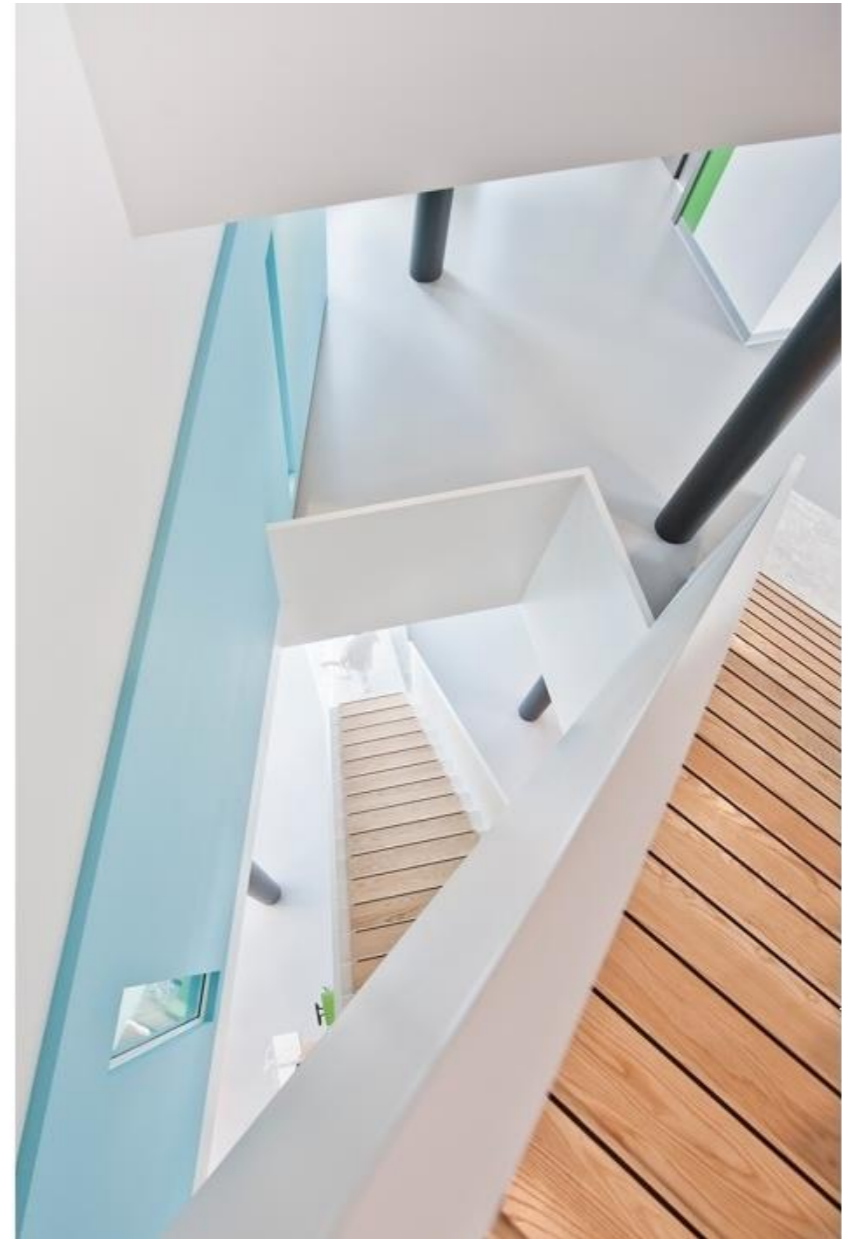


Varico 2 study

Radial EVLA vs ClosureFAST
of incompetent GSV
3-4 years follow-up

James Lawson



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Disclosure

Speaker name:

..James Lawson.....

I have the following potential conflicts of interest to report:

Unrestricted Grant Biolitec for Scientific Research : Tomy study



ELSEVIER



Randomised Controlled Trial Comparing Sapheno-Femoral Ligation and Stripping of the Great Saphenous Vein with Endovenous Laser Ablation (980 nm) Using Local Tumescant Anaesthesia: One Year Results

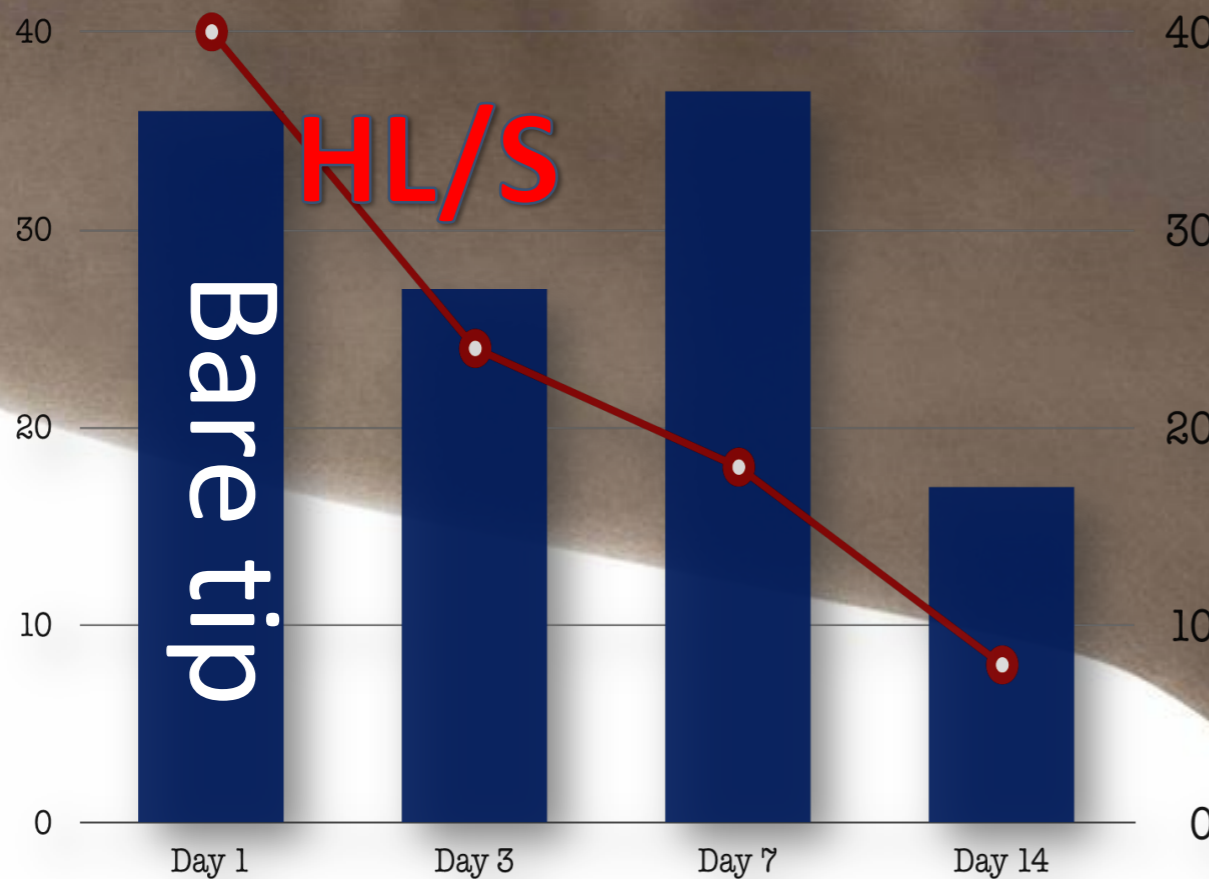
P. Pronk ^{a,*}, S.A. Gauw ^a, M.C. Mooij ^a, M.T.W. Gaastra ^a, J.A. Lawson ^a, A.R. van Goethem ^b, C.J. van Vlijmen-van Keulen ^a

