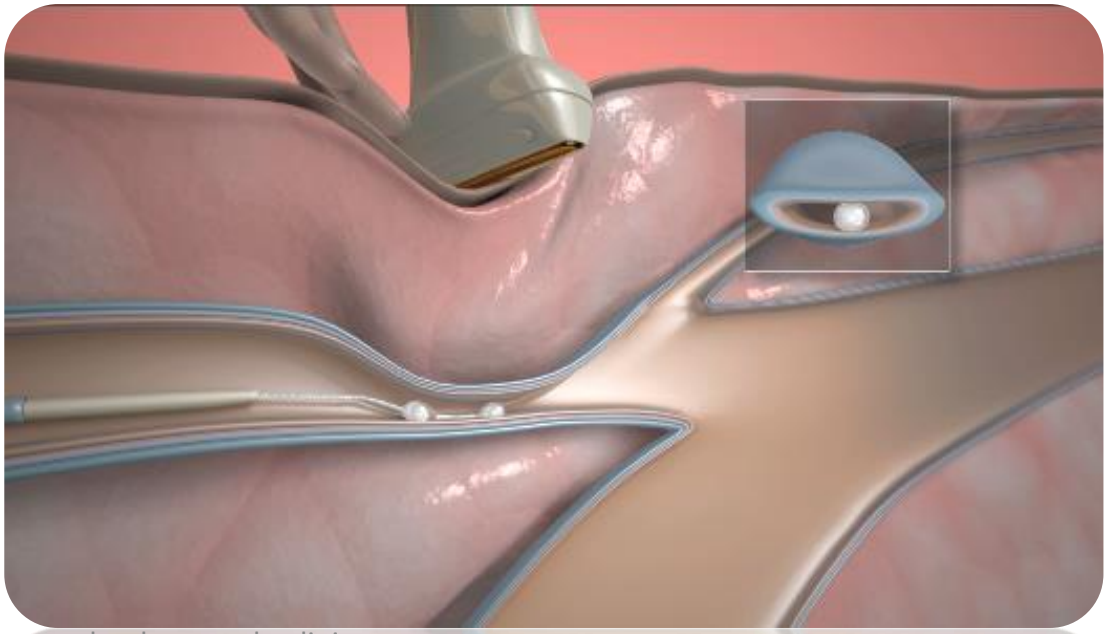


Pullback

- VenaSeal (Medtronic)
  - Segmental
- Variclose (Biolas)
  - Continuous

VenaSeal (Medtronic) pull-back sequence

- Compress the Proximal GSV and SFJ
- Dispense two doses (0.1 ml) of glue 1 cm apart
- Immediately pull back another 3cm
- Compress 3 minutes



