RADRIOFREQUENCY, LASER IS THERE ANY DIFFERENCE

Dr Jean Luc GERARD

Cannes 25 th June 2008

The advantages of the endovenous technic compared to vein stripping

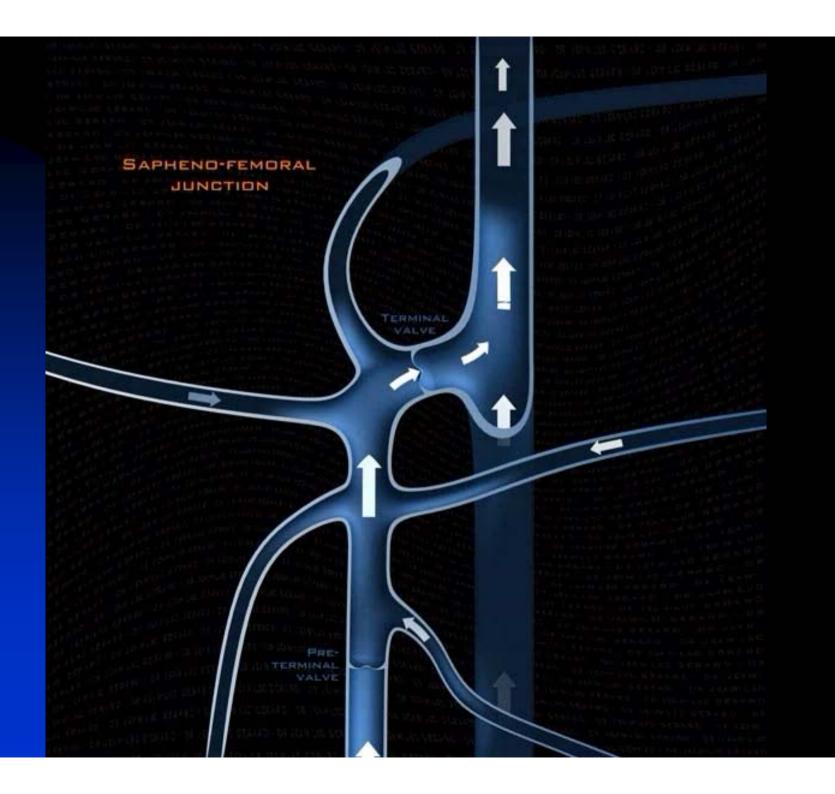
Advantages:

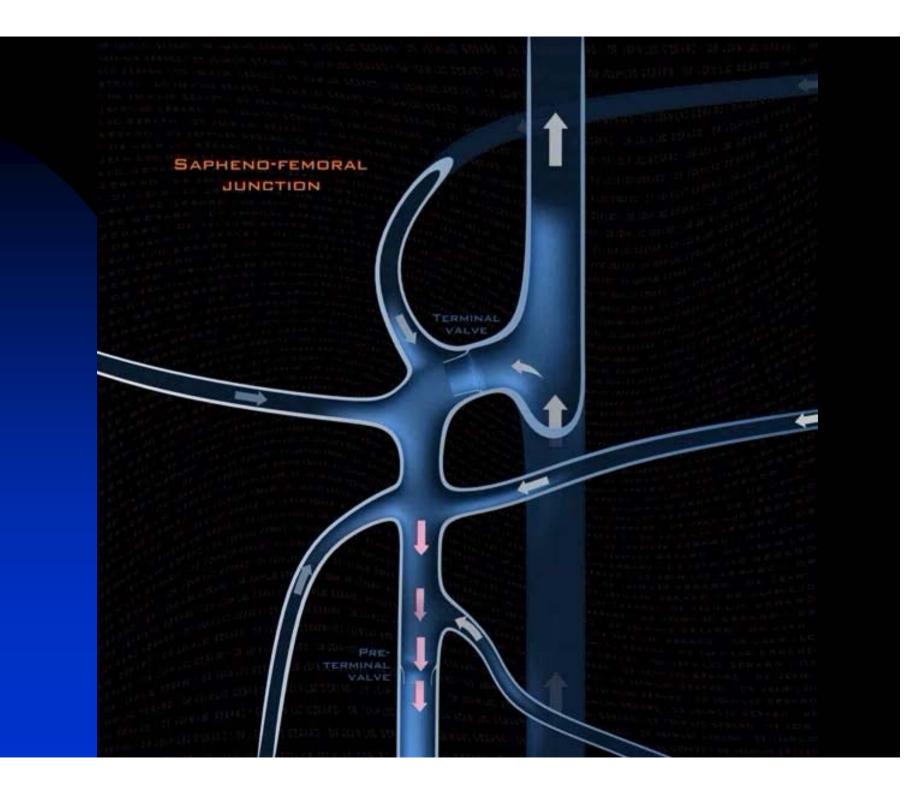
- Ambulatory technique (versus in average 1 or 2 days of hospitalisation for stripping)
- Less risk from a local anesthetic
- Less complications (dysesthesies paresthesias)
- No need for the patient to take much time off work (1 to 2 days compared to three weeks for stripping)
- Reduced hospital costs
- Using this technique will achieve similare results to traditional vein stripping.

