

## Disclosure

Speaker name: G.Geroulakos

.....

I do not have any potential conflict of interest

# **EVLT & Phlebectomies vs ultrasound guided foam sclerotherapy. A randomised controlled trial.**

Lattimer C<sup>1</sup>

Azzam M<sup>1</sup>

Trueman P<sup>2</sup>

Kalodiki E<sup>1</sup>

Shawish E<sup>1</sup>

Geroulakos G<sup>1</sup>

<sup>1</sup> Josef Pflug Vascular Laboratory, Ealing Hospital & Imperial College, SW7 2AZ

<sup>2</sup> Health Economics Research Group, Brunel University, Middlesex, UB8 3PH

# Study Design

- Prospective, single centre, **RCT**
- **AIM:** Quantify differences between both treatment options in term of effectiveness, cost, complications and recovery.
- **80% power**, type I error 0.05, meta-analysis <sup>1</sup>, GSV recanalisation at 5 years: EVLT 4.6%; UGFS 26.5%
- Minimum 86 patients required

<sup>1</sup> **Bos van den R, et al. J Vasc Surg 2009;49:230-9.**

## **Inclusion criteria**

- Patients with 1° symptomatic varicose veins
- SFJ reflux (>0.5 sec) extending into >10cm GSV
- Suitability for both techniques: EVLT & UGFS

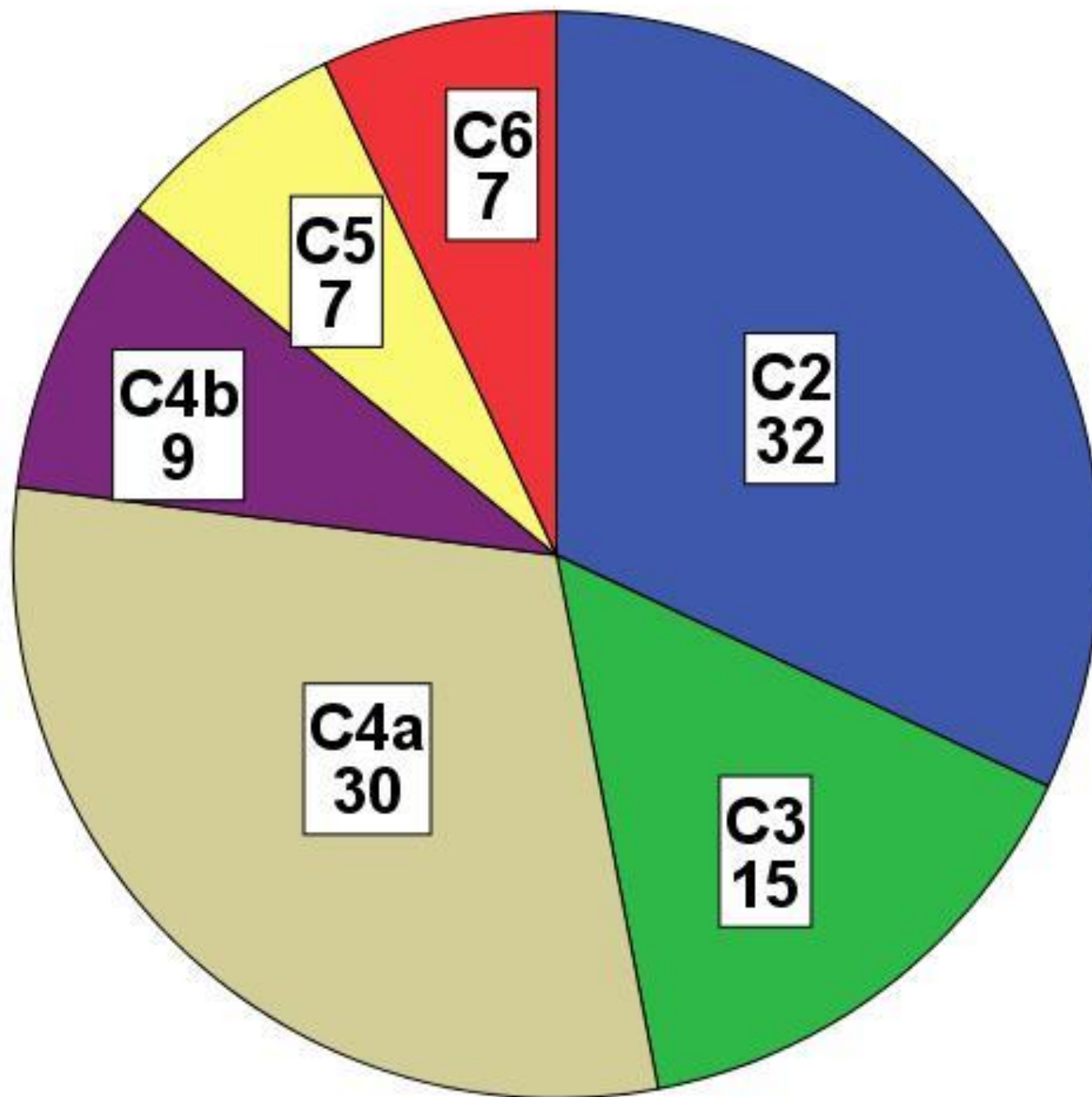
## **Exclusion criteria**

- Sapheno-popliteal junction incompetence
- Previous surgery or sclerotherapy
- Previous or current deep vein thrombosis / reflux
- Other: Coagulopathy, Arterial occlusive disease, Active malignancy, Pregnancy, Allergy to LA.

# Patient characteristics

	<i>EVLT</i>	<i>UGFS</i>	<i>P value</i>
Age	47 (21-74)	46 (22-78)	0.733
Female	31 (62%)	27 (54%)	0.423
Bilateral disease	28 (56%)	32 (64%)	0.419
VCSS	6 (2-20)	7 (3-17)	0.114
AVVQ	20 (1-53)	25 (4-50)	0.085
GSV Ø (mm)	7 (4-12)	8 (5-12)	0.115