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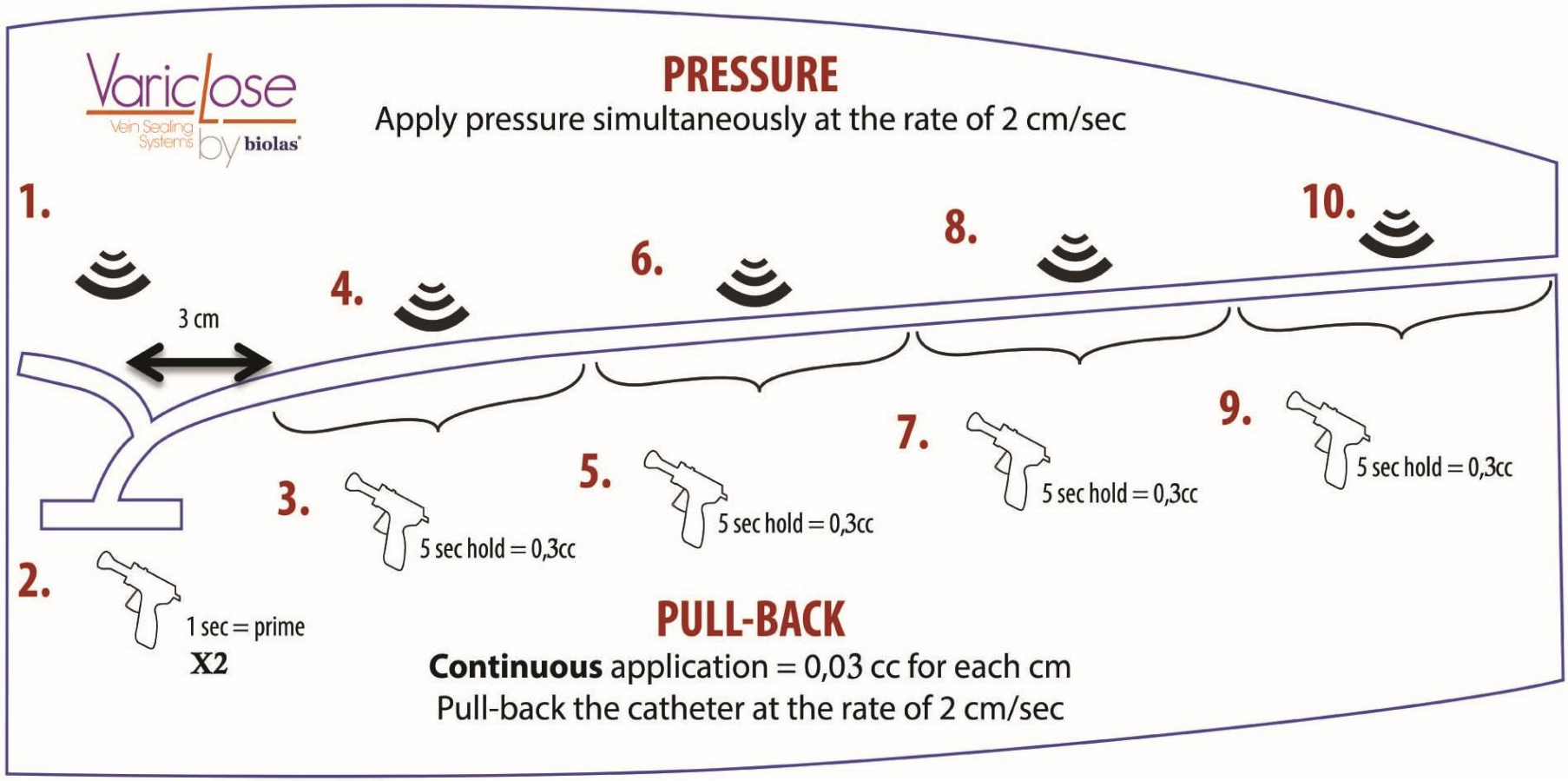
VenaSeal (Medtronic) pull-back sequence

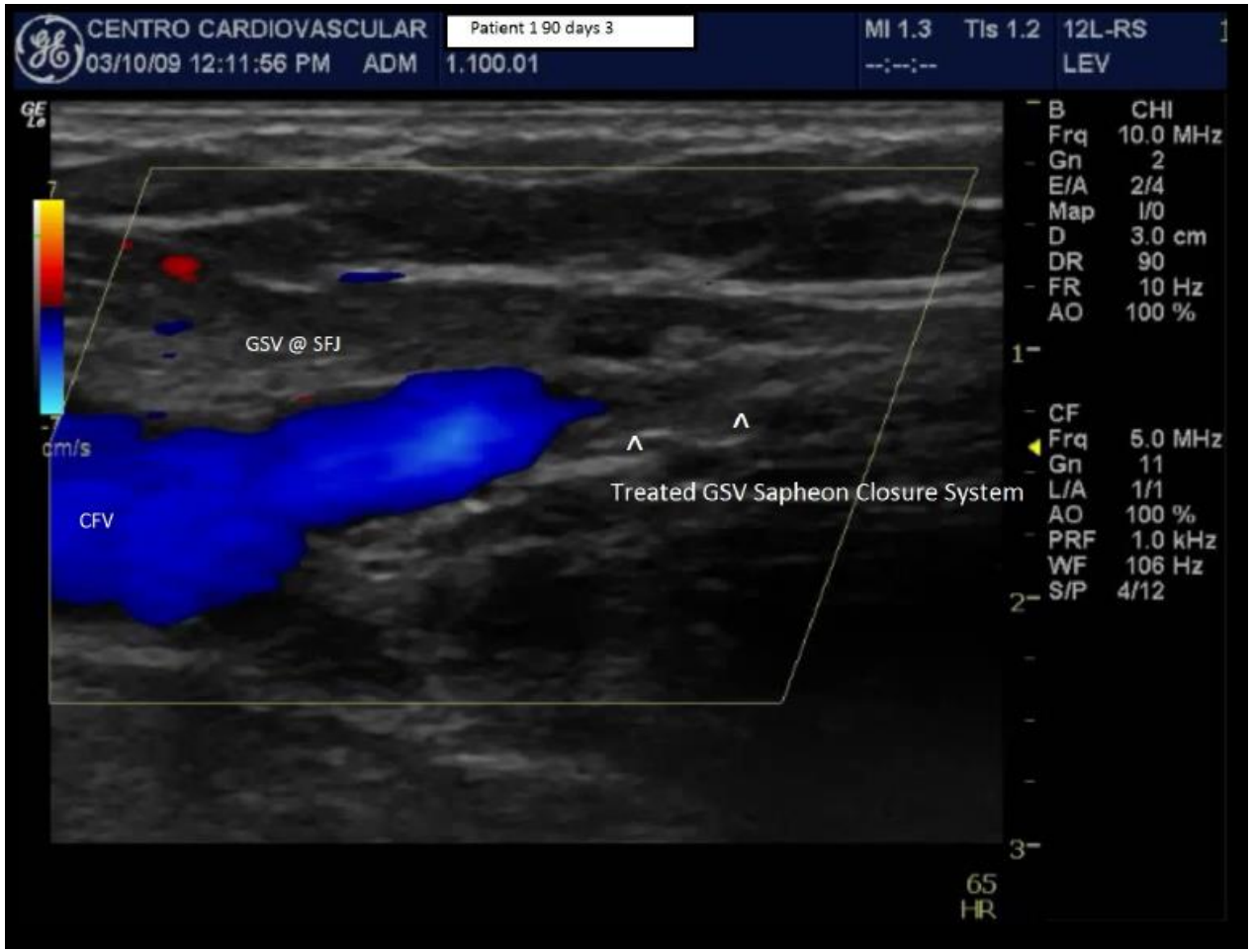
- Dispense further doses 3cm apart with 30 seconds pressure over each one (+/- ultrasound to localise)