^aFlebologisch Centrum Oosterwal, Overkrocht 10, 1815 KX Alkmaar, The Netherlands
^bBraam Kliniek, Assen, The Netherlands

Submitted 30 January 2010; accepted 2 August 2010

12 watt 50-70 joules/cm

Painscores EVLA > HL/S



Five-year follow-up of a randomized, controlled trial comparing saphenofemoral ligation and stripping of the great saphenous vein with endovenous laser ablation (980 nm) using local tumescant anesthesia

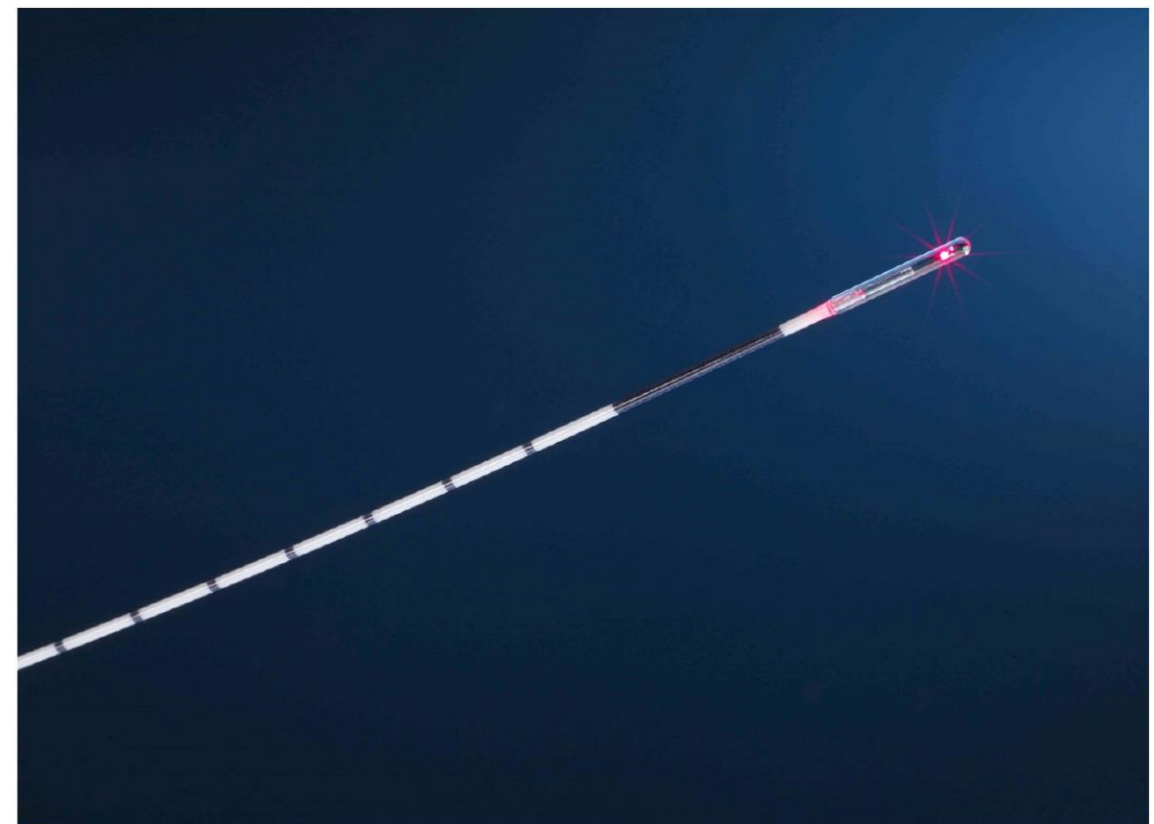
Stefanie A. Gauw, CRC, James A. Lawson, MD, PhD, Clarissa J. van Vlijmen-van Keulen, MD, PhD, Pascal Pronk, MD, Menno T. W. Gaastra, MD, and Michael C. Mooij, MD, Alkmaar, The Netherlands

Journal of Vascular Surgery Feb 2016 : Volume 63, Issue 2, Pages 420–428

More patient friendly alternatives than bare fibre



RFA ClosureFast



Radial 1470nm Laser

Recovery Study ClosureFast vs Bare Fibre

Significant less postoperative pain ,bruising and complications after ClosureFAST vs EVLA procedure
Better VCSS and QOL after ClosureFAST

Almeida JJ, Kaufman J, Göckeritz O, Chopra P, Evans MT, Hoheim DF, et al.
Journal of vascular and interventional radiology : JVIR. 2009 Jun;20(6):752–9.

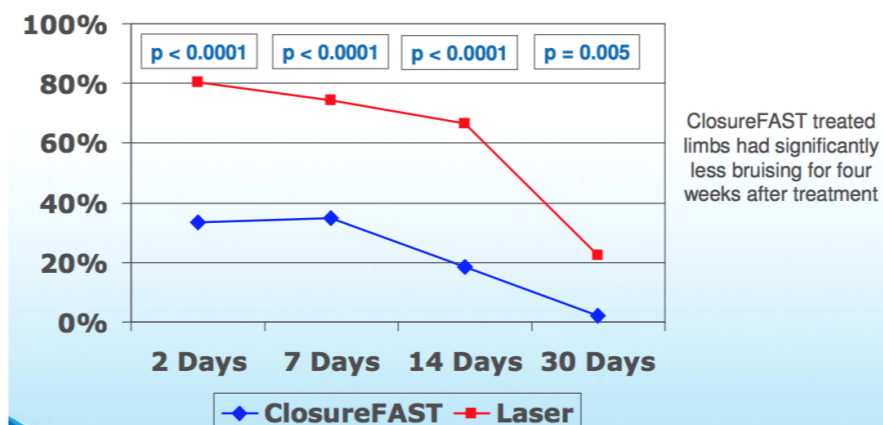
Pain Score at Follow Up Visits

(Scale: 0 none to 10 max)