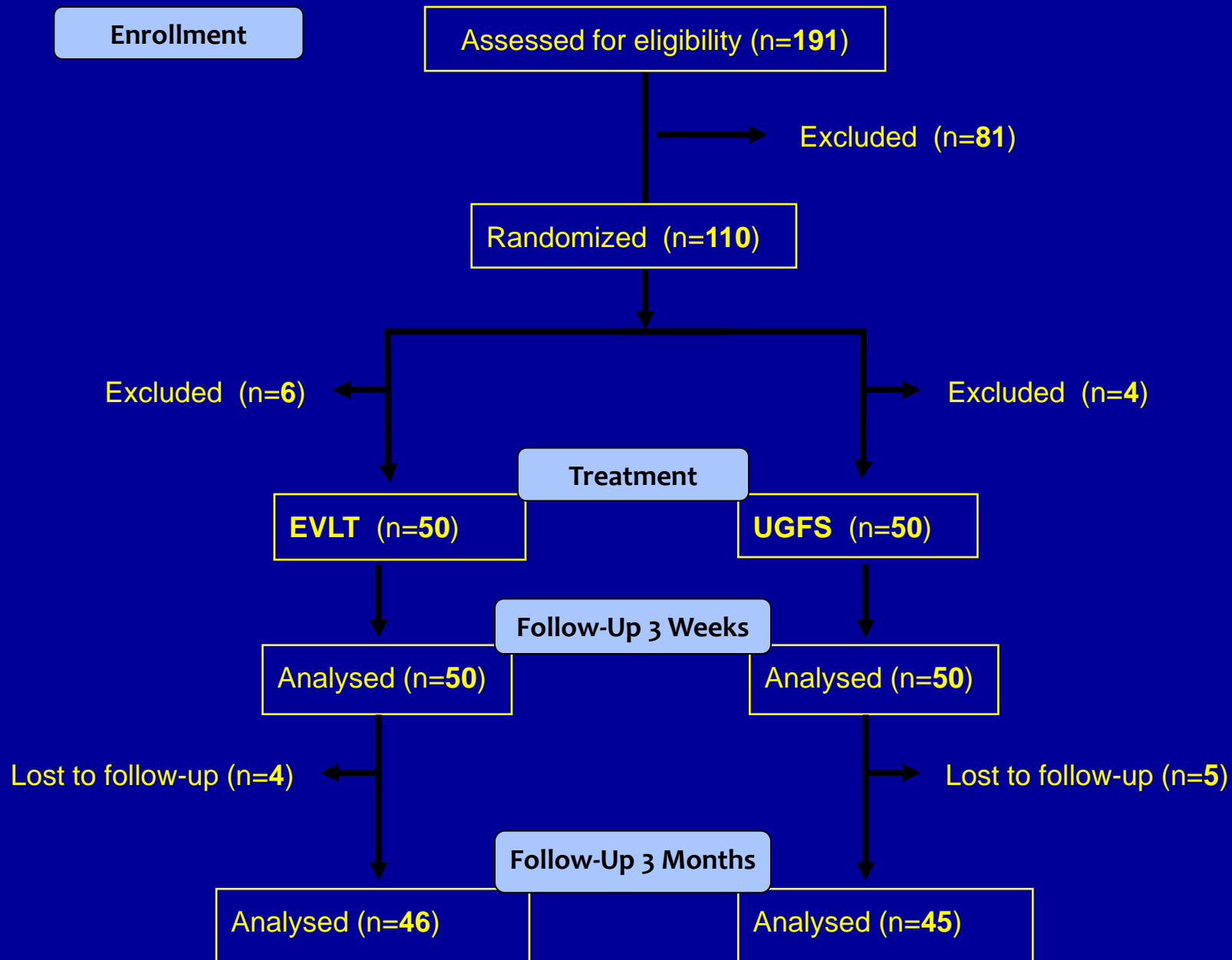
# C of CEAP



C2-6  
Ep  
As  
Pr

n = 100

# CONSORT Flow Diagram (Lattimer CR et al, 2012 EJVES 43: 594-600 )



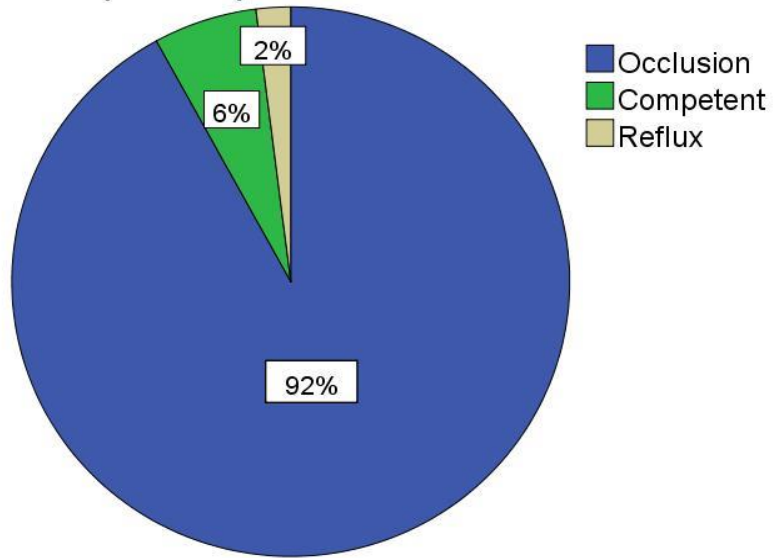
# Study Design 2

- **EVLT:** Day Theatres, ELVeS® PainLess 1470nm laser fibre
- **UGFS:** Outpatients, 12ml maximum 1% STS in air (1:5) into GSV
- **T-Foam:** Clinical room using tumescence and long-line cannulation GSV ( $\geq 8\text{mm } \varnothing$ )
- **Micro-costing:** Ground-up on timed treatments
- **F/U** 3/52 & 3/12. Up to 2 extra foam sessions, if required. EGC stocking 3/52.