Variclose (Biolas) pullback

Continuous pull back at 2cm per second
Squeeze trigger every 5 seconds/10cm



Treated Saphenofemoral Junction



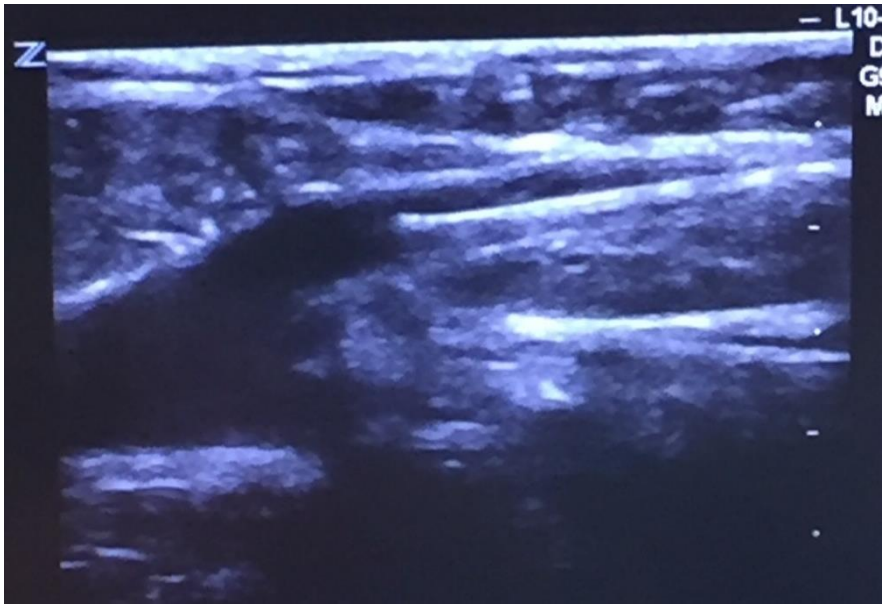
Timing of tributary treatment

Before

After (1week)

Pitfalls (Biolas)

- Bubbles in GSV from flushing air



Pitfalls (Biolas and Medtronic)

- Multiple trunks:
  - Potential to glue the catheter inside the introducer

Clinical data

- VenaSeal (Medtronic)
  - Lots of data
- Variclose (Biolas)
  - Little published data at present

Clinical Studies with the VenaSealSystem

Feasibility Study

- 38 Patients treated in 2011
- Safety and efficacy
- 92% closure maintained out to 3 years
- Improved VCSS

eSCOPE
(European multicenter study)