Ecchymosis

Presence of Any Ecchymosis (Bruising)



ClosureFAST treated limbs had significantly less bruising for four weeks after treatment

Pain Following 980-nm Endovenous Laser Ablation and Segmental Radiofrequency Ablation for Varicose Veins: A Prospective Observational Study

A. C. Shepherd, M. S. Gohel, L. C. Brown, M. J. Metcalfe, M. Hamish and A. H. Davies

Vascular and Endovascular Surgery, Vol. 44, No. 3, 212-216 (2010)

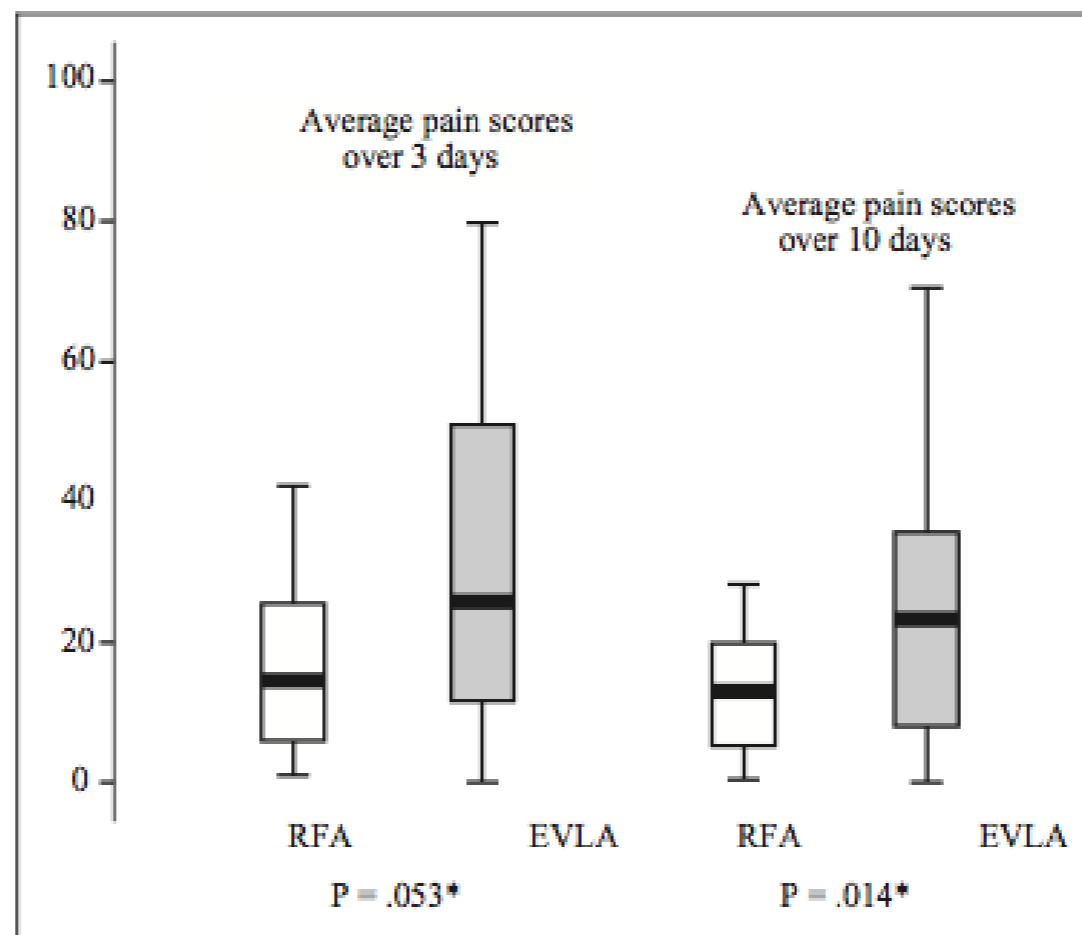


Figure 2. Box plots showing average pain scores 3 and 10 days following radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). *Mann-Whitney U test.