Endovenous technic

SIMPLERSAFEEFFICIENT

WHY HIGH LIGATION IS NOT NEEDED





Positioning tip of the fibre or Catheter

2 cm

PUBLICATIONS

Shaybourg Seldr 1989

.K.16:30

APPLICATION DU LASER ND-YAG DANS LE TRAITEMENT DU SYNDROME VARIQUEUX

. Puglisi - A. Tacconi - F.M. San Filippo - *

. Zanzi - **

Chirurgia Vascolare - Ospedale di Garbagnate Milanese - USSL 67 - MILANO - ITALIA * Centro Laser Pluridisciplinare - c/o Casa di Cura Columbus - Via Buonarroti, 48-MILANO - ITALIA -

es auteurs exposent un étude de la méthode personnelle du traitement du syndrome ariqueux en se servant d'un Laser Nd.- YAG.

ls exposent les advantages de cet étude, de cette méthode par rapport a celle raditionelle, en analysant les mines thecniques intraoperatoires, post operatoires et les résultats au bout d'un an.

Apollecul 1992

131

Nd-Yag laser and Argon laser for the radical and cosmetical treatment of the varicose syndrome

B. Puglisi A. Mazza F.M. San Filippo

The Authors, after experience f 276 cases to rough three years describs the results and the new technique that allows to make safenotomy instead of a safenectomy by stripping.

Further the Authors underline the indications and the advantages of this new technique that's less thraumatic than stripping,doesn't give hematoma and related septic compliances and offer a best cosmetical result.

First publications LASER

Boné C

- Tratamiento endoluminal de las varices con laser de diodo : studio prelimino . Rev Patol Vasc. 1999; 5: 35-46
- Navarro L, Min RJ, Bone C

Endovenous laser : a new minimally invasive method of treatment for varicose veins- preliminary observations using an 810 nm diode laser. Dermato Surg 2001; 27 : 117-122

First publications in RF

• Chandler JG

Treatment of primary venous insuffisance by endovenous saphenous vein obliteration .J Vasc Surg 2000; 34: 201-1