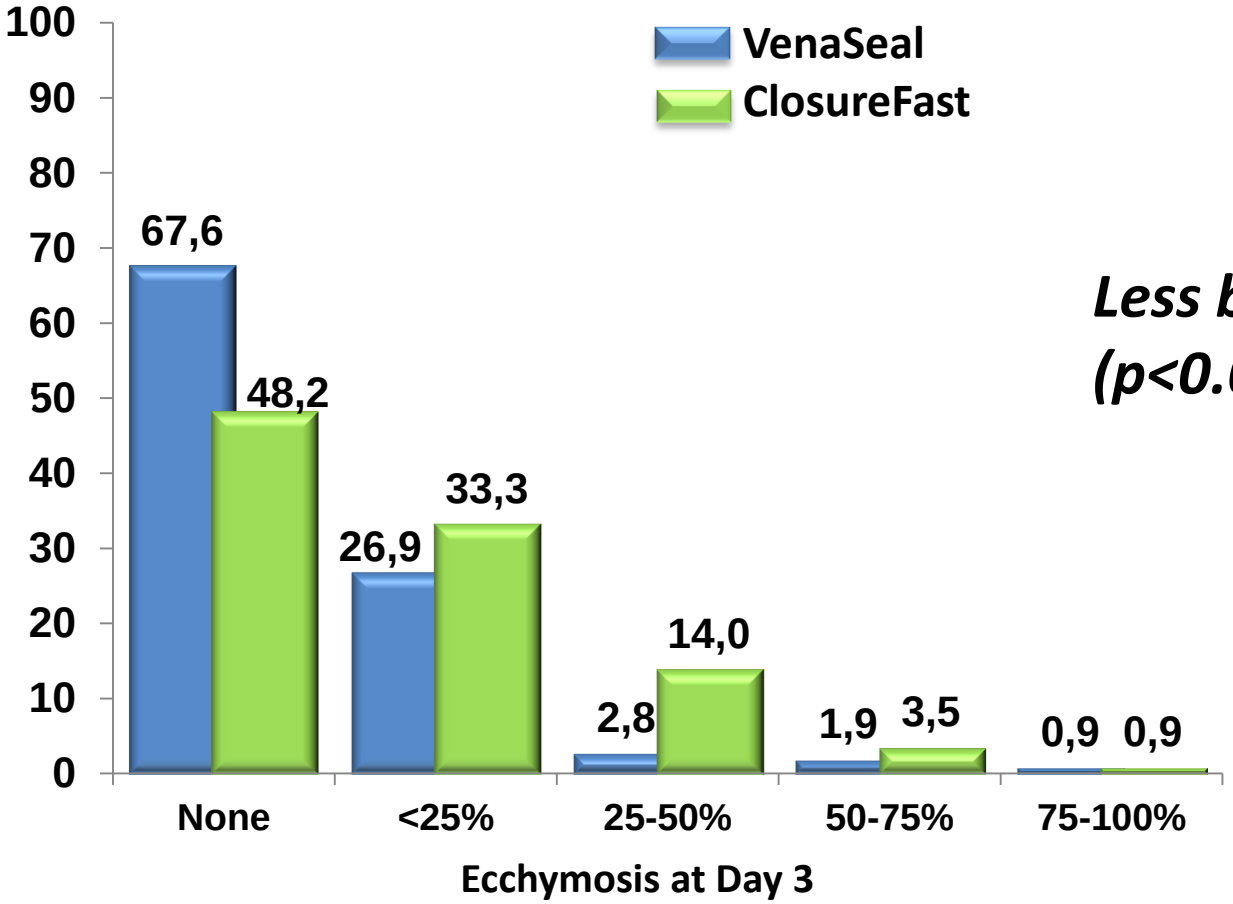
- 70 patients treated in 2012
- Primary endpoint: GSV closure at follow-up
- 93% occlusion at 1 year
- Improved VCSS

VeClose
(prospective RCT)

- 242 patients enrolled in 2013
- Primary endpoint: GSV closure at 3 months (non-inferiority study)
- Secondary endpoint: ecchymosis and patient-reported pain

VeClose RCT Results

Bruising at Day 3



Less bruising with glue (p<0.01)