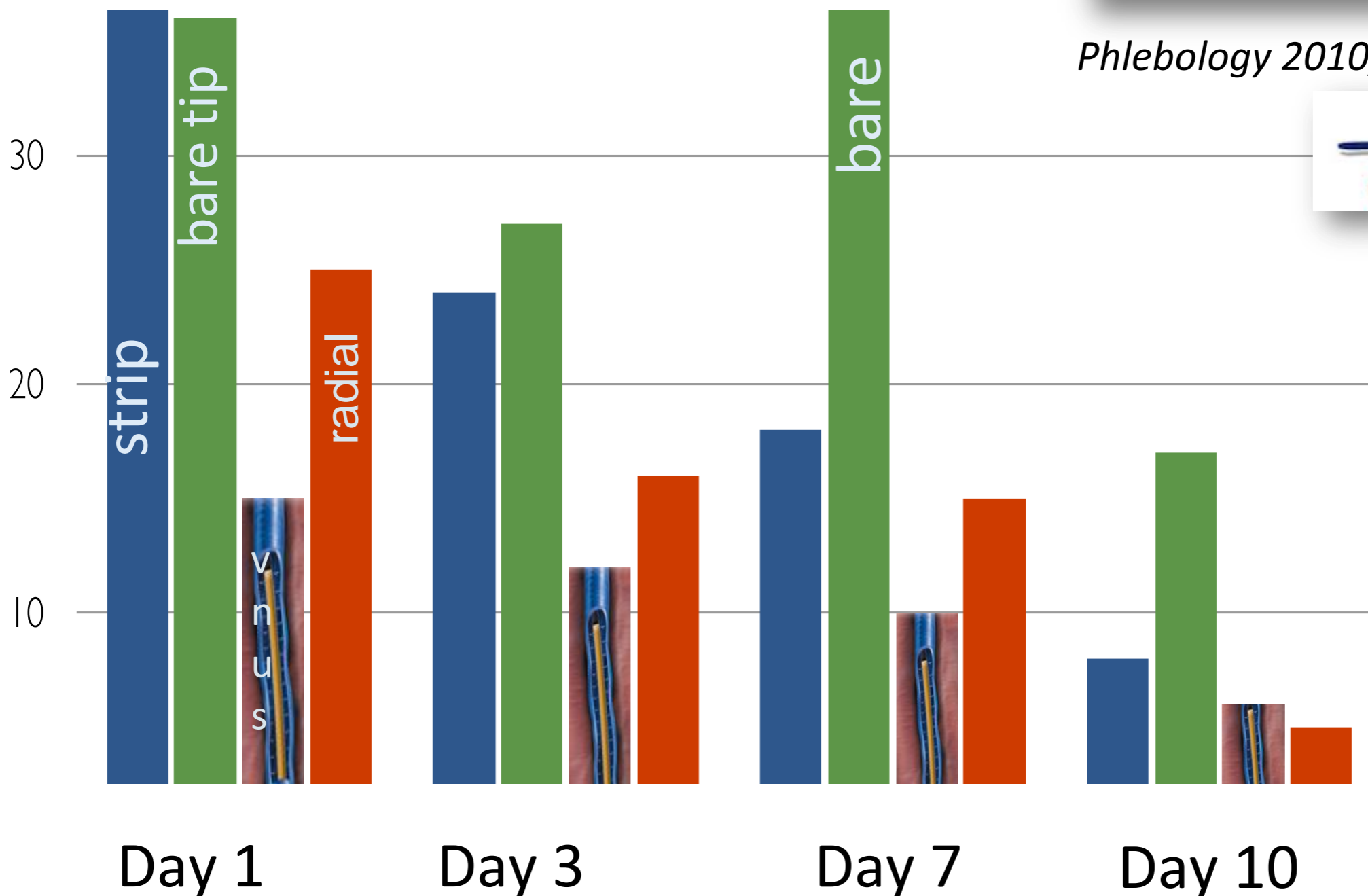
Recovery study VAS Painscores

Paper 4.1

A prospective recovery study after high ligation and stripping or endovenous treatment of the insufficient great saphenous vein using local anaesthesia

P Pronk, S A Gauw, M C Mooij, M T W Gastra, J A Lawson and C J van Vlijmen-van Keulen
Flebologisch Centrum Oosterwal, Alkmaar, The Netherlands

Phlebology 2010;25:296–311





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Phlebology 2010;25:296–311

Procedure	no	1 year occlusion	Time to normal function	Back to work in days
ClosureFAST	83	100 %	1,4	2,6
Radial Fibre	51	93 %	1,4	2,9
EVLA 980nm	62	98 %	3,2	4,4
HL/S	66	95,6	3,2	4,2

Study design

Varico 2: ClosureFAST vs Radial Fibre

- Parallel observational study (adjusting for confounding variables)
- Allocated by consecutive months (pseudo-randomised)
- All patients got tumescent anesthesia without iv sedation
- Postoperative Recovery
- Occlusion rate
- Duplex and clinically detected recurrences at the saphenofemoral junction
- Clinical results, CEAP, VCSS, AVVQ , general QoL (EuroQOL5)
- Long term endpoints (till 5 year follow-up):

Patient characteristics

	Venefit ClosureFAST	EVLA radial (1470)	P-value
Patients	n=158	n=153	t-test
Patients female/male	120/38	110/43	NS
Age, mean (SD)	49,8 (13)	50,0 (12,3)	NS
BMI (SD)	25,2 (3,9)	25,7 (4,2)	NS
Length patient cm (SD)	174,6 (8,4)	174,1 (8,4)	NS
Legs	n=175	n=172	
Left/right	86/89	84/88	NS

Leg CEAP Classification of venous disease

	VNUS ClosureFAST n=175 n (%)	EVLA radial (1470) n=172 n (%)	P-value χ^2
C2	40 (23)	35 (20)	NS
C3	115 (66)	116 (67)	NS
C4	18 (10)	18 (11)	NS
C5	2 (1)	3 (2)	NS