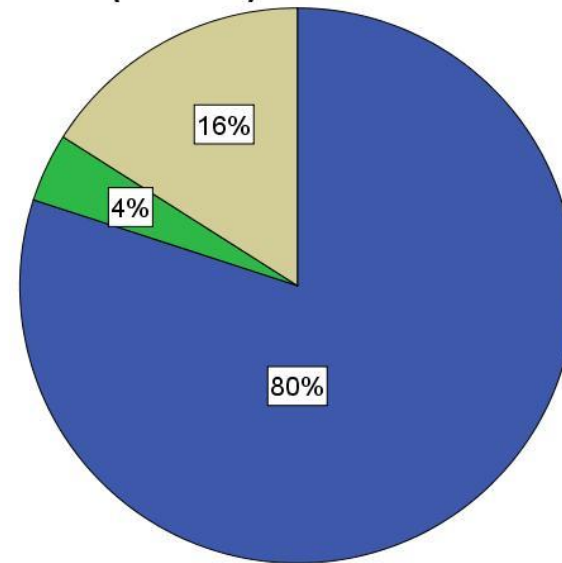


# Duplex Outcomes: AK GSV

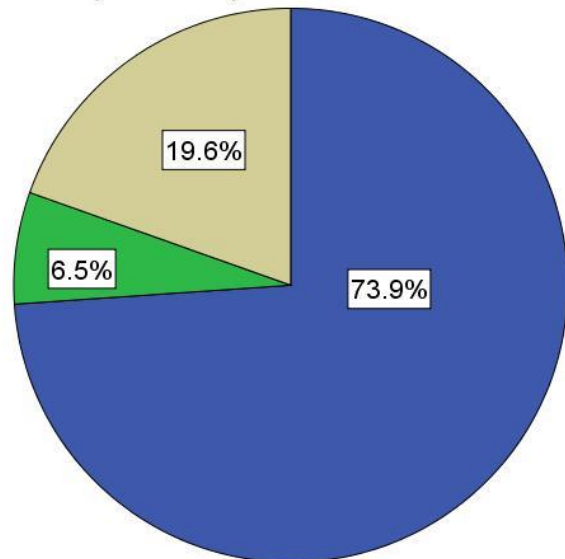
**EVLT (3 weeks)**



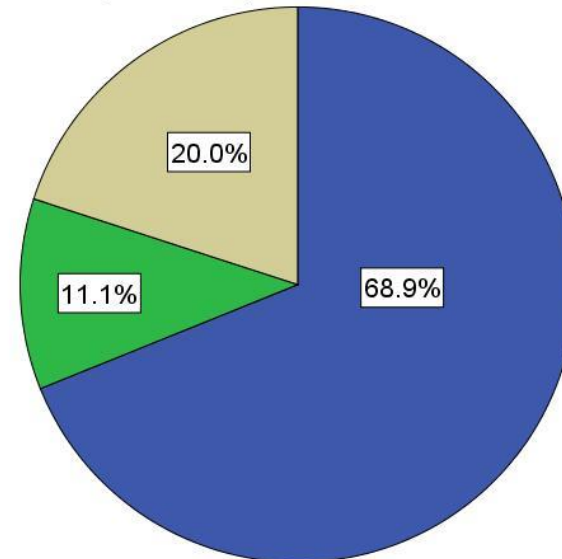
**UGFS (3 weeks)**



**EVLT (3 months)**

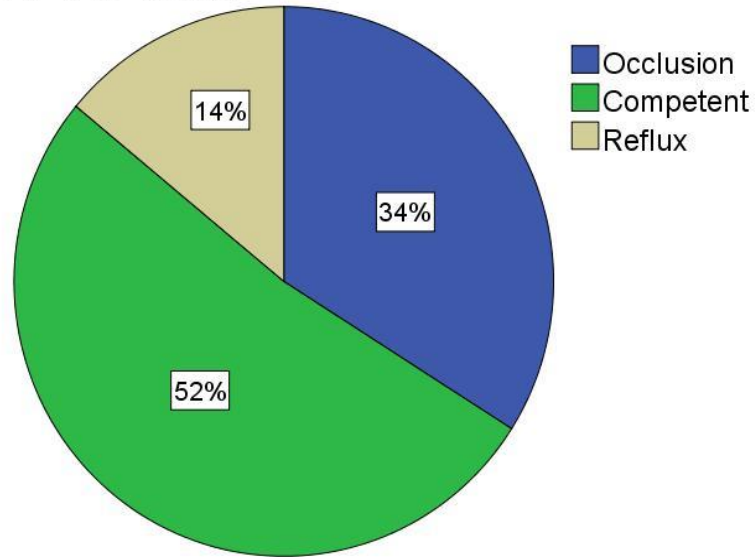


**UGFS (3 months)**

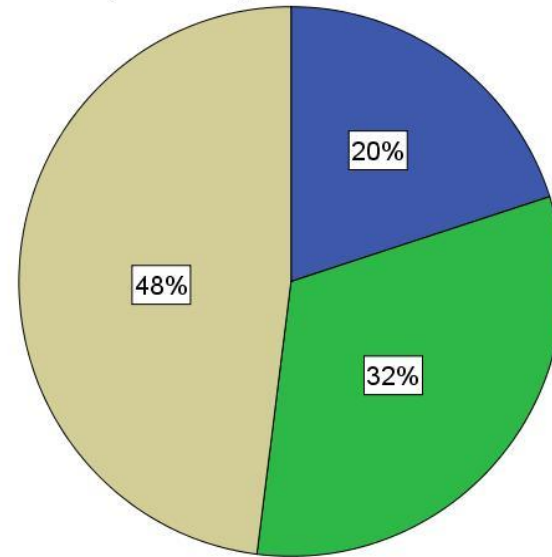


# Duplex Outcomes: BK GSV

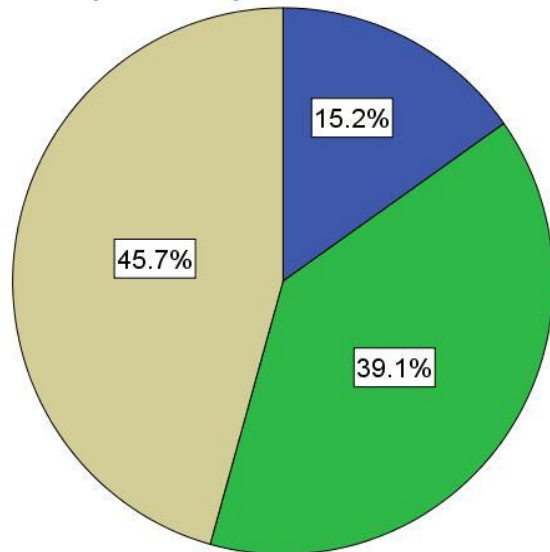
**EVLT (3 weeks)**



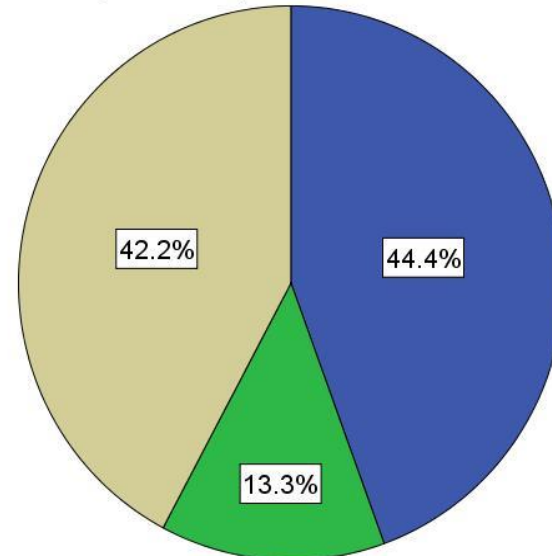
**UGFS (3 weeks)**



**EVLT (3 months)**

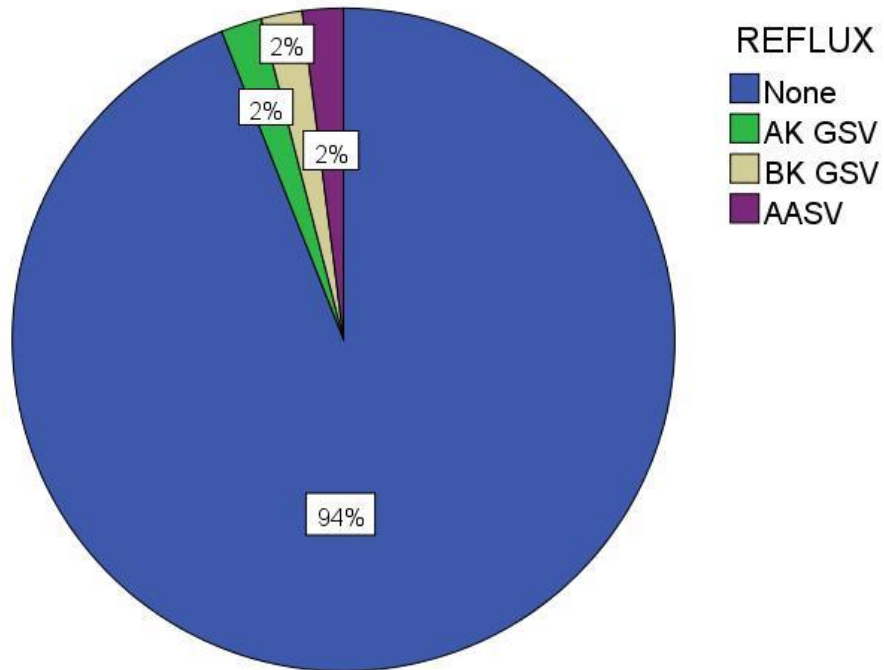


**UGFS (3 months)**

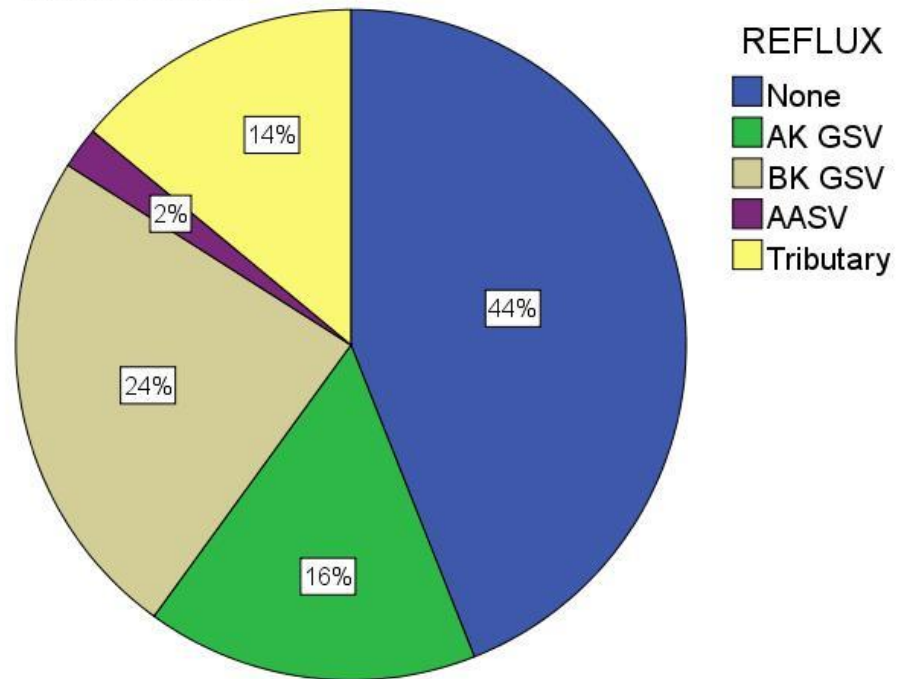


# Duplex Findings in Patients Receiving Additional Foam

EVLT GROUP



UGFS GROUP



Number of patients with side-effects or complications.