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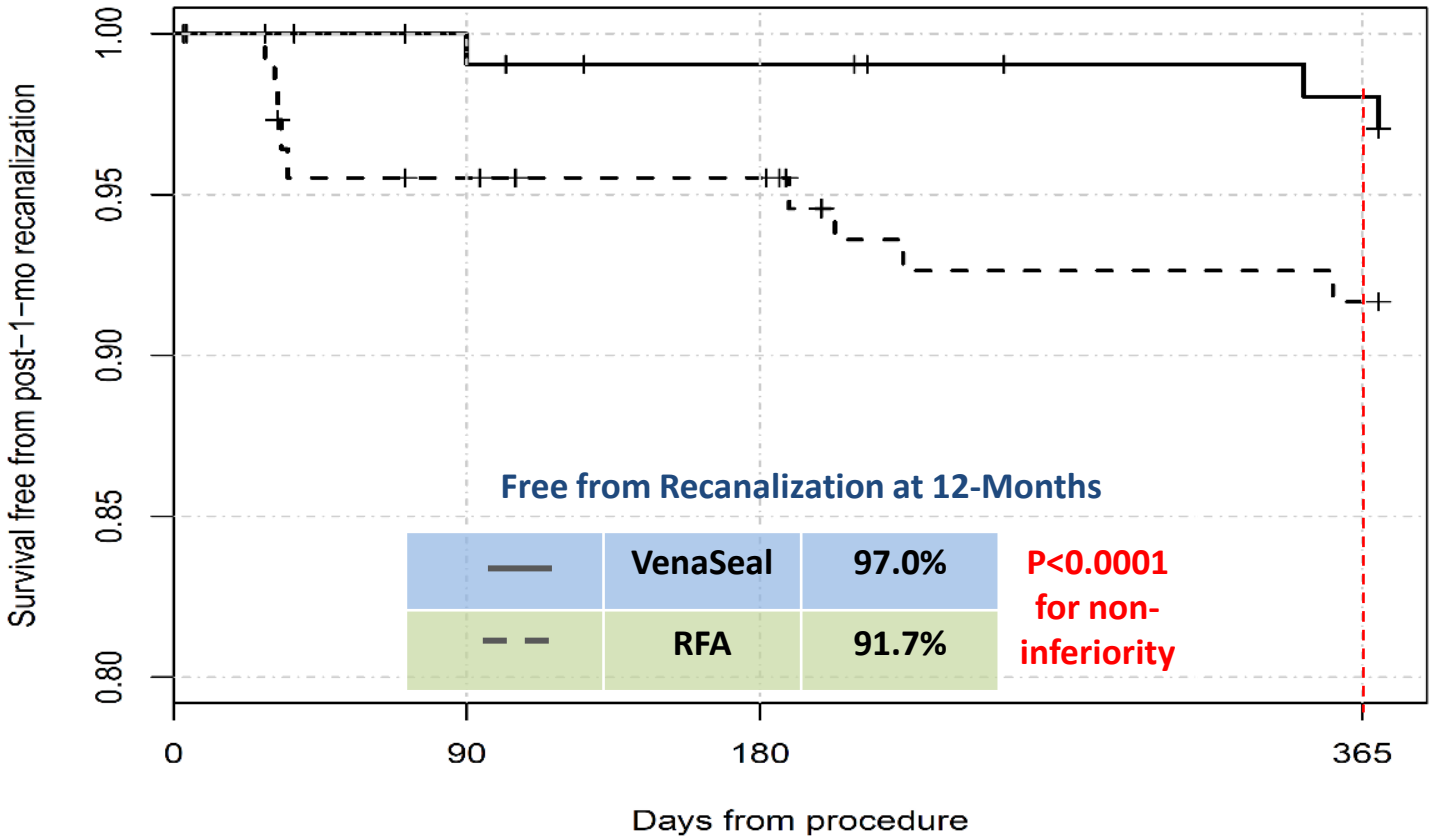
VeClose Results
3 Month Endpoint Data

