iMeet May 2018, Nice France

Catheter-based treatments for varicose veins: evidence and practice.

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Venous Disease

- C0: 38.5%
- C1: 21.4%
- C2: 15.35%
- C3: 15.8%
- C4: 7.37%
- C5: 1.23%
- C6: 0.44%

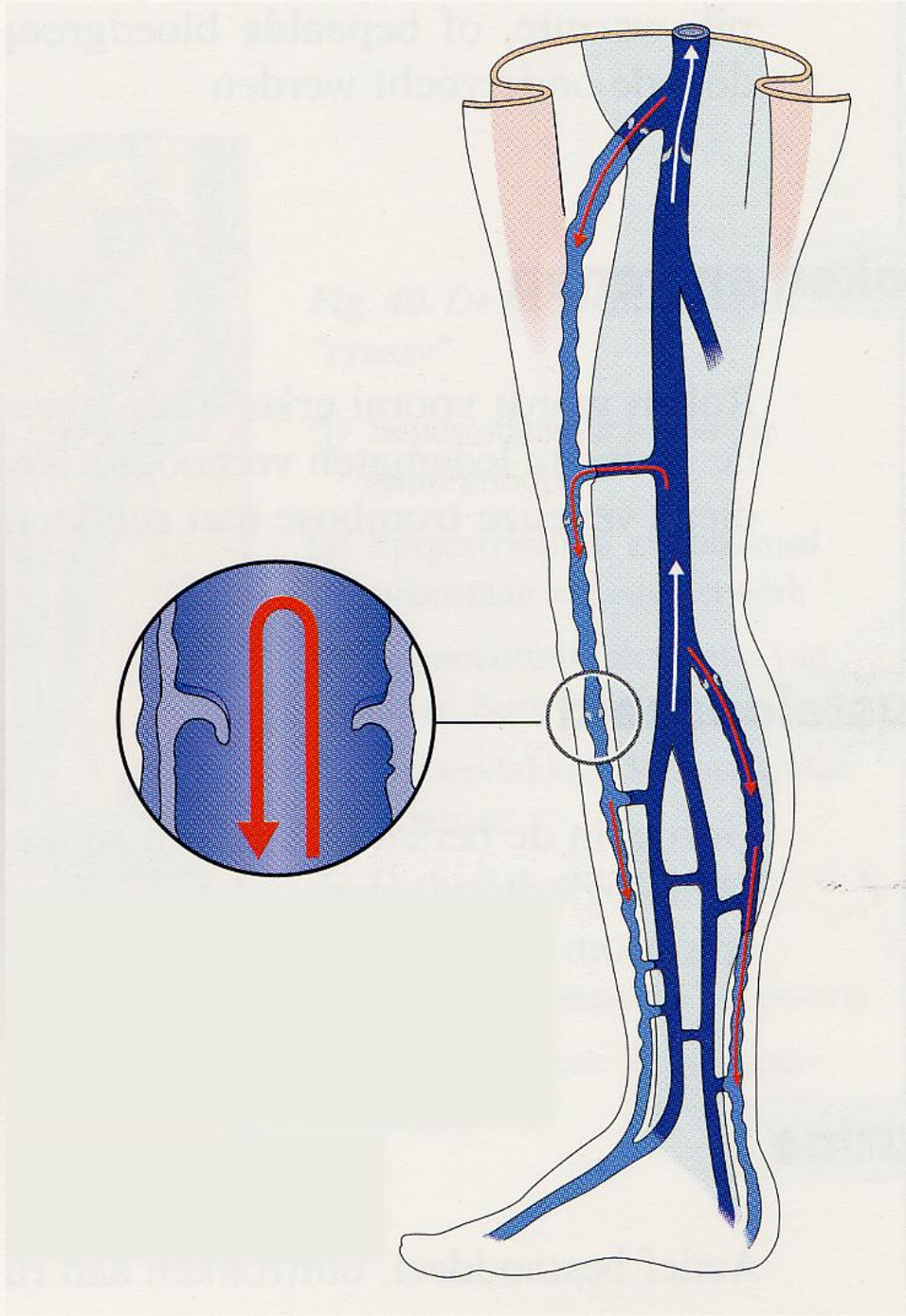
CVD: 61.6%

CVI: 24.8%

Vuylsteke ME, Colman R, Thomis S, Guillaume G, Van Quickenborne D, Staelens I. An epidiomological survey among general practitioner attendees in different geographical regions on the globe: the final results of the vein consult program. Angiology 2018, ahead of publication

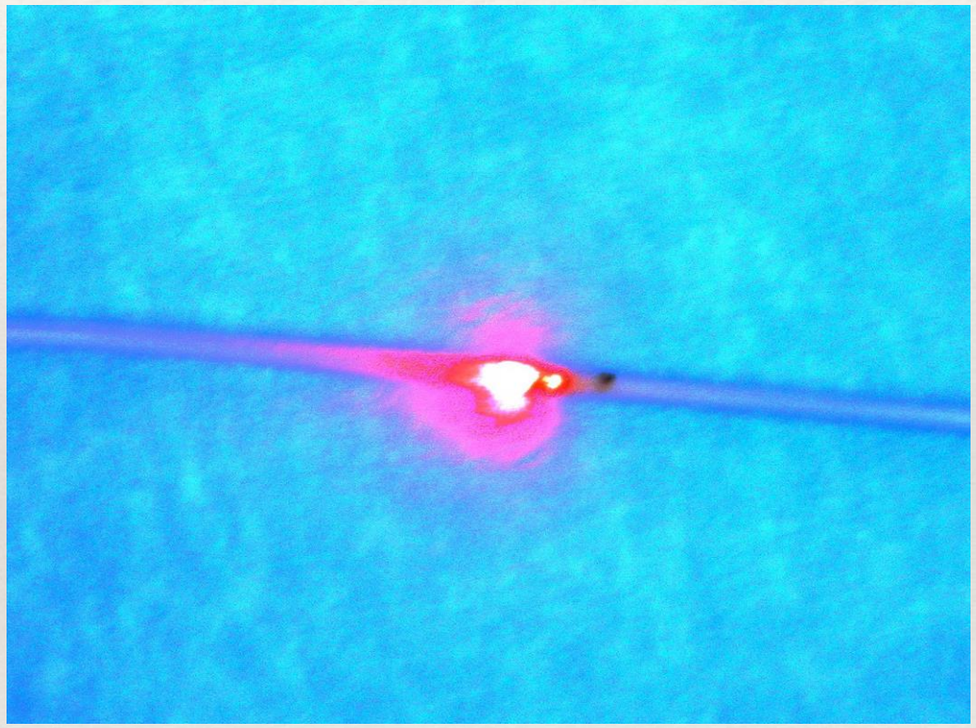
Varicose veins

- Truncal veins
  - GSV
  - AASV
  - SSV
  - Giacommuni
- Non-truncal veins
  - Tributaries
  - perforating veins
- Deep venous system
- Pelvic veins