Patient Event	EVLA Group	UGFS Group
DVT (30% <sup>a</sup> DVT into Common Femoral Vein)	1	
GSV thrombosis (both re-attended)	1	1
GSV saccular thrombosis (1 re-attended)		3
Tributary thrombosis	1	4
Groin haematoma (1 treated by family doctor)	2	
Dermal thermal injury (1 re-attended)	2	
Phlebectomy granuloma	1	
Severe procedural pain (1 required a GA)	3	
Headache/cough/dizziness (procedural)		4
Shingles (viral reactivation)		1
Vasovagal episode (procedure re-scheduled)		1
Severe stocking discomfort (re-attended)		1

<sup>a</sup> Deep vein thrombosis which disappeared within 8 weeks on oral Warfarin.

# Staff pay per minute (£)

	<i>EVLT</i>	<i>T-UGFS</i>	<i>UGFS</i>
Surgeon (SPR)	0.83	0.83	0.83
Duplex (MA)		0.56	0.56
Assistant (F2)	0.50		
Nurse (b6)	0.40		
Nurse (b5)	0.33	0.33	
HCA (b2)	0.21		
<b>Subtotal A</b>	<b>2.27</b>	<b>1.72</b>	<b>1.39</b>

# Consumables (£)

	<i><b>EVL</b></i>	<i><b>T-UGFS</b></i>	<i><b>UGFS</b></i>
Laser Kit	235.00		
Thigh stocking		27.57	27.57
Micropuncture set	20.23		
Central line		16.33	
Foam (STS)		10.25	10.25
Basic Set	10.00		
Tumescent tubing	6.00	6.00	
Velband & Crepe	3.78		
Sterilization	2.77		
Needles	1.12	1.12	
<b>Subtotal B</b>	<b>278.90</b>	<b>61.27</b>	<b>37.82</b>

# Summary Cost (£)

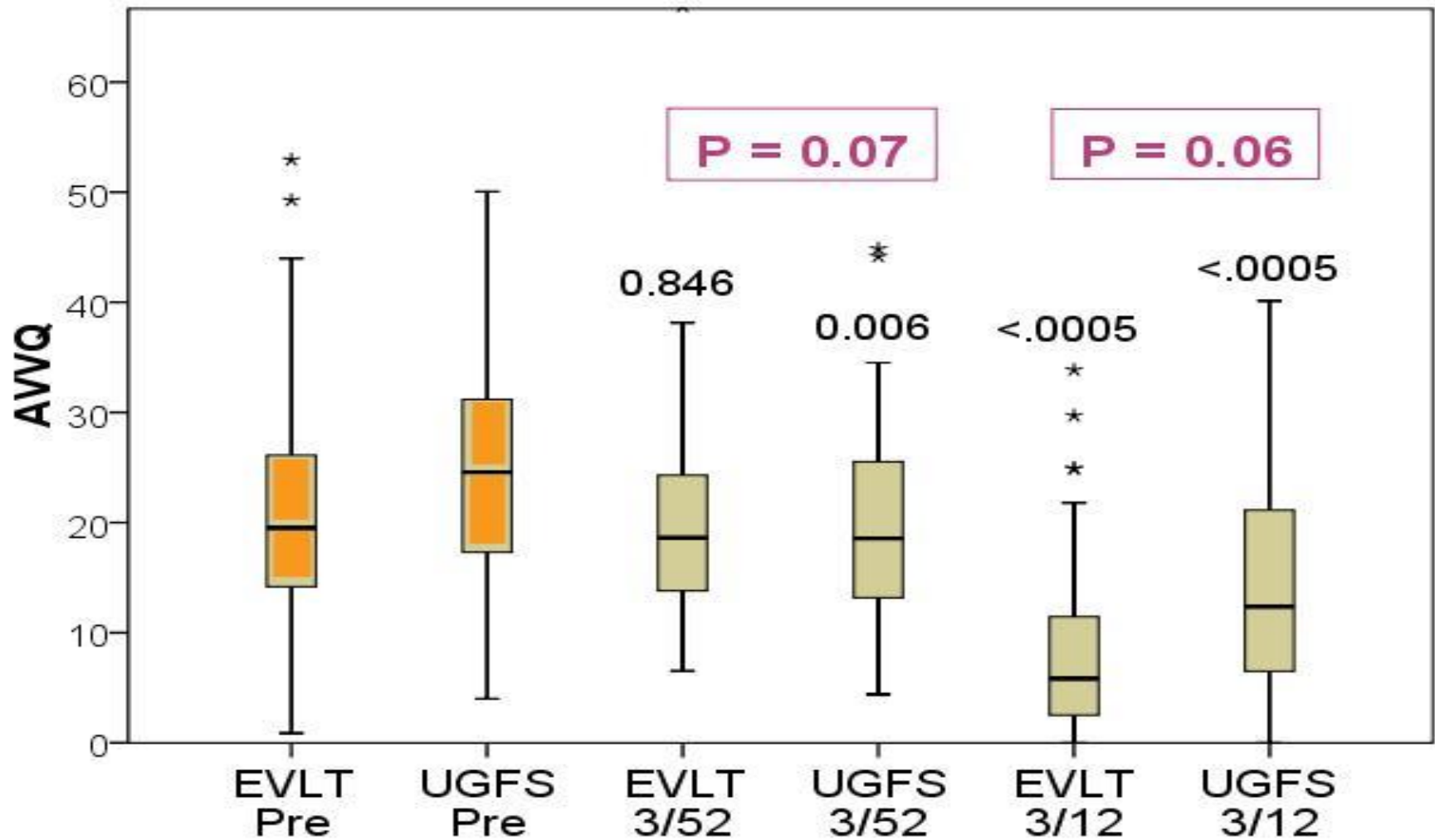
		<i>EVLT</i>	<i>T-UGFS</i>	<i>UGFS</i>
Holding Area				
	£11.40 / hour	45.60	22.80	11.40
Overheads				
	Theatre (£/min)	2.30		
	Percent (15%)		x 1.15	x 1.15
Summary				
	Fixed Cost (£)	324.50	84.07	49.22
	Variable Cost (£/min)	4.57	1.72	1.39
	Median treatment (min)	85	48	27
	<b>Grand Total (£)</b>	<b>712.95</b>	<b>191.62</b>	<b>99.76</b>