Data supported non-inferiority of the VSCS procedure compared to RFA

3 Month Visit (CoreLab data)*	VenaSeal (N=108)	RFA (N=104)	P-value
	99%	**96%**	<0.01
Number with Non-Closure (>5cm)	1	5	

VeClose Results

Time to Recanalization of the Target Vein



Morrison N. 12-month Results of the VeClose Trial. European Venous Forum. 2015

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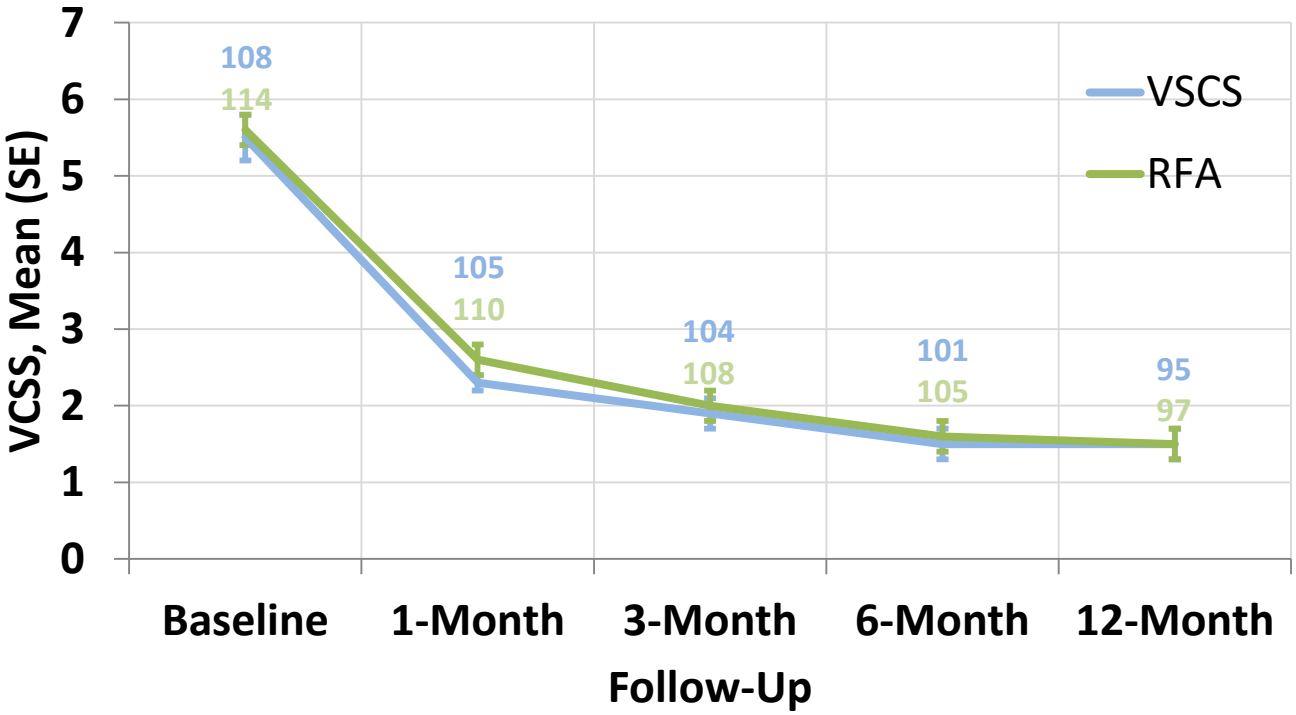
VeClose Results

VCSS Mean & (SD) by Visit and Treatment



(No adjuctive procedures before 3 months)

Morrison N. 12-month Results of the VeClose Trial. European Venous Forum. 2015

VeClose Results

Adverse Events Through 6-Months

NO SAEs were categorized as device- and/or procedure-related

	Venaseal (N=108)	RFA (N=114)	P-value
# Subjects with events (%)	34 (31%)	29 (25%)	NS
Reported AEs			
Phlebitis, any zone	22 (20.4%)	16 (14.0%)	0.3571
Phlebitis in treatment zone	11 (10.2%)	10 (8.8%)	0.8199
Phlebitis not in treatment zone	8 (7.4%)	4 (3.5%)	0.2430
Phlebitis in both treatment zone and non-treatment zone	1 (0.9%)	1 (0.9%)	1.0
Paresthesia in treatment zone	3 (2.8%)	3 (2.6%)	1.0
Stocking irritation	2 (1.9%)	3 (2.6%)	1.0
Access site infection	1 (0.9%)	1 (0.9%)	1.0
Superficial thrombophlebitis	4 (3.7%)	3. (2.6%)	0.7157
Access site burn	0 (0%)	1 (0.9%)	1.0
Paresthesia not in treatment zone	0 (0%)	1 (0.9%)	1.0
Paresthesia in treatment zone	3 (2.8%)	3 (2.6%)	1.0