Catheter based treatments

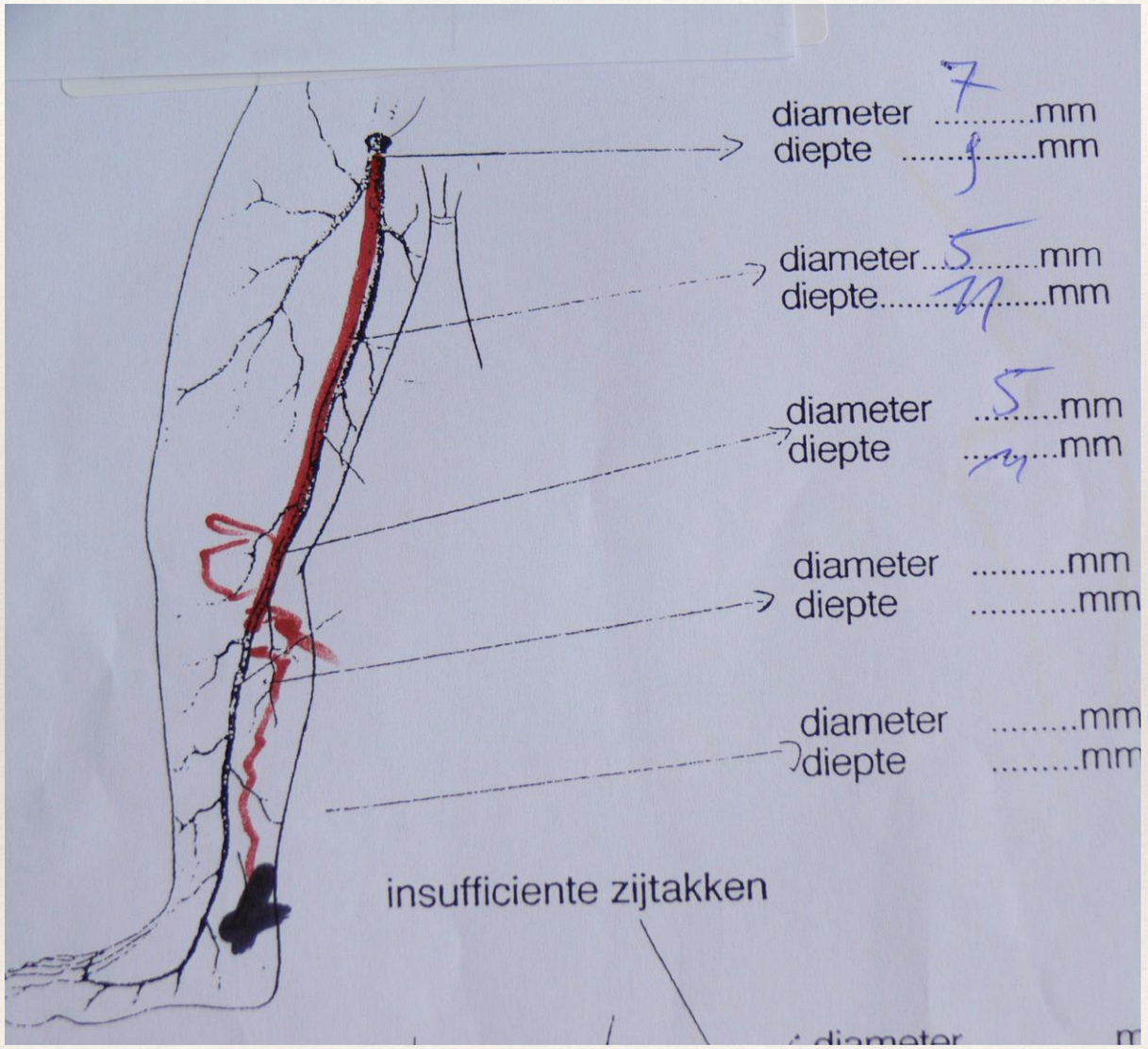
- Endovenous thermal ablation
  - EVLA
  - RFA
  - Steam
- MOCA (mechanochemical ablation)
- UGFS
- Glue
- Embolisation techniques
- Venous stenting



Great Saphenous vein incompetence

- Male, 48y
- C2
- heavy legs, sensation of swelling and night cramps

Great Saphenous vein incompetence

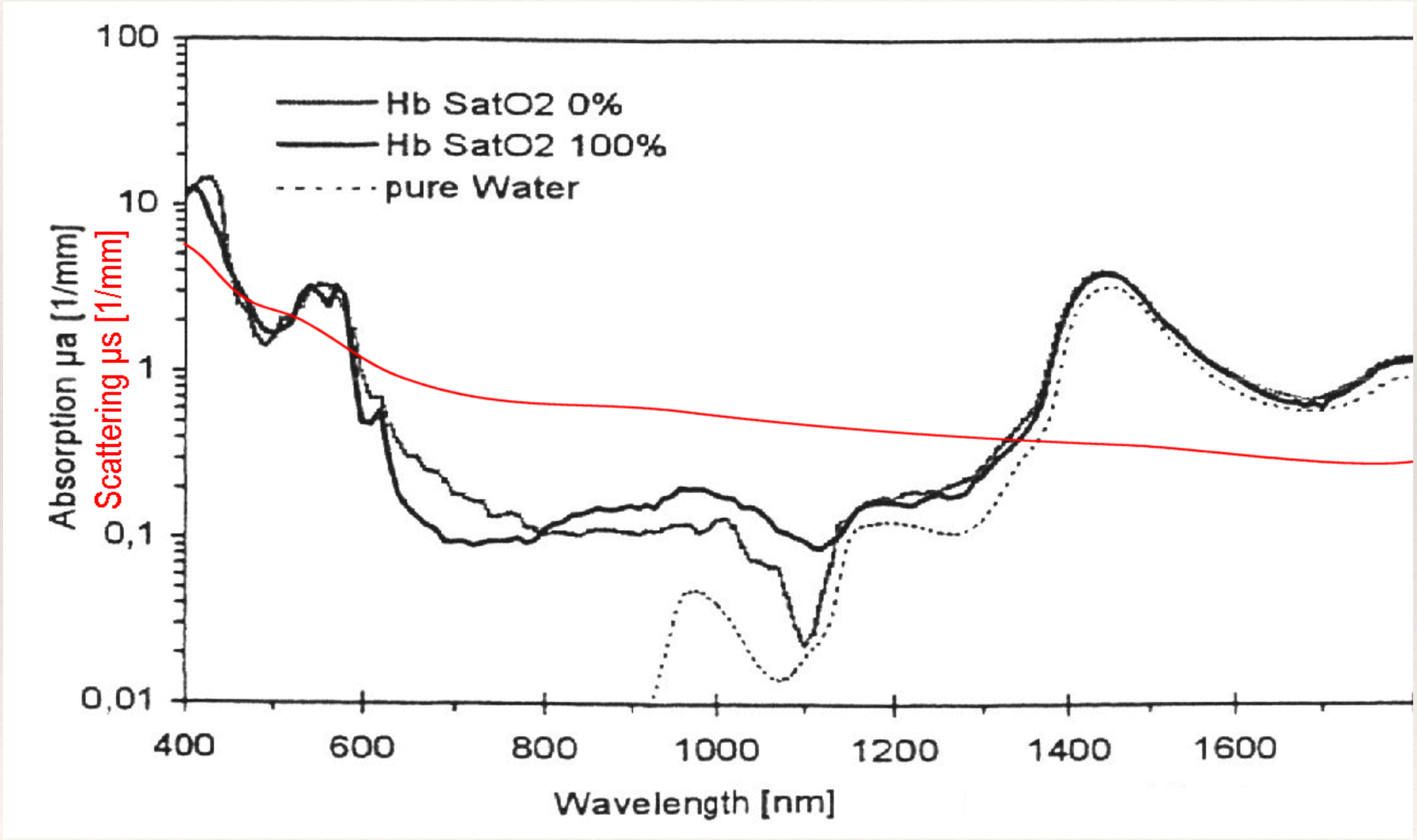


Great saphenous vein incompetence

- EVTA?
  - laser
  - RFA
    - Steam?
- Foam?
- MOCA?
- Glue?