# Sensitivity Cost Analysis

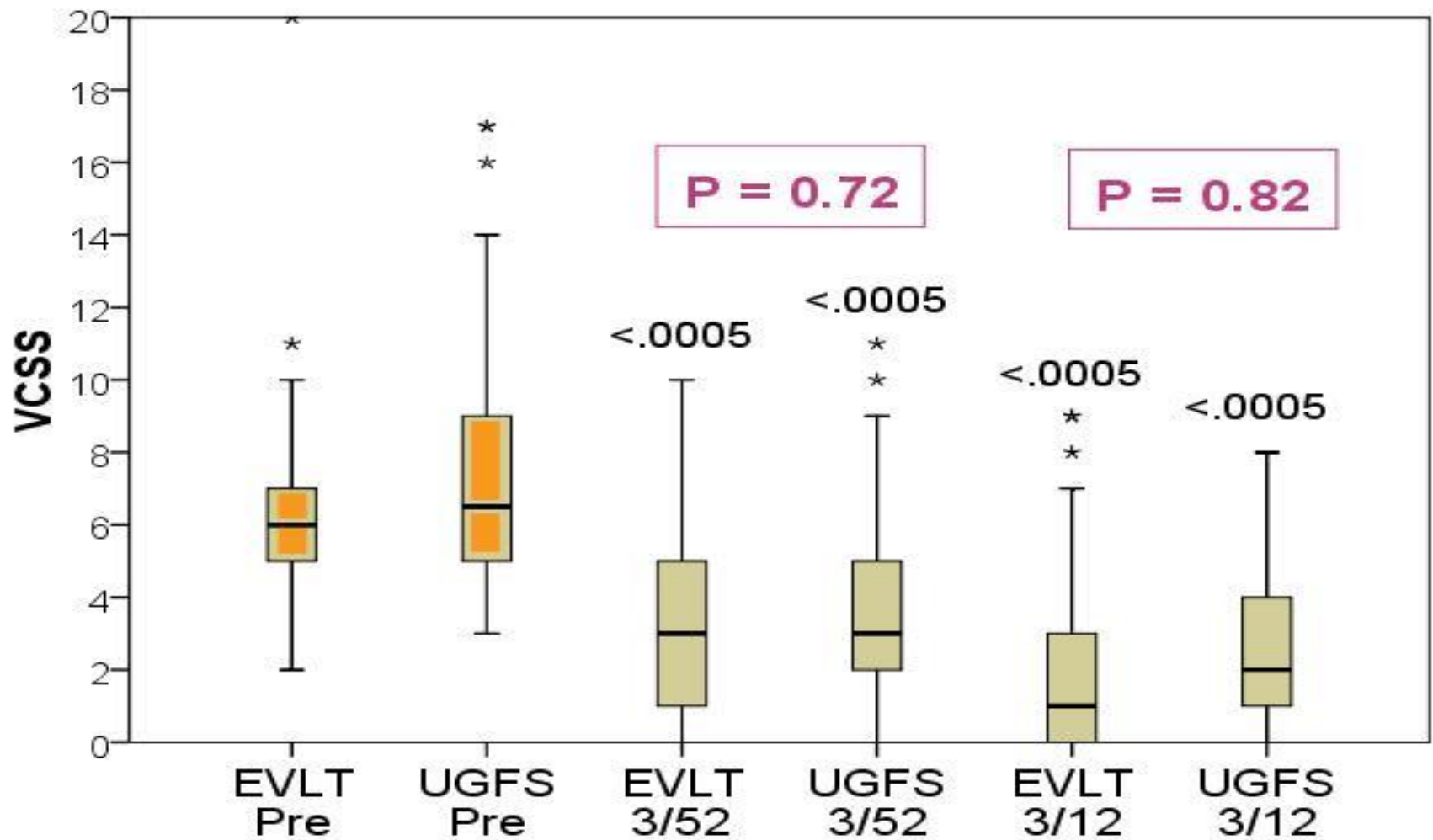
- Change of EVLT location
  - £595.07 ( $((2.27 \times 85) + 324.50) \times 15\%$ )
- Removal of trainee from EVLT
  - £670.45  $((4.07 \times 85) + 324.50)$
- Additional foam sessions
  - £718.94 per person for EVLT (3 more)
  - £231.84 per person for UGFS (33 more)