CEAP, Clinical severity, Etiology, Anatomy, Pathophysiology

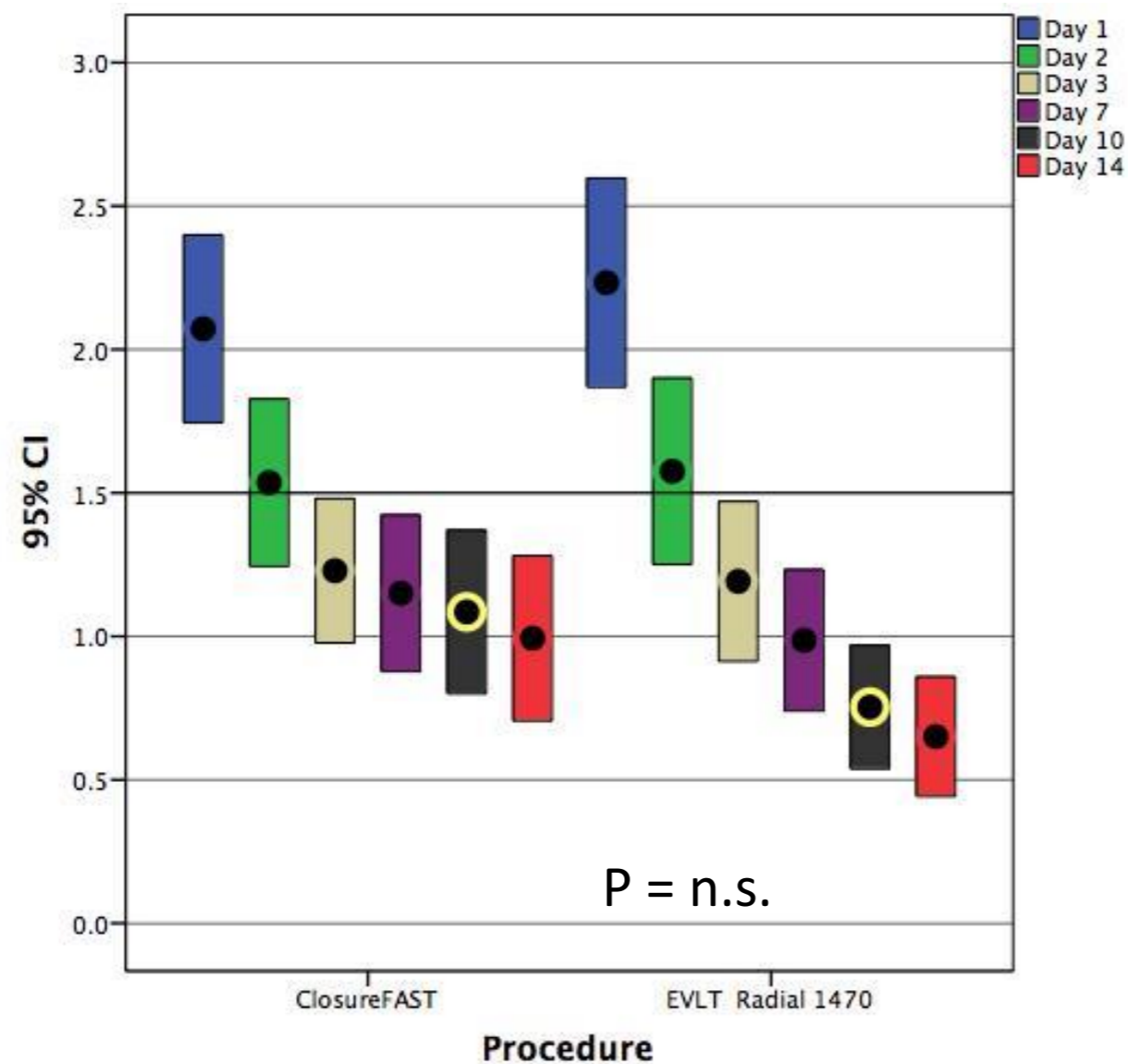
Preoperative symptoms

	RFA ClosureFAST N=175	EVLA radial (1470) N=172	P-value
	n (%)	n (%)	χ^2
Edema	93 (53)	95 (55)	NS
Itching	67 (38)	67 (39)	NS
Restless legs	23 (13)	18 (11)	NS
Cramping	18 (10)	21 (12)	NS
Pain	54 (31)	54 (31)	NS
Heaviness	112 (64)	120 (70)	NS
Other	31 (18)	22 (13)	NS
Compression therapy	42 (24)	41 (24)	NS

OR characteristics

	RF VNUS ClosureFAST n=175	EVLA radial (1470) n=172	
	M (SD)	Mean (SD)	P
Length treated vein cm	39,6 (10,3)	39,1 (11,5)	ns
Joules/cm (LEED)		77,8 (10,5)	
Diameter GSV knee cm	0,55 (0,14)	0,59 (0,15)	<.05
AASV diameter cm	0,19 (0,07)	0,20 (0,09)	ns
Mean ablation time	2,2 minutes	5,2 minutes	
	n (%)	n (%)	
AASV visible before treatment	126 (72)	121 (70)	ns
Incompetent SFJ	125 (71)	122 (71)	ns

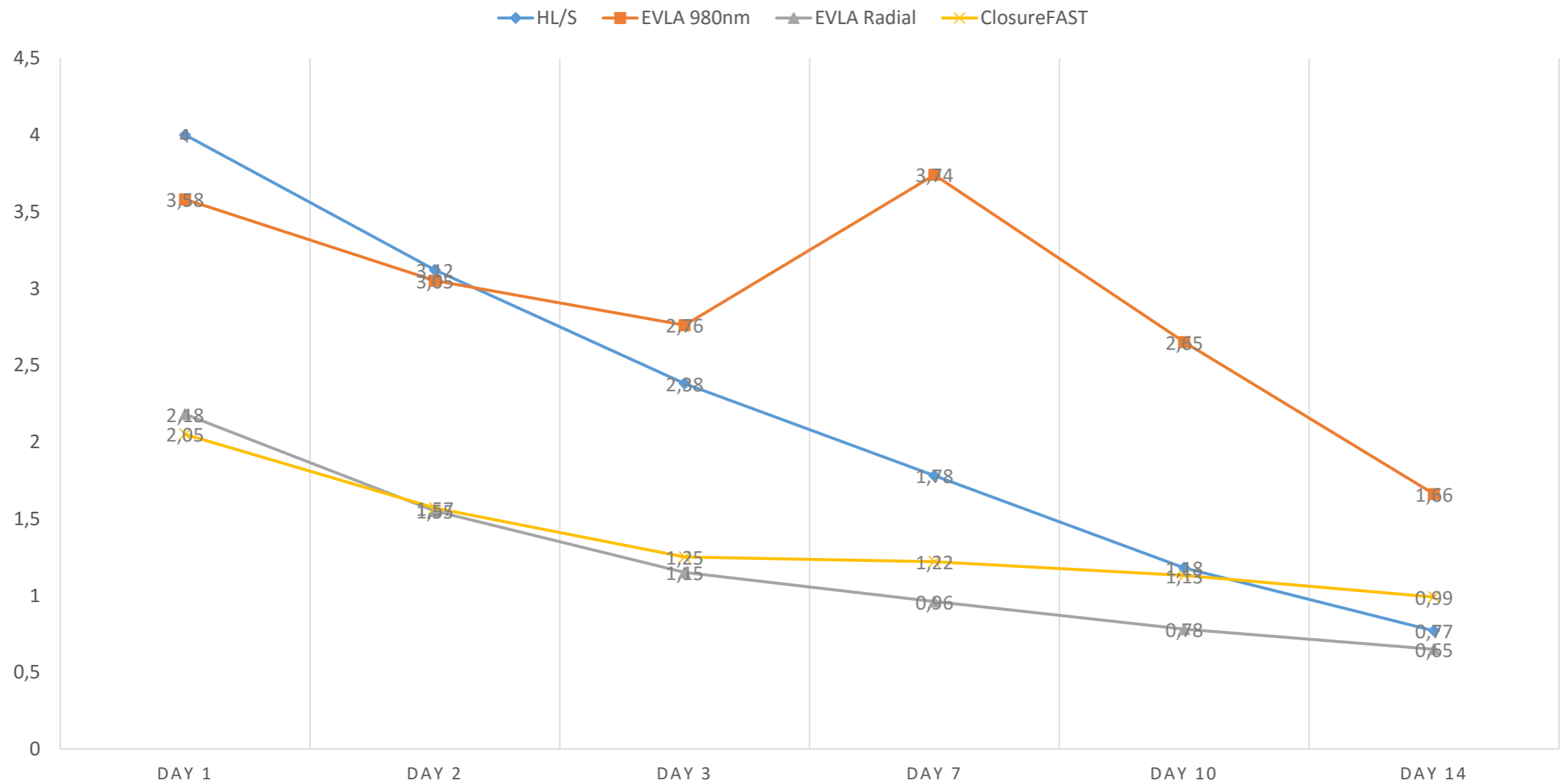
VAS pain scores ClosureFAST vs Radial Fibre