EVLA - Wavelengths

Different wavelengths: 810,940,980,1320,1470,1500nm



- Absorption coefficient and Scattering coefficient © Serge Mordon – INSERM

Wavelengths

		810	940	980	1320	1470
Blood	μ_a (mm^{-1})	0.16	0.25	0.28	0.38	3.0
	μ'_s (mm^{-1})	0.73	0.64	0.6	0.54	0.52
	μ_{eff} (mm^{-1})	**0.65**	**0.82**	**0.86**	**1.02**	**5.63**
Vessel wall	μ_a (mm^{-1})	0.2	0.12	0.1	0.3	2.4
	μ'_s (mm^{-1})	2.4	2.13	2.0	1.8	1.7
	μ_{eff} (mm^{-1})	**1.25**	**0.9**	**0.79**	**1.37**	**5.43**
Perivenous Tissue	μ_a (mm^{-1})	0.017	0.027	0.030	0.045	0.35
	μ'_s (mm^{-1})	1.2	1.1	1.0	0.9	0.84
	μ_{eff} (mm^{-1})	**0.25**	**0.3**	**0.3**	**0.36**	**1.12**

Extinction coefficients (red) related to wavelength and different biological tissues.

μ_a (mm^{-1}) : absorption coefficient in tissue

μ'_s (mm^{-1}) : reduced scattering coefficient

μeff: optical extinction

$$\mu_{eff} = \sqrt{3\mu_a(\mu_a + \mu_s')}$$

M.Vuylsteke, S Mordon, Endovenous laser ablation. Review of the mechanisms of action. Ann Vasc Surg 2012;26:424-33.

Evidence

	p-value	940nm	1470nm
n	180	70	72
LEED		40J/cm	40J/cm
fibre		Tulip	Tulip
Ecchymosis score		0	0
HRQoL 12W (AVVQ)	0.77	7.13 (1.89-15.29)	4.58(1.72 vs 8.5)
pain VAS 1W	4	6 (3-8)	3(2-7)
intake of analgetics: days	0,03	2,89 SD:1,3	1,82 SD:1,2
DVT		0	0
satisfaction rate (VAS)	0,062	6(3-8)	9 (8-10
occlusion rate 12 months	0.51	60/66 (91%)	62/66 (94%)

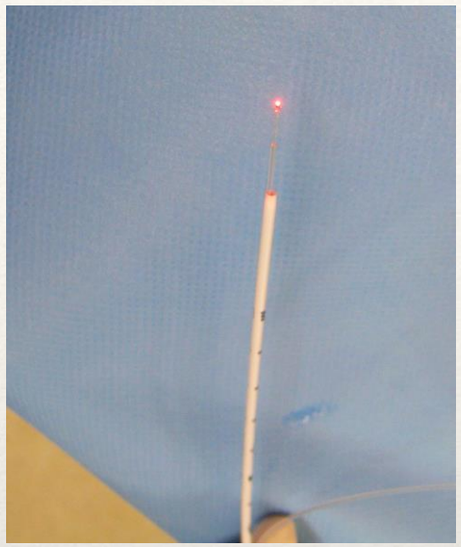
	p-value	980nm	1500nm
n	180	88	87
LEED		80,J/cm	60J/cm
fibre		bare	bare
Ecchymosis score	0,09	1,2 SD:2,3	0,69 SD:0,8
Induration 1 week	<0,01	1,17 SD:2,45	0,28 SD:1,2
Induration 1 month	<0,01	0,48 SD:1,2	0,03 SD:O,3
intake of analgetics: days	0,03	2,89 SD:1,3	1,82 SD:1,2
Quality of life (20-100)	0,018	37,41 SD:12,6	33,23 SD:9,62
satisfaction rate	0,66	0,99 SD:0,1	0,98 SD:0,15
occlusion rate 6 months	0,34	95,5% (84/88)	93,1% (81/87)

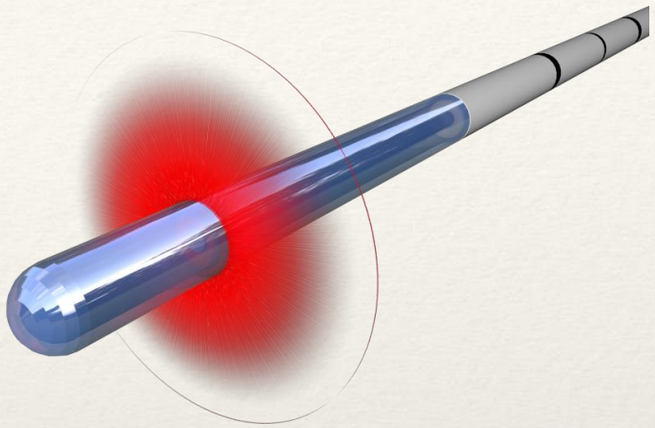
Malskat W, Gang J, De Maeseneer M et al. Randomized clinical trial of 940- versus 1470nl endovenous laser ablation for great saphenous vein incompetence. Br J Surg 2016;103:192-198.

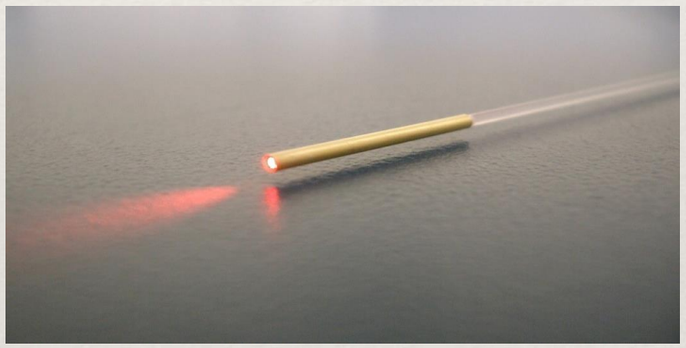
Vuylsteke ME, De Bo Th, Dompe G, Di Crisci D, Abbad CM, Mordon S. Endovenous laser treatment: is there a clinical difference between using a 1500nm and a 980nm diode laser? A multicentre randomised clinical trial. International Angiology. 2011; 30(4):327-34.

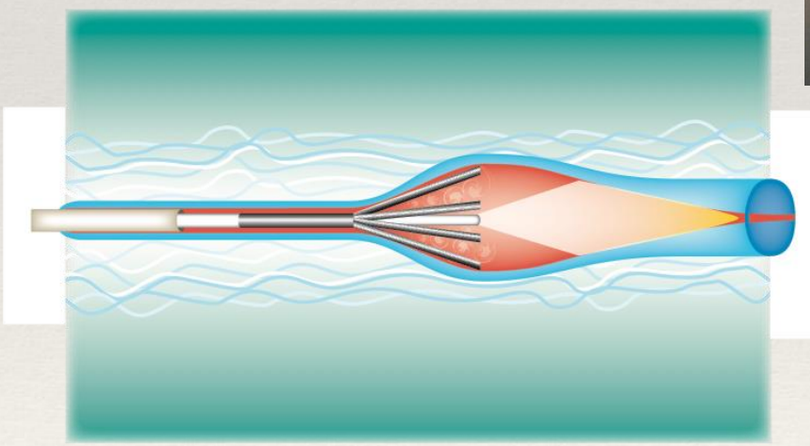
Endovenous thermal ablation

- EVLA
  - different fibres
    - Bare fibre
    - Tulip fibre
    - Radial fibre
    - Never-touch
    - Ball-tip fibre