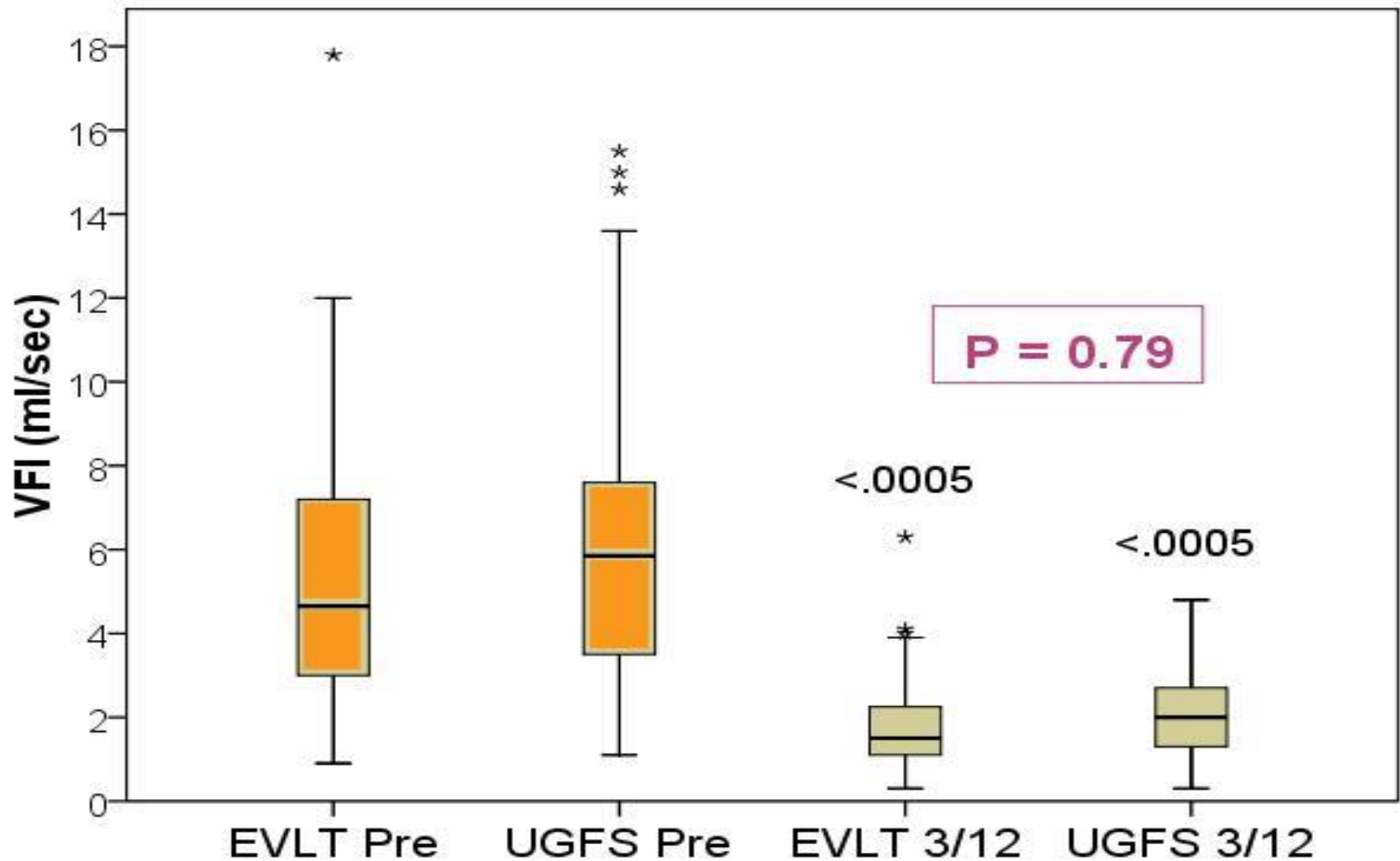
# AVVQ Improvements



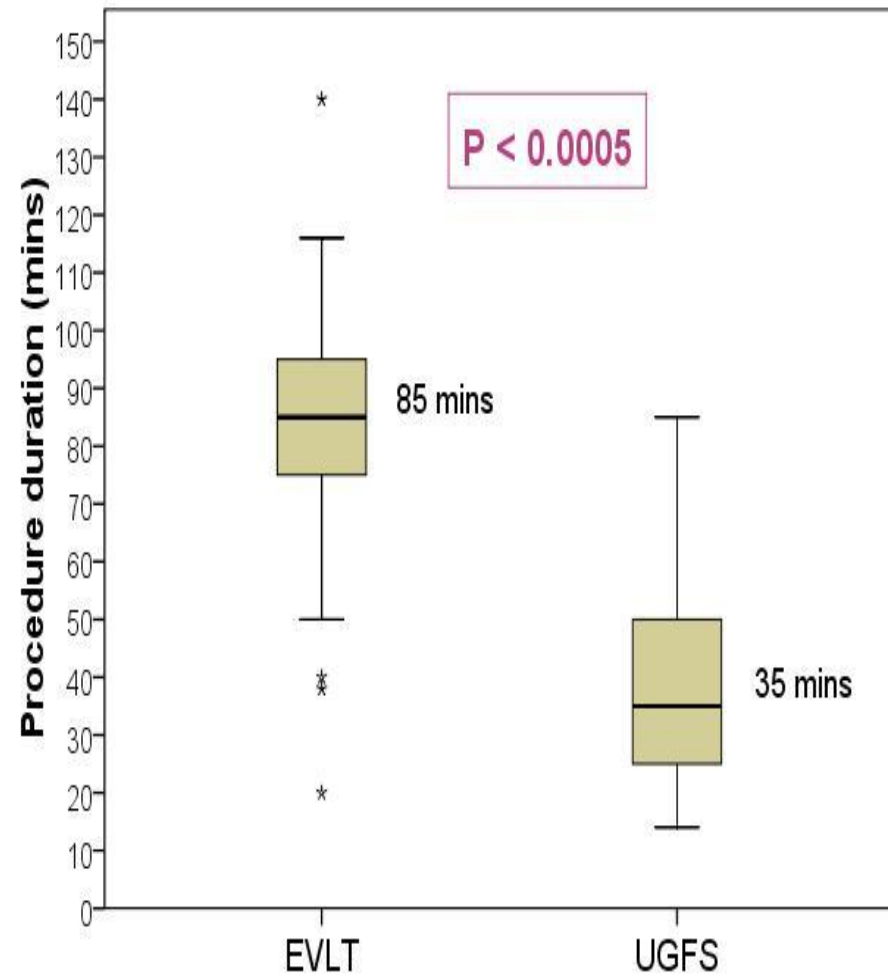
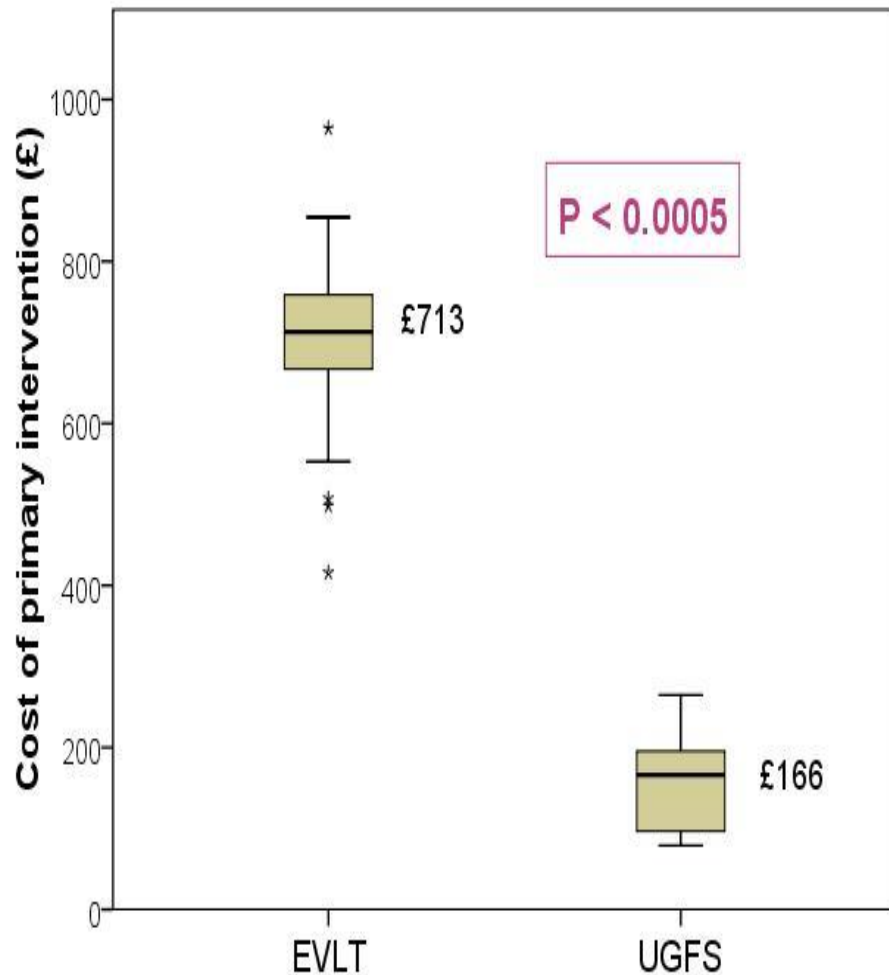
# VCSS Improvements



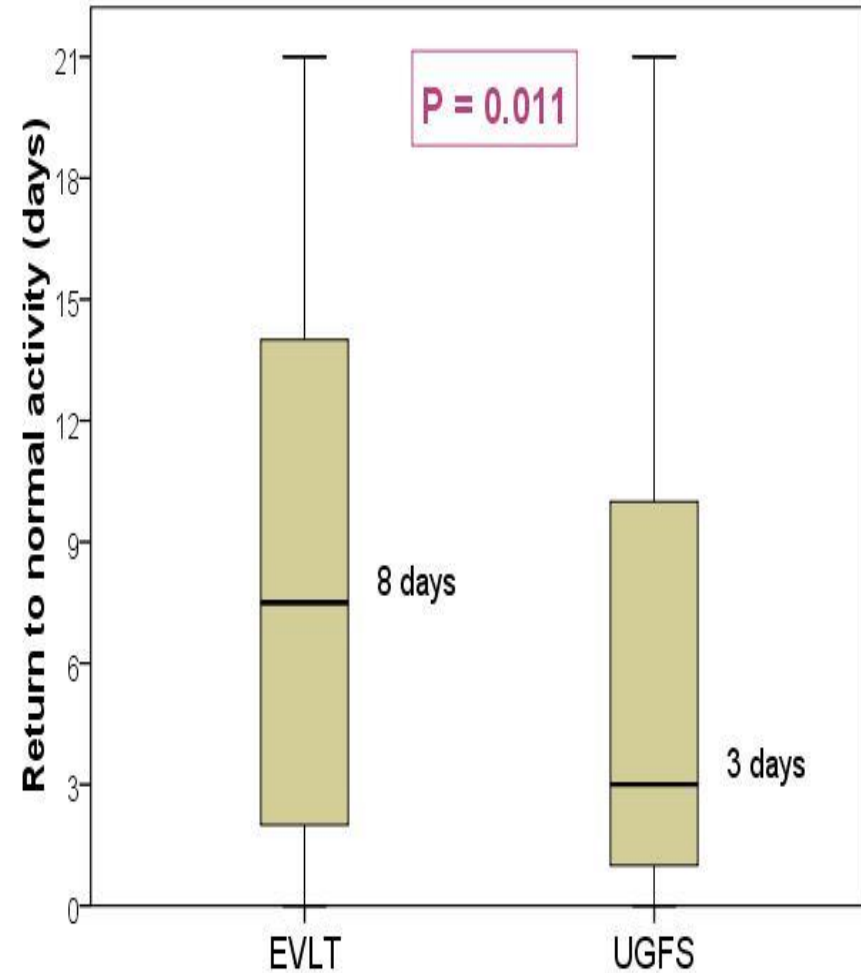
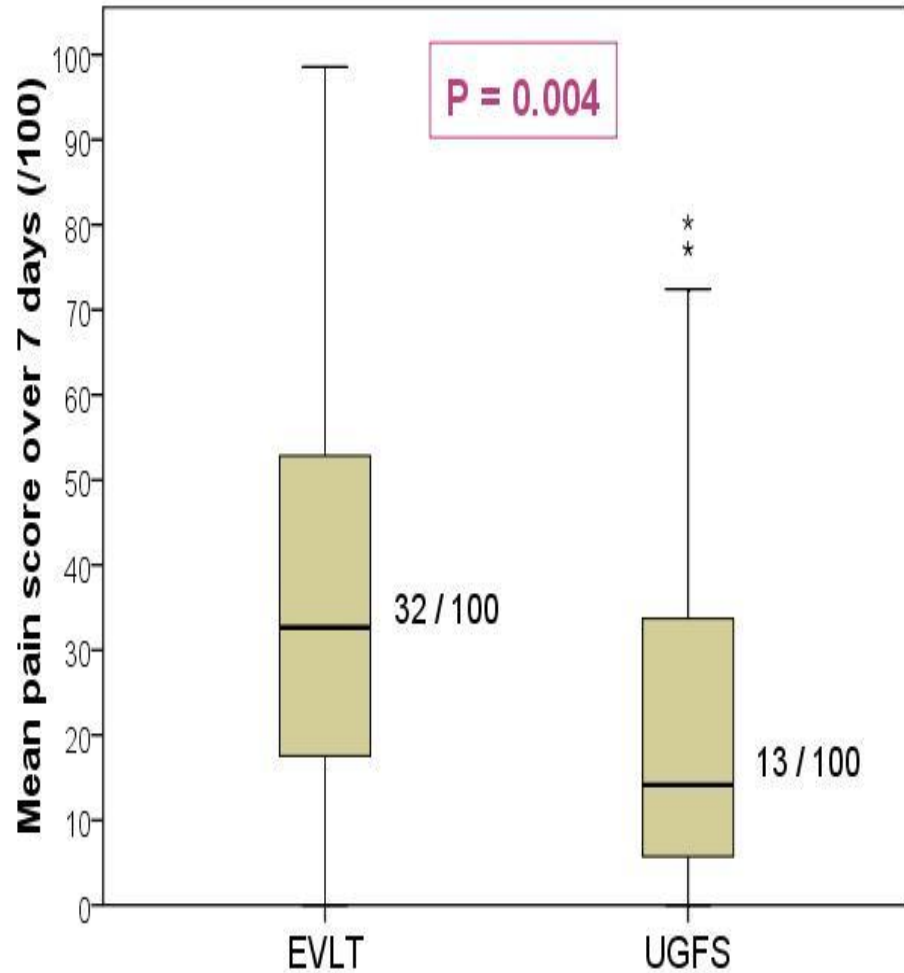
# VFI Improvements