61 % of VNUS and 64% of radial patients does not use painkillers

Comparison with Bare Fibre and HL/S

POSTOPERATIVE VAS PAIN SCORES



Daily activities and back to work

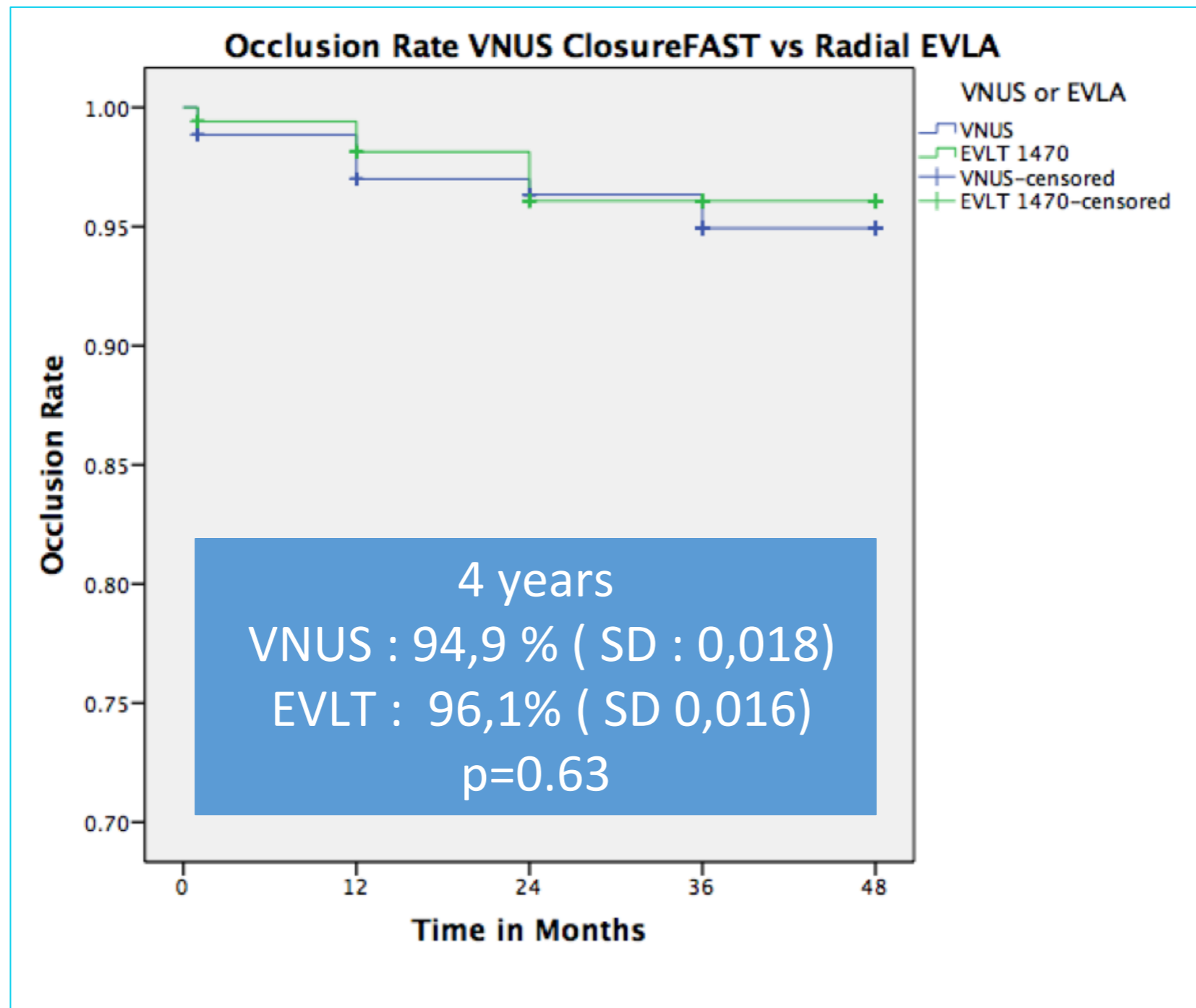
		N	Mean (days)	SD
Daily Activities	ClosureFAST	161	1,47	1,40
	Radial	155	1,13	0,92
Back to Work	ClosureFAST	127	2,13	1,91
	Radial	117	2,32	2,38

Does not want to undergo this surgery again : VNUS 3,7 % Radial 1,3%

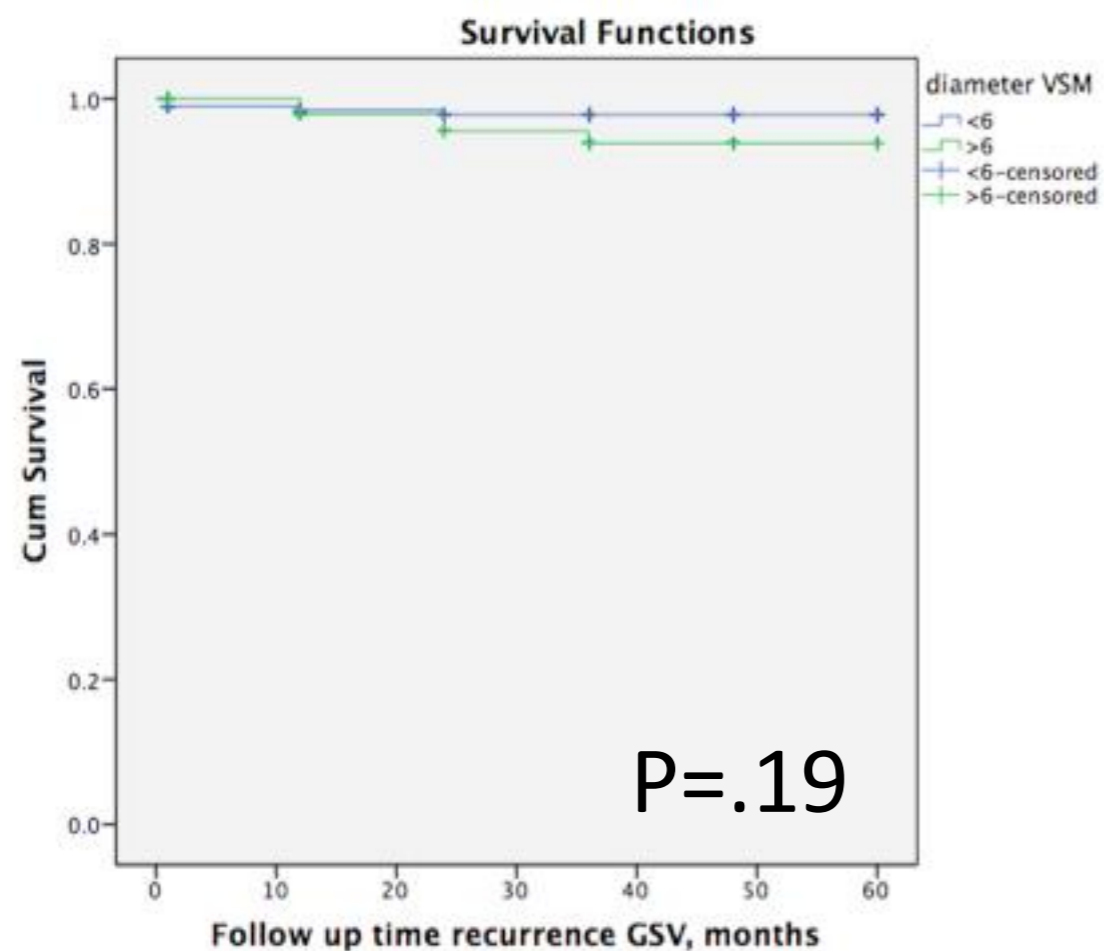
Complications

	ClosureFAST	Radial	P value
Bruising	26/175 (14,9%)	32/172 (18,7%)	ns
Temporary Paresthesia	3/175 (1,8%)	4/172 (3,7%)	ns
Persistent Paresthesia	1/158 (0,6 %)	5/139 (3,6%)	ns
Ipsilateral DVT	0/158 (0,0 %)	1/139 (0,7%) (crural vein)	ns