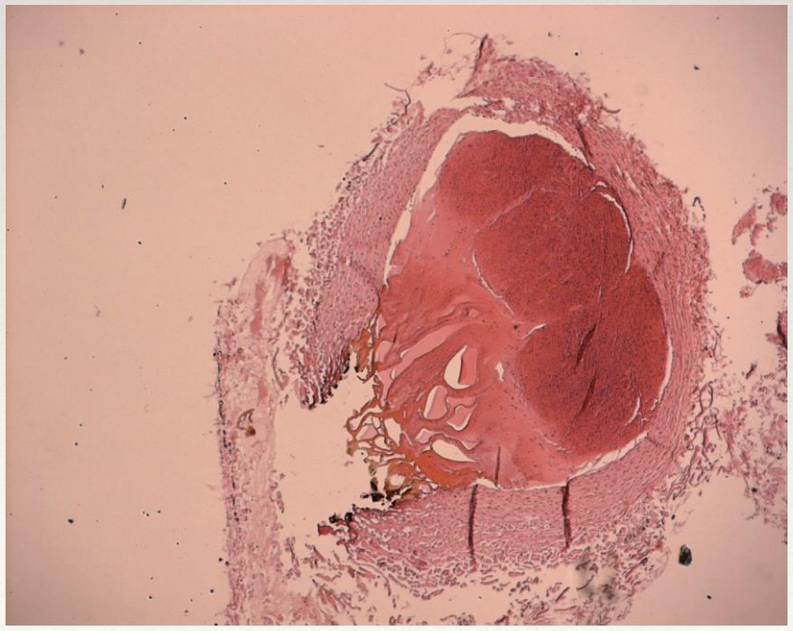




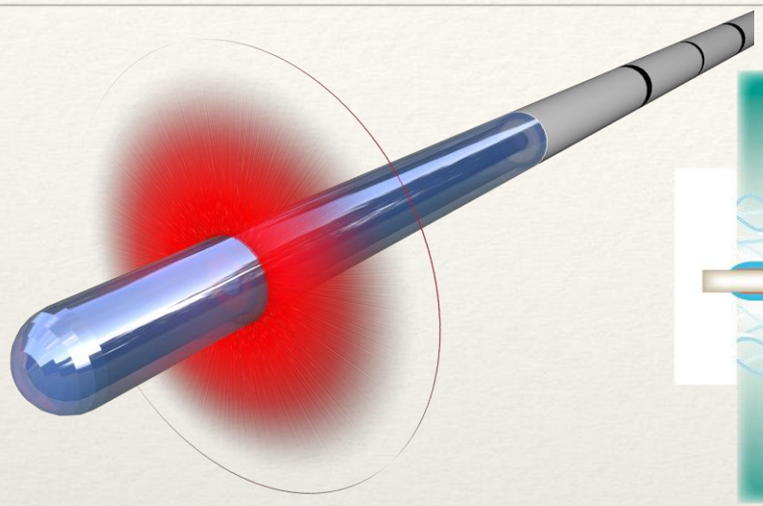


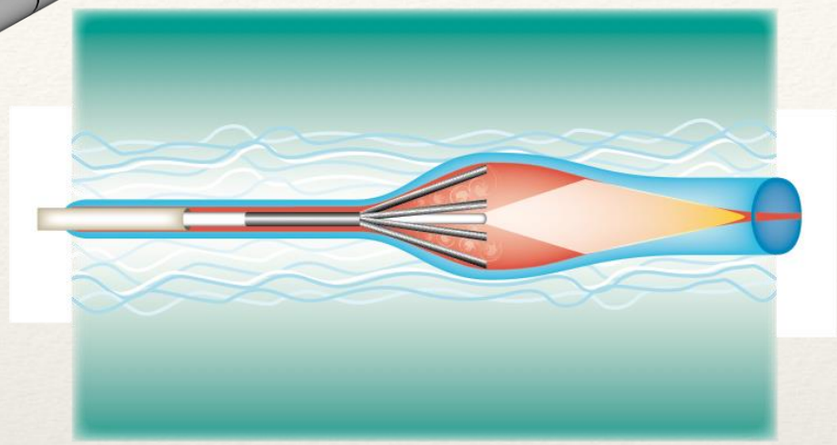


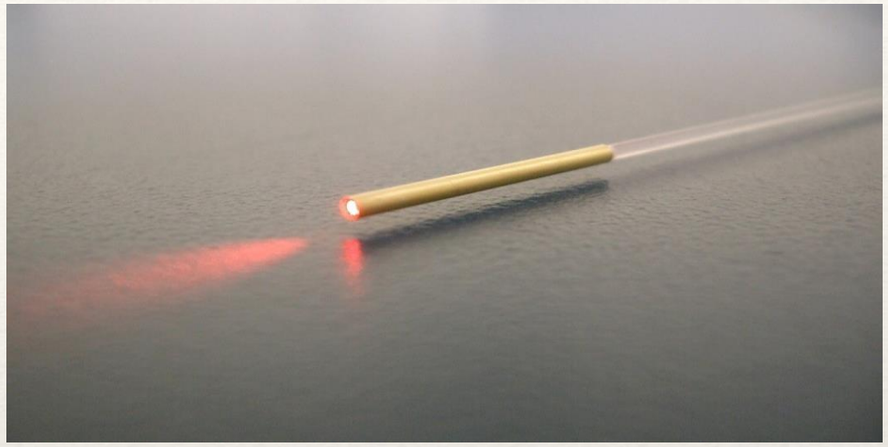
Bare fibre

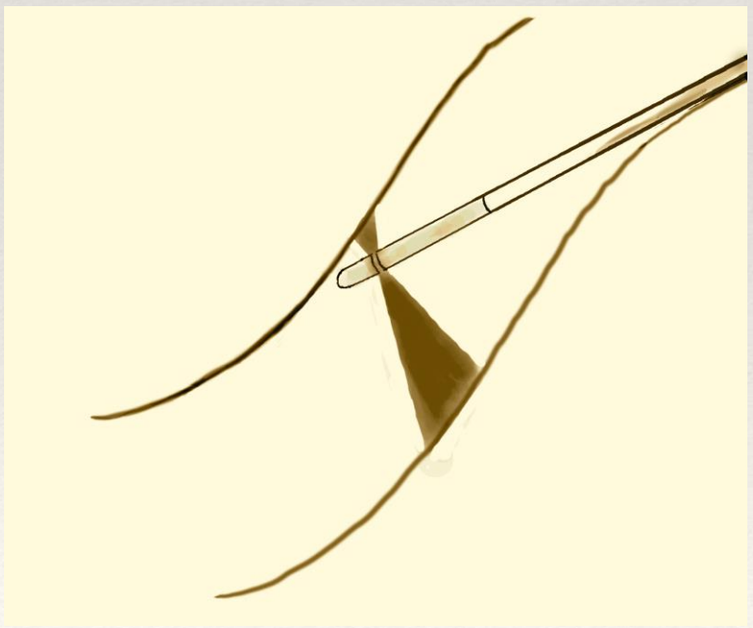


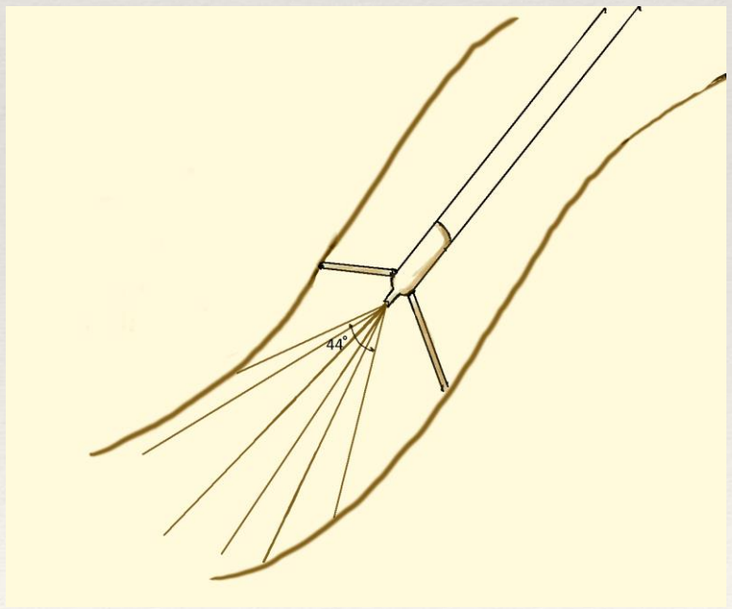
New fibre

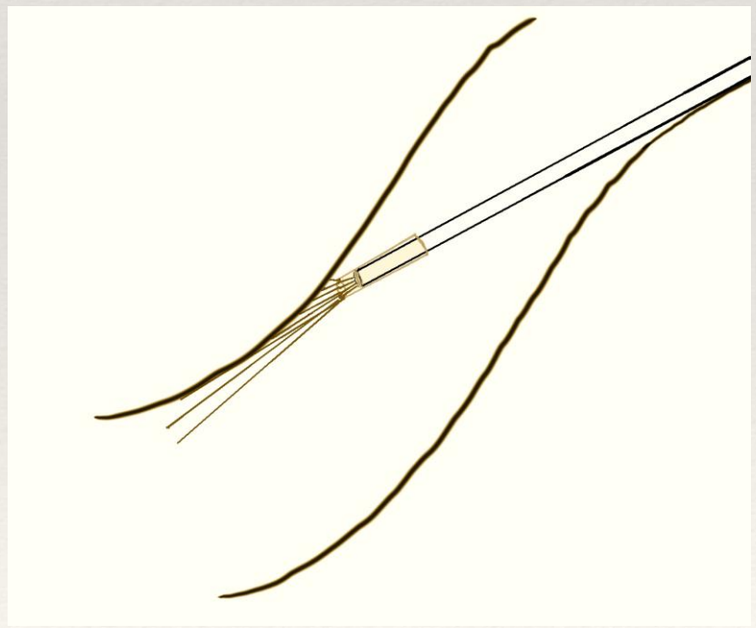












Endovenous Thermal ablation

- Higher wavelengths: equal occlusion rates (97-100%), less postoperative pain.
- New fibre design: equal occlusion rates, fewer side -effects.

Yamamoto T, Masahiro S. Influence of fibre and wavelengths on the mechanism of action of endovenous laser ablation. J Vasc Surg venous and Lymphatic disorders. 2014;2:61-69.

Doganci S, Demirkilic U. Comparison of 980nm laser and bare-tip fibre with 1470nm laser and radial fibre in the treatment go great saphenous vein varicosities: a prospective randomized clinical trial. Eur J Vasc Endovasc Surg 2010;40:254-9.

Vuylsteke ME, Thomis S, Mahieu P, Mordon S, Fourneau I. Endovenous Laser Ablation of the Great Saphenous Vein using a Bare Fibre versus a Tulip Fibre: A Randomised Clinical Trial. Eur J Vasc Endovasc Surg 2012;44:587-592.

Tulip trial

368 patients with GSV insufficiency

Excluded: 153
- Bilateral
- Incompetent SSV or ASV
- Diameter >15 mm
- Deep venous insufficiency
- Hypo/hypercoagulopathy
- Occlusive arterial disease
- Pregnancy
- <18 years old

215 fulfilled incusion and exclusion criteria

41 refused randomisation

174 Randomised

87 **Bare** fiber

87 **Tulip** fiber

Analysed with a follow-up of 1 month(n=87)

Analysed with a follow-up of 6 months(n=83)

Analysed with a follow-up of **1 year (n=82)**

Analysed with a follow-up of 1 month (n=87)

Analysed with a follow-up of 6 months (n=85)

Analysed with a follow-up of **1 year (n=85)**

Results

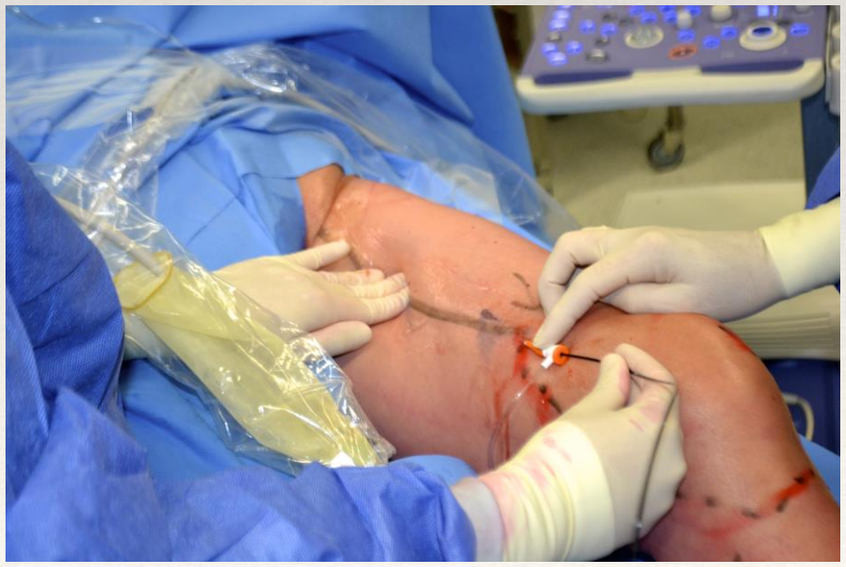
	BARE			*TULIP*			