MATERIALS

Different wavelenghts in Laser

DOES THE WAVELENGTH MATTER

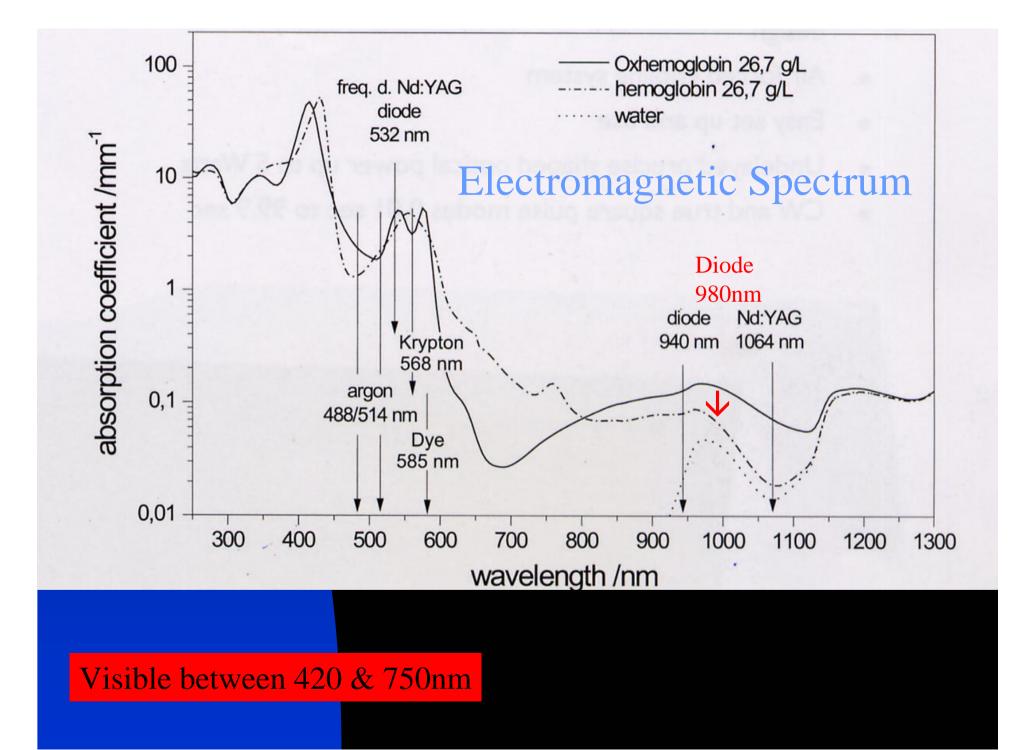
▶1064nm
▶810nm
▶940nm
▶980nm

▶810nm▶940nm▶980nm

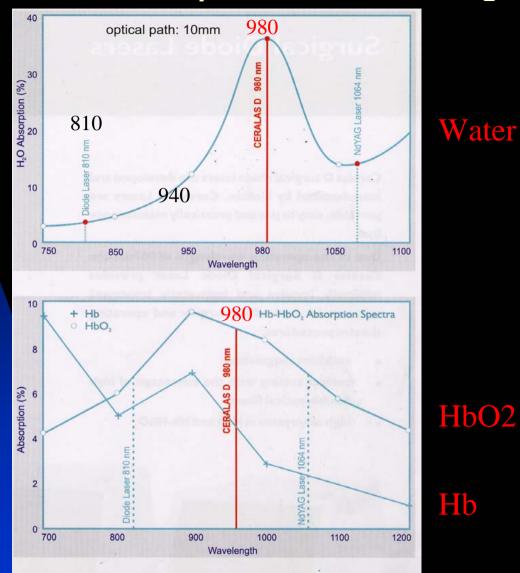
▶940nm▶980nm

▶940nm
▶980nm
▶1320nm ?