Occlusion Rate

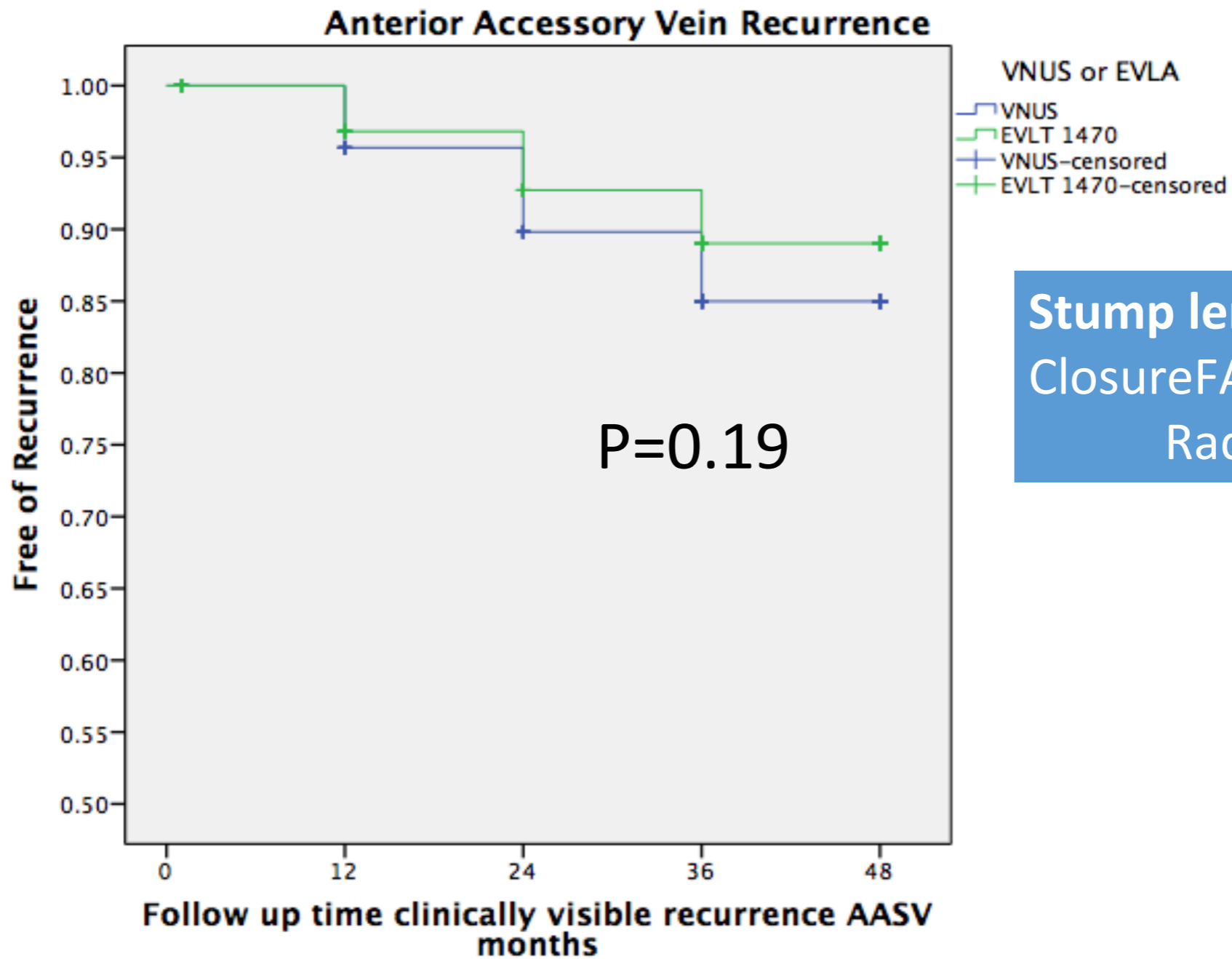


Adjustment for diameter GSV at the knee



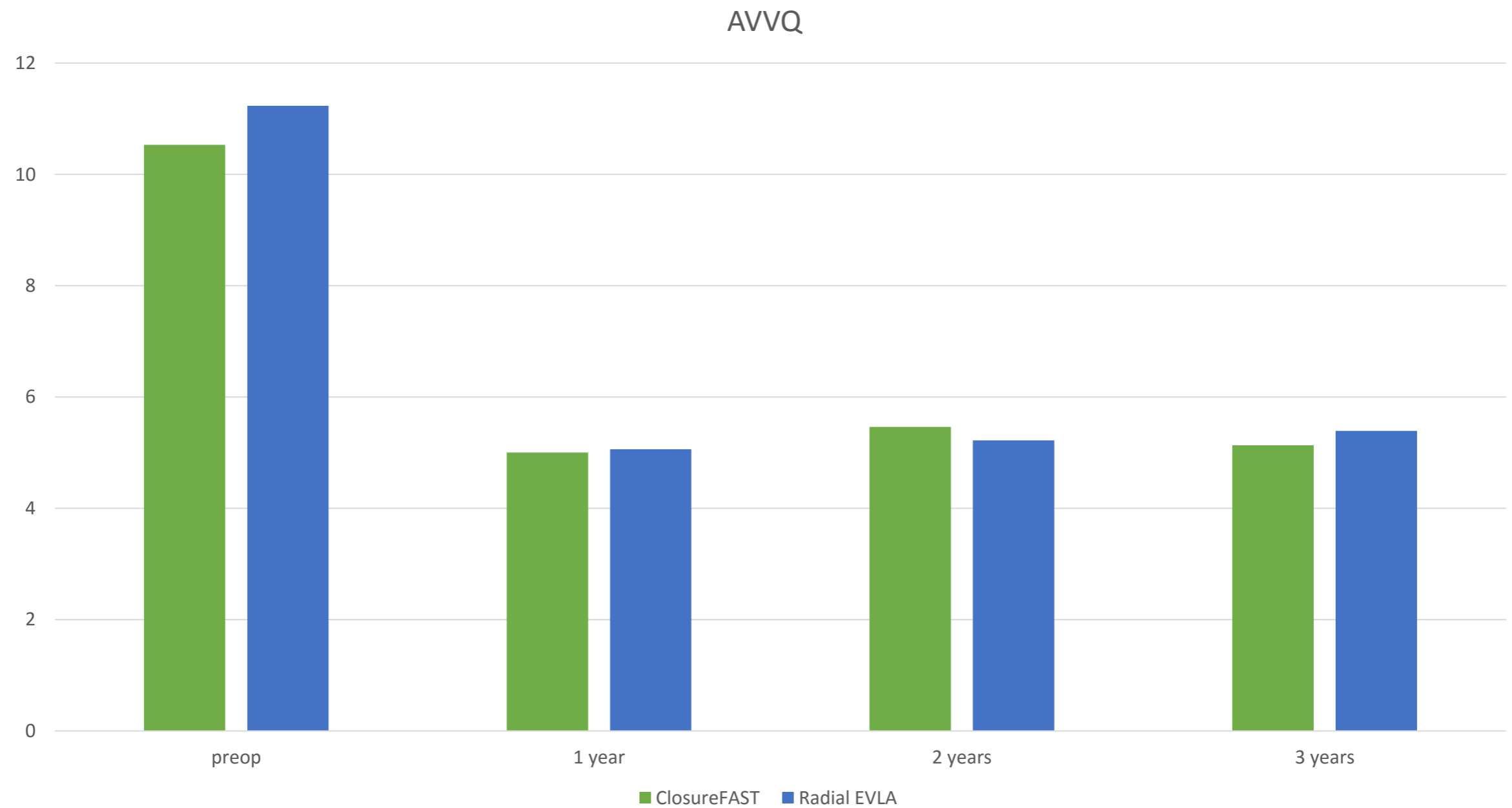
	P	Odds ratio	95% CI	
			Lower	Upper
Radial/VNUS	.57	1.40	.44	4.5
Adjusted	.4	1.62	.496	5.29