Factor	***25%***	***Median***	***75%***	***25%***	***Median***	***75%***	***Sig***
Echymosis Score	0.08	0.21	0.66	0.00	0.04	0.14	0
Painscore d5-	1.00	2.00	3.50	0.00	1.00	2.00	0
Painscore 2 weeks	1.00	2.00	3.00	1.00	2.00	3.00	0.180
analgesics, days	0.00	1.00	2.00	0.00	0.00	1.00	0.111
analgesics, total number	0.00	1.00	2.50	0.00	0.00	2.00	0.119
QOL (20-100) CIVIQ2	24	32	40	23	27	34	0,023
Satisfaction	9.00	10.00	10.00	8.00	9.50	10.00	0.564
Occlusion rate one month		85/87 (97.7%)			83/86 (96.5%)		0,974
Occlusion rate six months		82/85 (96.5%)			76/83 (91.6%)		0,179
Occlusion rate one year		82/85 (96.5%)			81/82 (98.7%)		0,745

Mann Withney U-test

non-inferiority Newcombe's test

Radiofrequency

- Radiofrequency
  - Closure Plus
  - Closure Fast
- RFA/EVLA
  - Similar occlusion rates.
  - RFA: less postoperative bruising and pain (EVLA: bare fibre-lower wavelengths).



Evidence

Nordon IM, Hinchliffe RJ, Brar R, Moxey P, Black SA, Thompson MM, et al. A prospective double-blind randomized controlled trial of radiofrequency versus laser treatment of the great saphenous vein in patients with varicose veins. Ann Surg 2011;254:876-81.

Lawaetz M, Serup J, Lawaetz B, BjoernL, Eklof B, Rasmussen L. Comparison of endovenous ablation techniques and surgical stripping of the great saphenous varicose veins. Extended -years follow-up of a RCT. Int Angiol 2017;36:281-288.

Rasmussen LH, Lawaetz M, Bjoern L et al. Randomized clinical trial comparing endogenous laser ablation, radio frequency ablation, foam sclerotherapy, and surgical stripping for great saphenous veins.Br J Surg 2011;98:1079-87.

Goode SD, Chowdhury A, Crockett M et al. Laser and radiofrequency ablation study (LARA study): a randomized study comparing radiofrequency ablation and endovenous laser ablation 810nm. Eur J Vasc Endovasc Surg 2010;40:246-53.