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Variclose (Biolas) data (unpublished)

- Yasim et al
  - 180 patients
  - 3-7 month follow up, no recanalisations
  - VCSS reduced from mean of 10.2 to 3.9

- Calik et al
  - 181 patients
  - 97% occlusion at 6 months

Unpublished RCT: Bozkurt et al

- 310 patients randomised
- Variclose glue versus 1470 radial laser
- Primary endpoint: occlusion of target GSV anything over 5cm considered failure

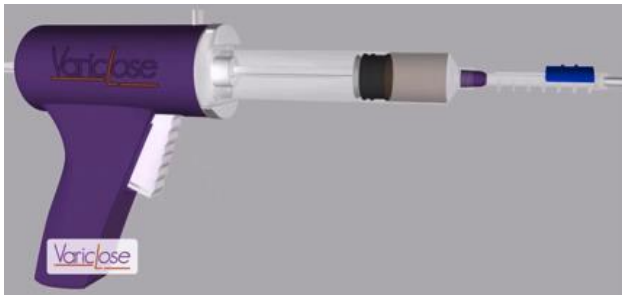
Unpublished RCT: Bozkurt et al

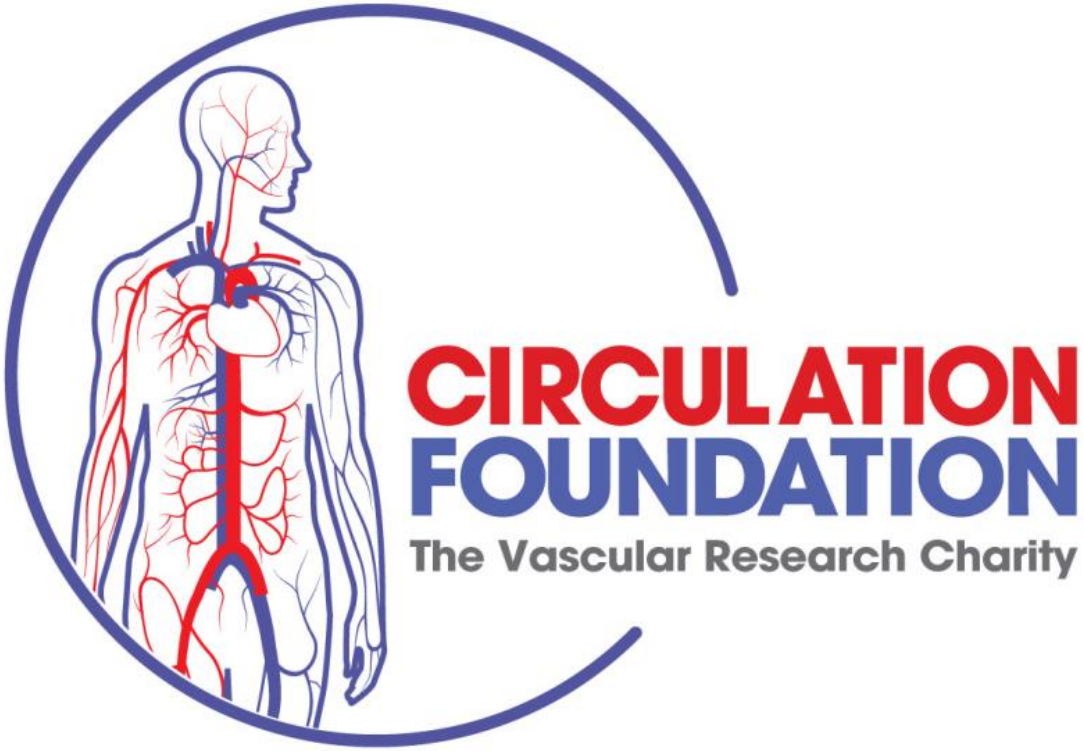
- Mean GSV diameter 7.2 mm
- Mean length treated 30 cm

- No serious adverse events
- 4% paraesthesia in EVLT group
- Closure rate: 92% EVLT and 95% glue at one year
- Similar VCSS and AVVQ improvement in both groups

Glue differences

- VenaSeal (Medtronic)
  - Viscous
  - Segmental pullback
  - Lots of data
- Variclose (Biolas)
  - Runny
  - Continuous pullback
  - Little data





CIRCULATION FOUNDATION

The Vascular Research Charity