AASV Clinical Neoreflux

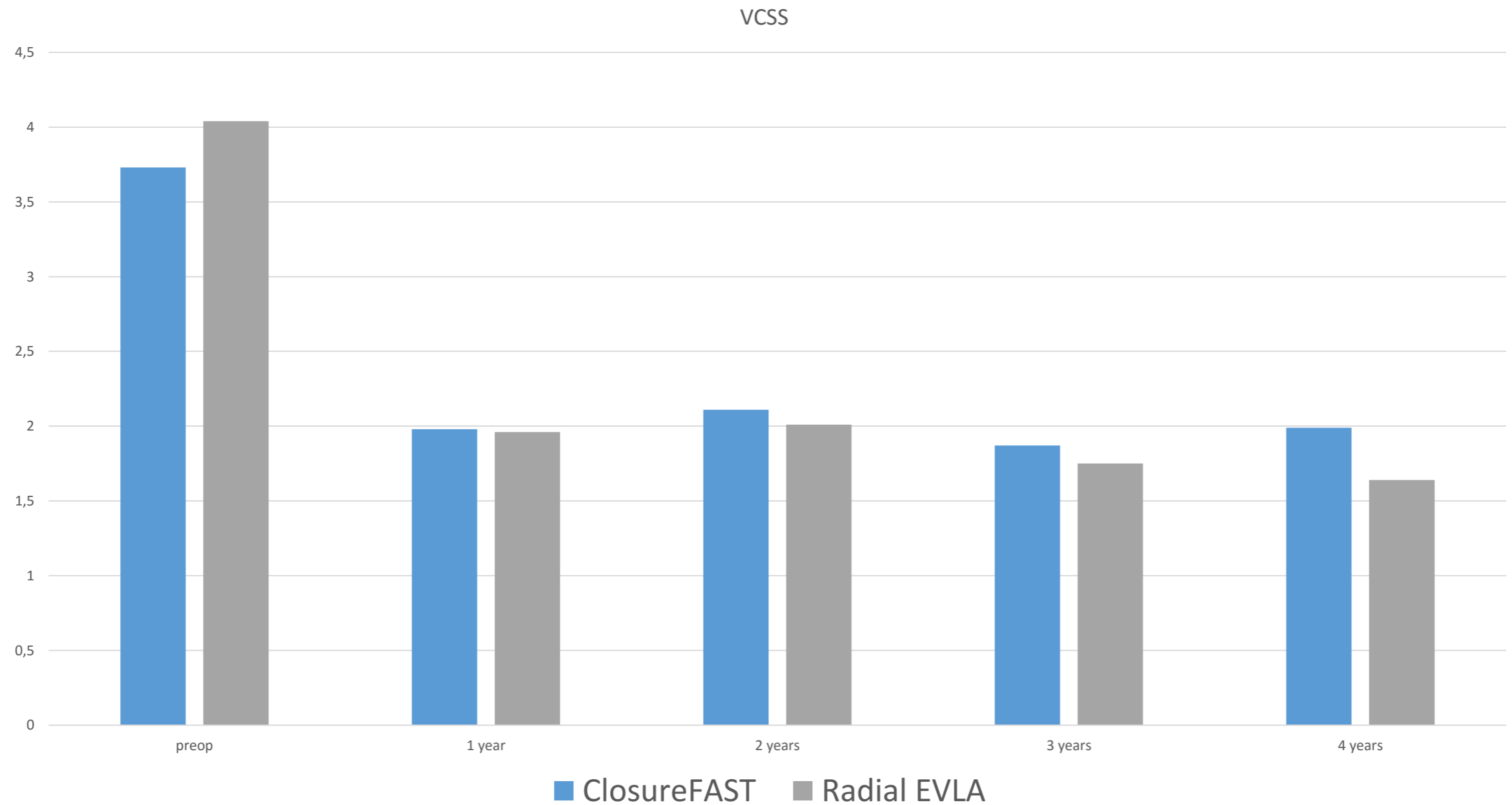


Stump length 2 years
ClosureFAST: 8,3 mm
Radial: 7,8 mm

Aberdeen Quality of Life (AVVQ)



VCSS (Venous Clinical Severity Score)



Conclusions

- Both procedures are well tolerated and safe
- Both procedures are comparable : very low postoperative pain, smooth recovery and short time back to work.
- Ablation time is shorter with ClosureFAST
- Non inferiority in occlusion rate (4 years > 94 %)
- Similar recurrences from the sapheno-femoral junction up to 4 years
- Persistent similar improvement in AVVQ (QoL) , VCSS,
- Bare fibers are obsolete (in our hands)
- Endovenous ablation with ClosureFAST or Radial fibre are the golden standard for new innovative non-tumescent techniques