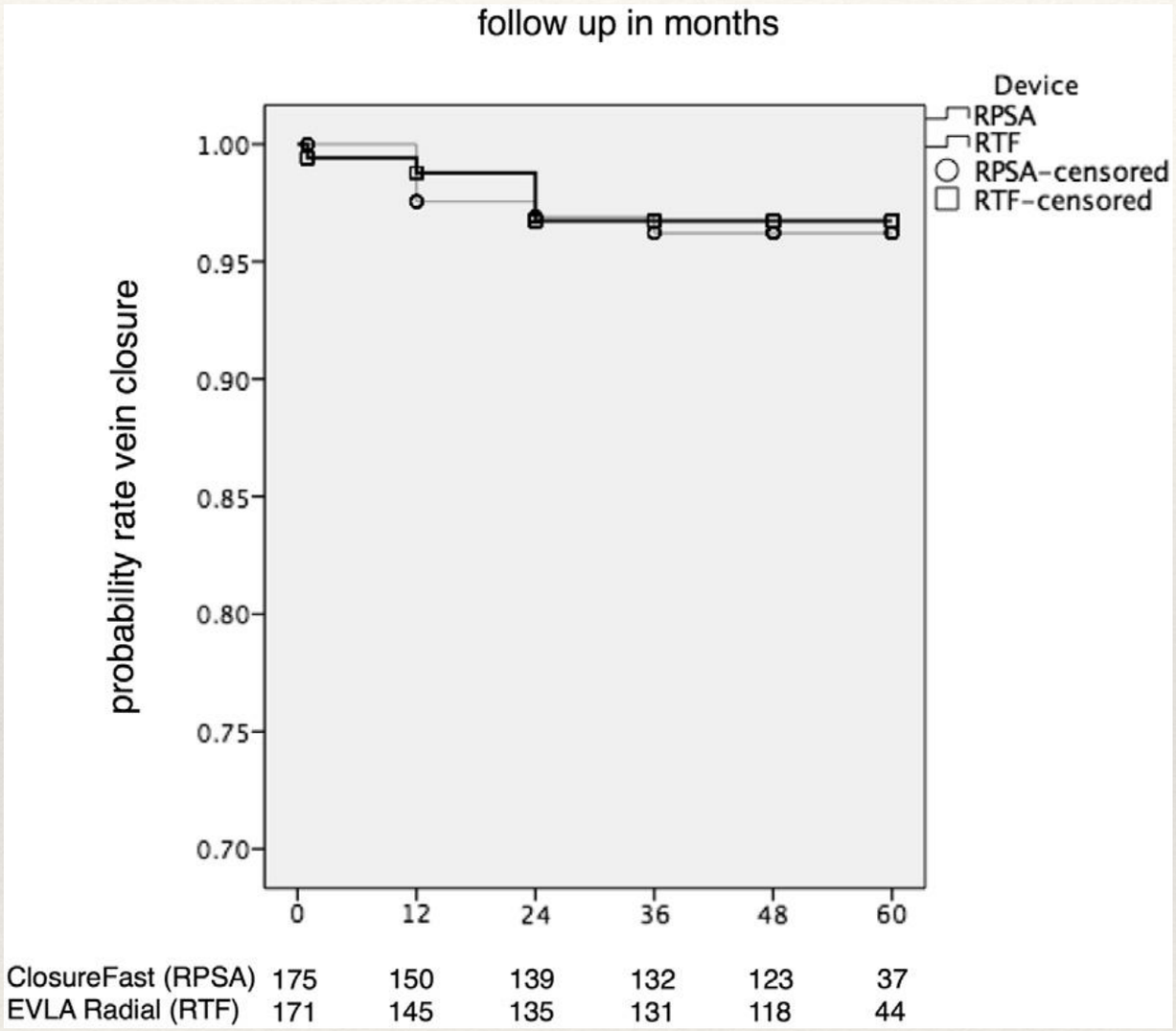
Gale SS, Lee JN, Walsh ME et al. A randomized controlled trial of endovenous thermal ablation using the 810nm wavelength laser and the Closure Plus radio frequency ablation methods for superficial venous insufficiency of the great saphenous vein. J Vasc Surg 2010;52:645-50.

Shepard AC, Gohel MS, Brown LC et al. Randomized clinical trial of VNUS ClosureFast radio frequency ablation versus laser for varicose veins. Br J Surg 2010;97:810-818.

Almeida JL, Kaufman J, Gockeritz et al. Radiofrequency endovenous ClosureFast versus laser ablation for the treatment of great saphneous reflux: a multicenter, single blinded randomized study (RECOVERY study). J Vasc Inter Radiol 2009;752-9.

Lawson J, Gauw S, van Vlijmen CJ et al . Prospective comparative cohort study evaluating incompetent great saphenous vein closure using radio frequency powered segmental ablation or 1470nm endovenous laser ablation with radial-tip fibre. J Vasc Surg Venous and lymphat dis 2018;6:32-40.

Varico 2 study

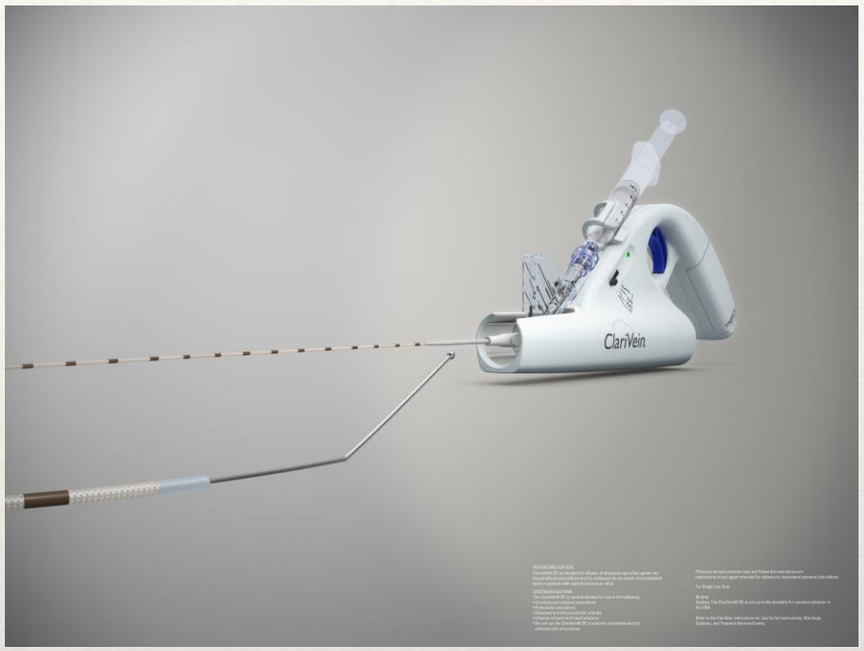


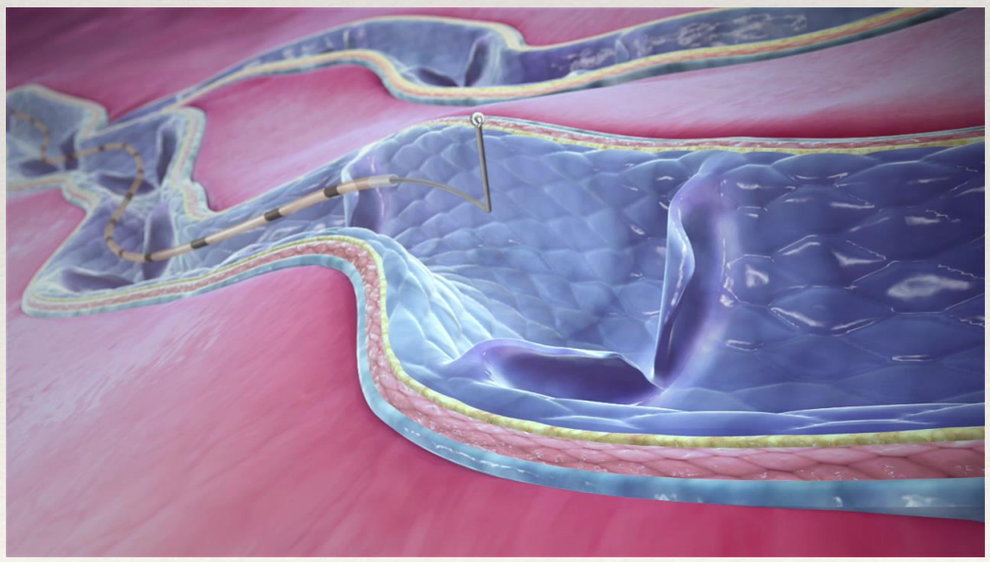
pain d1-10
pain medication
bruising
paresthesia
DVT
HRQoL (AVVQ)