# Cost & Procedure Duration

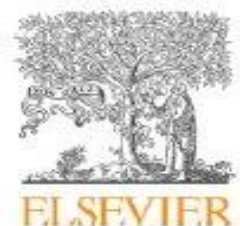


# Pain & Return to Normal



# Conclusions

1. EVLT is over 7 times more expensive than standard UGFS in outpatients
2. Cost differences remain after a sensitivity analysis
3. UGFS is equivalent to EVLT (3/12) in terms of reflux obliteration, QoL, clinical improvements and VFI
4. UGFS outperforms EVLT in terms of pain, analgesia requirements & return to normal



## Cost and Effectiveness of Laser with Phlebectomies Compared with Foam Sclerotherapy in Superficial Venous Insufficiency. Early Results of a Randomised Controlled Trial<sup>☆</sup>

C.R. Lattimer<sup>a,\*</sup>, M. Azzam<sup>a</sup>, E. Kalodiki<sup>a</sup>, E. Shawish<sup>a</sup>, P. Trueman<sup>b</sup>, G. Geroulakos<sup>a</sup>

<sup>a</sup>Josef Pflug Vascular Unit, Ealing Hospital & Imperial College, London SW7 2AZ, UK

<sup>b</sup>Health Economics Research Group, Brunel University, Middlesex, UB8 3PH, UK