Lawson J, Gauw S, van Vlijmen CJ et al . Prospective comparative cohort study evaluating incompetent great saphenous vein closure using radio frequency powered segmenta

Mechanochemical ablation

- No tumescence
- No perivenous tissue destruction
- MOCA is safe and effective in the treatment of SV reflux. One-year anatomic success rate was 94%





MOCA (Clarivein)

- No randomized trials available
- One retrospective observational trial: less pain compared to RFA

Elias S, Lam YL, Wittens C. Mechanochemical ablation: status and results. Phlebology 2013;28 S: 10-14.

van Eekeren R, Boersma D, Elias S et al. Endovenous Mechanochemical Ablation of Great Saphenous Vein Incompetence Using the Clarivein Device: A safety study. J Endovasc Ther 2011;18:328-334.

Boersma D, van Eekeren R, Werson D et al. Mechanochemical Endovenous Ablation of Small Saphenous Vein Insufficiency Using the Clarivein Device: one-year results of a prospective series. Eur J Vasc Endovasc Surg 2013;45:299-303.

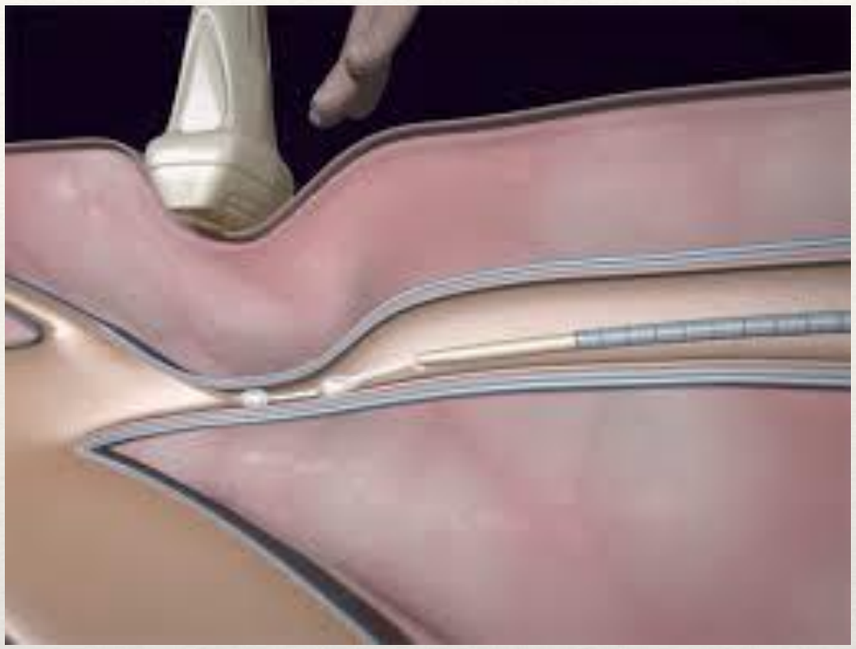
Vos CG, Unlü CU, Bosma J et al. A systematic review and meta-analysis of two novel techniques of non thermal endivenous ablateon of the great saphenous vein. J Vasc Surg; Venous and Lymphatic Disorders 2017;5:880-896.

van Eekeren R, Boersma D, Konijn V et al. Postoperative pain and early quality of life after radiofrequency ablation and mechachemical endivenous ablation of incompetent great saphenous vein. J Vasc Surg 2013;57:445-450.

Elias S, Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. Phlebology 2012;27:67-72.

Cyano acrylate glue

- No tumescence
- No stockings
- Glue: non-inferiority compared to RFA
- $$



Morrison N, Gibson K, McEnroe S et al. Randomized trial comparingcyanoacrylate embolisation and radio frequency ablation for incompetent great saphenous veins J Vasc Surg 2015;61:985-94.
Almeida JI, Min RJ, Raabe R, McLean DJ, Madsen M. Cyanoacrylate adhesive for the closure of truncal veins: 60-day swine model results. Vasc Endovascular Surg 2011;45:631-5.
Lam YL, De Maeseneer M, Lawson J, De Borst GJ, Boersma D. Expert review on the VenaSeal(R) system for endovenous cyano-acrylate adhesive ablation of incompetent saphenous trunks in patients with varicose veins. Expert Rev Med Devices 2017;14:755-62.
Proebstle TM, Alm J, Dimitri S, et al. Twelve-Month Follow-up of the European Multicenter Study on Cyanoacrylate Embolization of Incompetent Great Saphenous Veins. J Vasc Surg Venous Lymphat Disord 2014;2:105-6.

Endovenous Thermal ablation

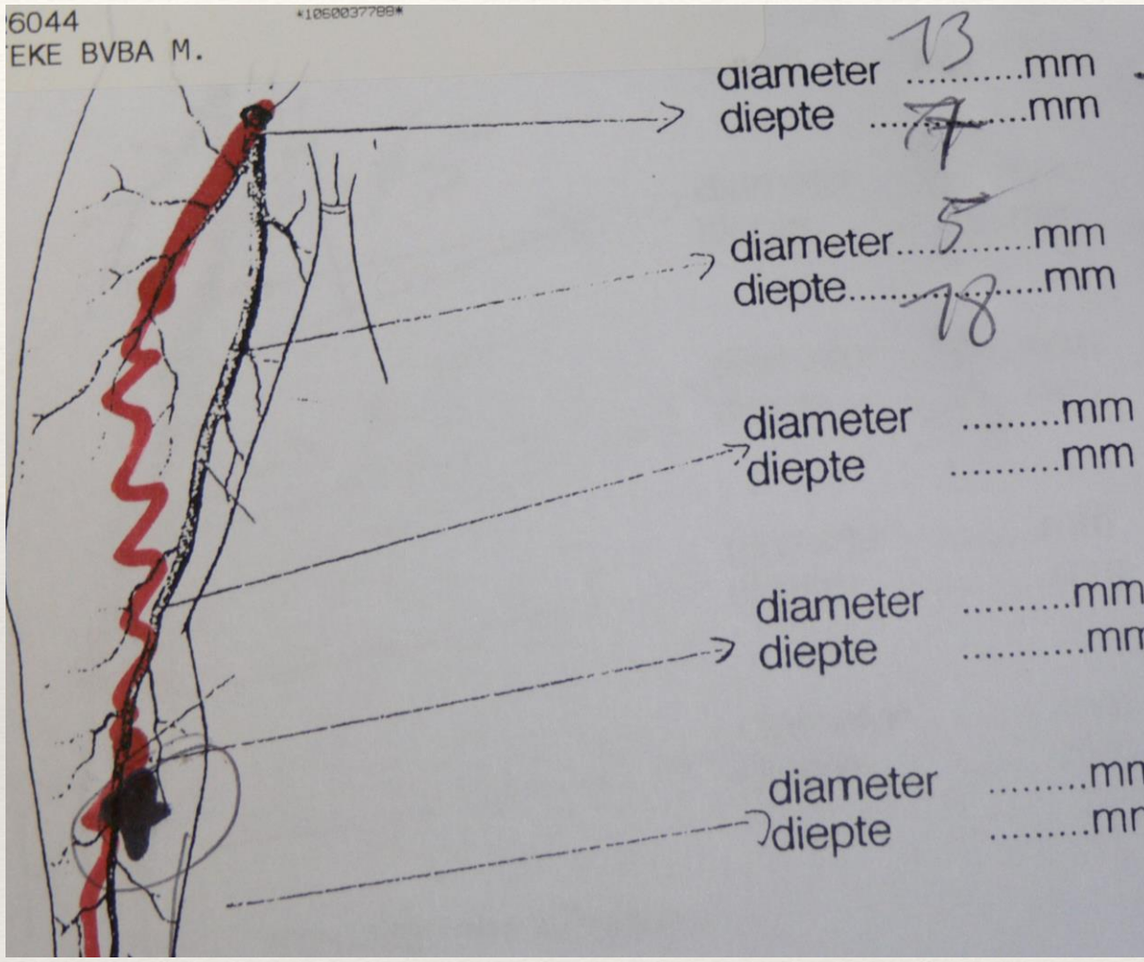
Recommendation 43	Class	level
For the treatment of great saphenous vein reflux in patients with symptoms and signs of chronic venous disease, EVTA techniques are *recommended in preference to surgery*	I	A

Wittens C, Davies A, Wittens, A. Davies, Bækgaard N, Broholm R, Cavezzi A, Chastanet S,de Wolf M,Eggen C, Giannoukas A, Gohel M, Kakkos S, Lawson J, Noppeney T, Onida S, Pittaluga P, Thomis S, Toonder I, Vuylsteke M. Management of Chronic venous disease. Clinical practice guidelines of the European Society for vascular Surgery. Eur J Vasc Surg 2015,49:678-737.

Anterior accessory saphenous vein incompetence

- Female pt
- age 42y
- swelling, pain, restless legs, heaviness

Anterior accessory saphenous vein incompetence



Anterior accessory saphenous vein

- Endovenous ablation of truncal vein
- Phlebectomy of side branches (simultaneously or not?)
- Perforator?

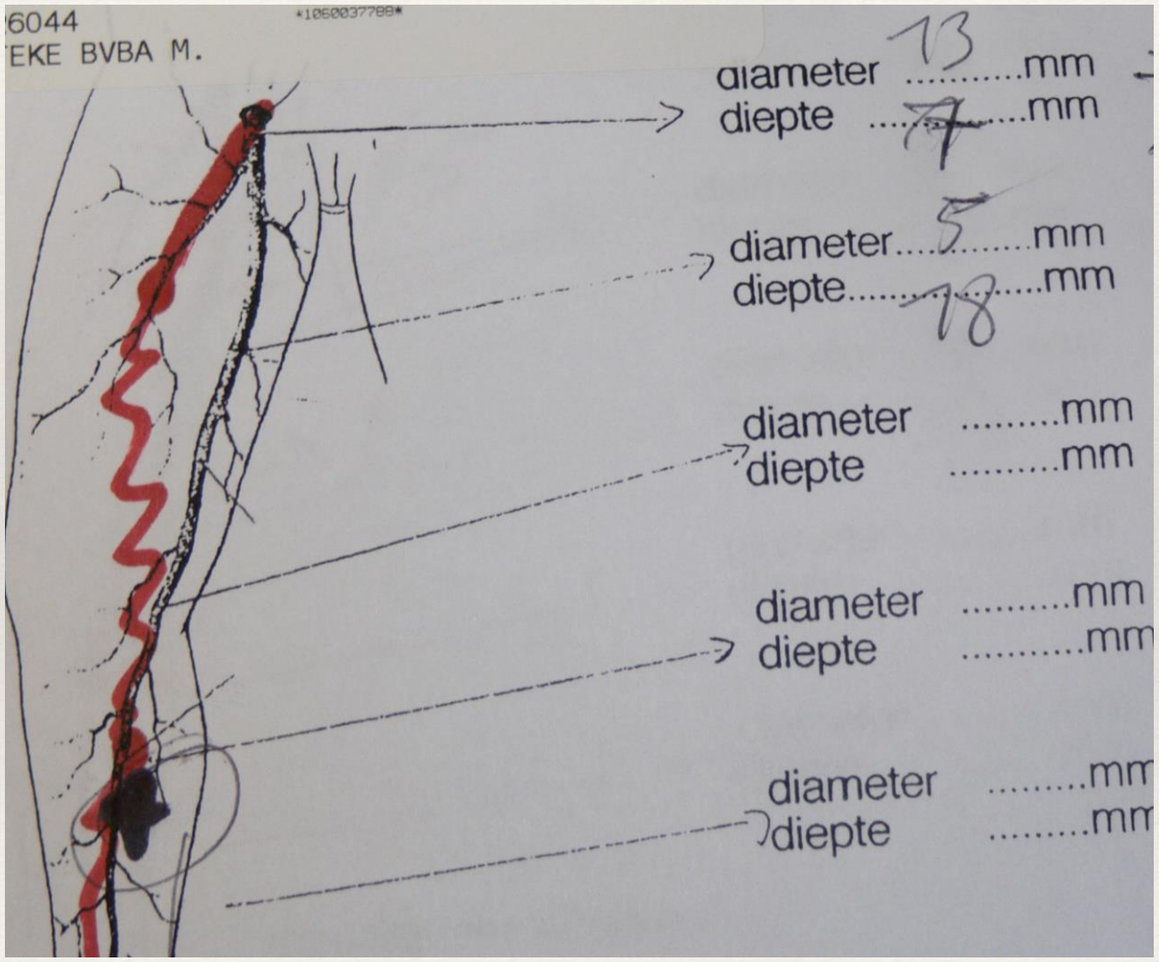
When performing endovenous thermal ablation of a refluxing saphenous trunk; adding concomitant phlebotomies should be considered. Class 2a, Level B

Chaar CI, Hirsch SA, Cwenar MT et al. Expanding the role of endovenous laser therapy: results in larger diameter saphenous, small saphenous and anterior accessory saphenous vein. Ann Vasc Surg 2011;25: 656-661.

Mekako A, Hattfield J, Bryce J et al. Combined endovenous laser therapy and ambulatory phlebectomy: refinement of the technique. Eur J Vasc Endovasc Surg 2006, 32,725-729

Harlander M, Jimenez J, Lawrence P et al. Endovenous ablation with concomitant phlebectomy is a safe and effective method of treatment for symptomatic patients with axial reflux and large incompetent tributaries. J Vasc Surg 2013; 58:166-172.

Perforating veins?



Concomitant ablation of perforating veins?

- More than half of the incompetent perforating veins become competent after truncal ablation.
- Perforating surgery results in an objective reduction in the number of detectible perforating veins. However this is not clinical significant for the patients.

Stuart WP, Adam DJ, Allan PL, Ruckley CV, Bradbury AW: Saphenous surgery does not correct perforator incompetence in the presence of deep venous reflux. J Vasc Surg 28:834-838, 1998

14. Mendes RR, Marston WA, Farber MA, Keagy BA: Treatment of superficial and perforator venous incompetence without deep venous insufficiency: Is routine perforator ligation necessary? J Vasc Surg 38:891-895, 2003

15. Al-Mulhim AS, El-Hoseiny H, Al-Mulhim FM, et al: Surgical correction of main stem reflux in the superficial venous system: Does it improve the blood flow of incompetent perforating veins? World J Surg 27:793-796. 2003

Conclusions

- Several options are available in the treatment of varicose veins.
- No real superiority between the different endovenous techniques.

“That which is new at this time will one day be ancient; as what is ancient was once new. It is not the length of time which gives value to things, it is their own excellency.”

–Auguste Belloste, 1645-1730