### 3 MONTHS

GSV occlusion rate: **EVLA 89%**    **UGFS 78%**

GSV occlusion without reflux: **EVLA 74%**    **UGFS 69%**

**Interim = 15 MONTHS ?**

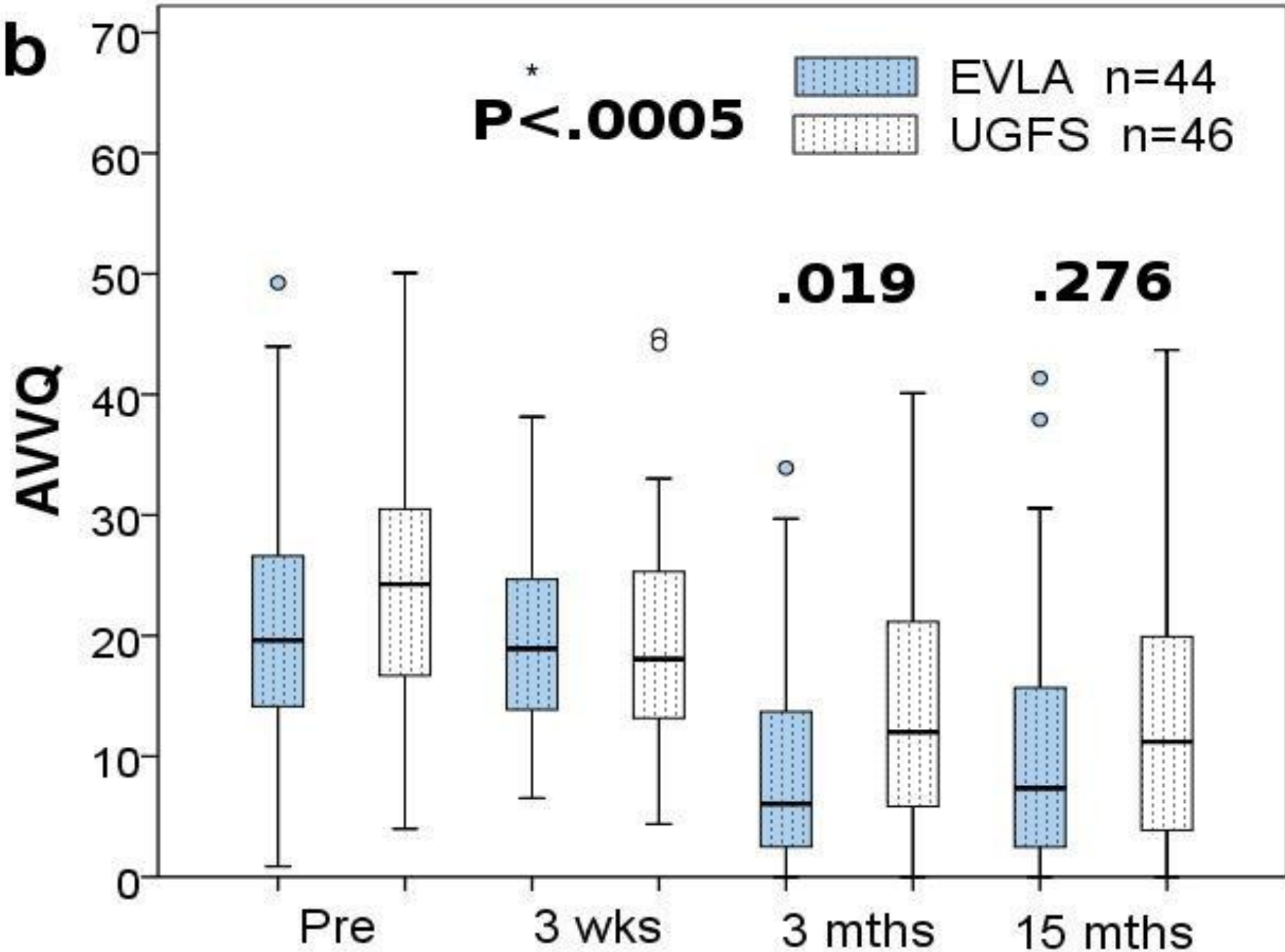
# Great saphenous vein outcomes

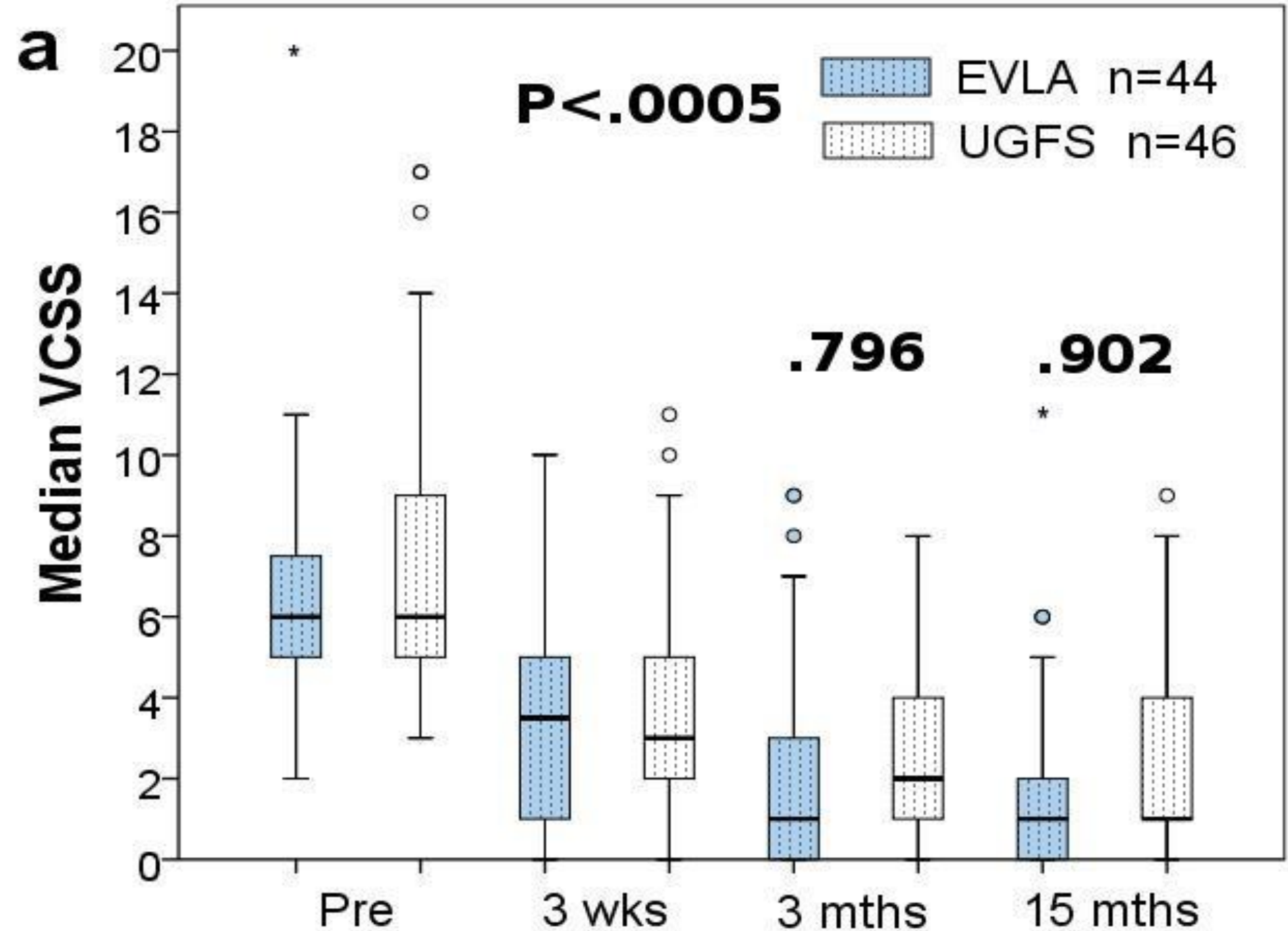
<i>DUPLEX OUTCOME (15 months)</i>	<i>EVLA n = 44</i>	<i>UGFS n = 46</i>	<i>P value</i>
GSV occlusion at some point in the thigh	42 (95.5%)	31 (67.4%)	0.001
GSV occlusion of entire thigh length	35 (80%)	24 (52.2%)	0.011
GSV occlusion thigh and upper 1/3 calf	9 (20.5%)	9 (19.6%)	1.000
GSV occlusion without refluxing segments	29 (65.9%)	24 (52.2%)	0.267
GSV competency of entire thigh length	2 (4.5%)	9 (19.6%)	0.059
Addition of last 2 rows	31 (70.4%)	33 (71.7%)	1.000

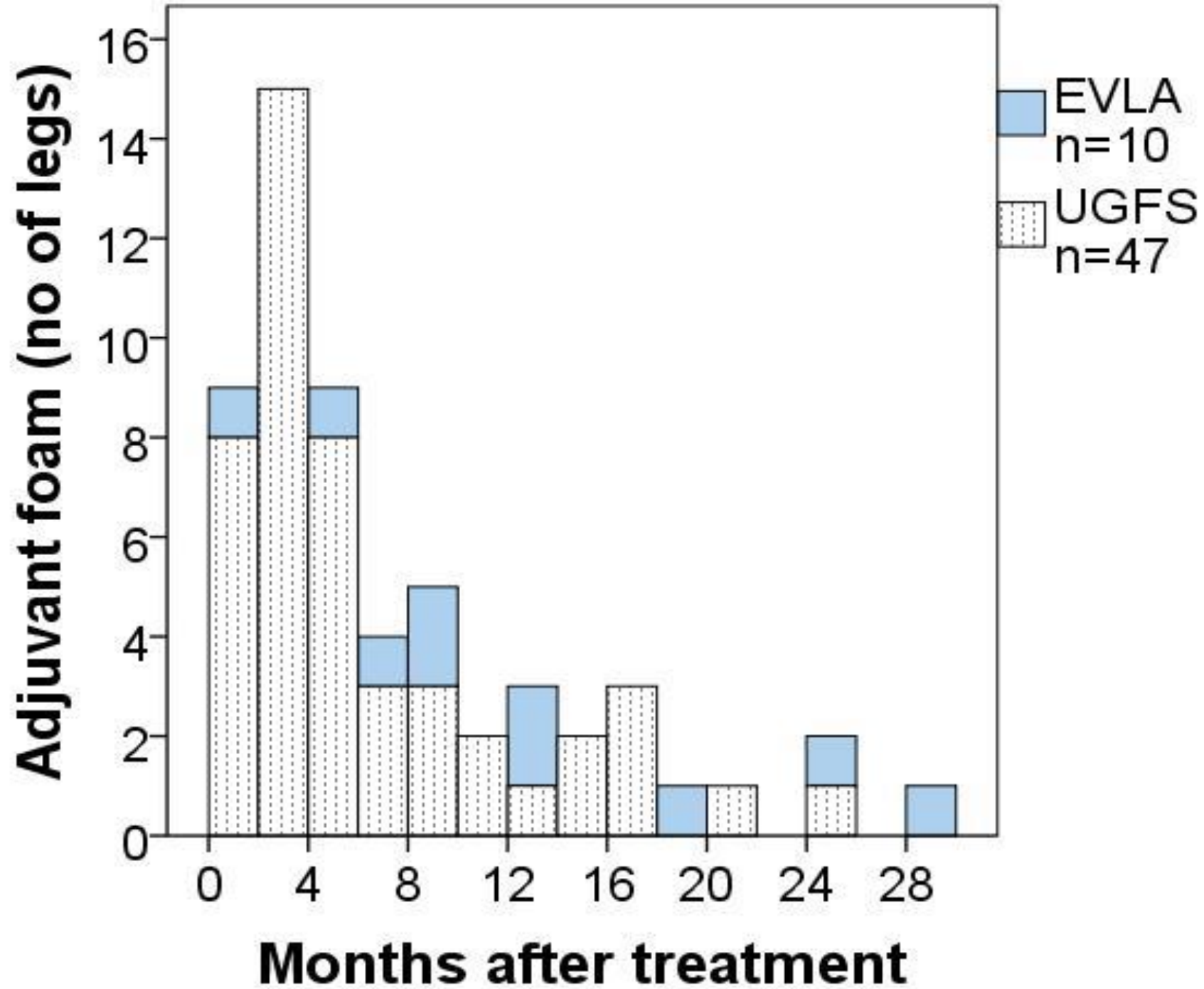


Global abolition of reflux in saphenous veins, varicose tributaries and perforators at 15 months.

- EVLA 43%
- UGFS 41%

**b**





# Conclusions

1. GSV occlusion was better with EVLA
2. EVLA  $\equiv$  UGFS at  
Saphenous & Global reflux abolition
3. QoL and severity scores equivalent
4. Remaining reflux was mostly  
symptomless