>940nm>980nm>1470nm



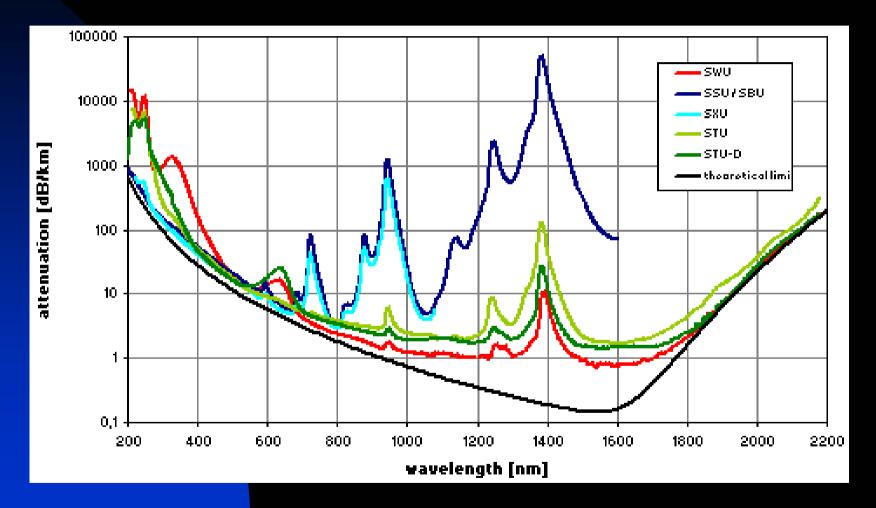
Laser Diode 980 nm : optimum wave lengh



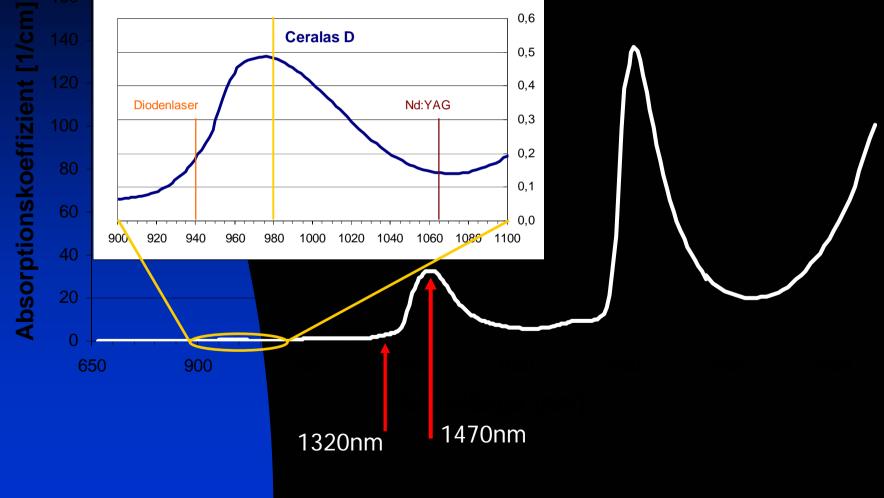
Photobiology research has identified 980nm as the optimal wavelength for absorption in water and hemoglobin. Compared to 810nm it is eight times higher and up to four times higher than 1064nm.

This enables the operator to achieve better results with lower energy settings during medical laser treatments.

Electromagnetic Spectrum



Spectrum absorption water





CoolTouch 1320 nm Flash lamp pumped Nd :YAG (neodymium-doped yttrium aluminium garnet)

Impulse pulses :

 1.2ms pulse duration and 135w peak power

Power 5w, 6.5w and 8watts

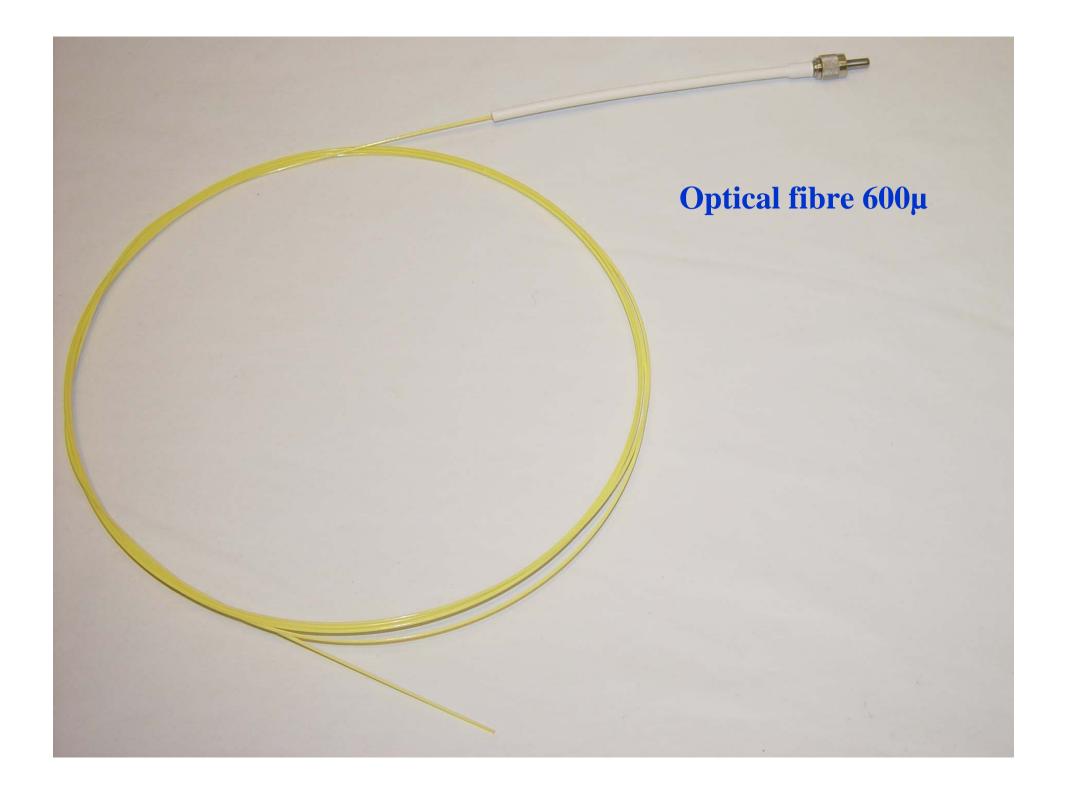


Diode laser 980nm

Diode laser 1470nm

Different fibres in Laser ablation

DOES THE FIBRES MATTER



JACKET-TIP' FIBER VS BARE-TIP FIBER FOR GSV LASER ABLATION

Lowell S. Kabnick, MD, FACS, FACPh New York University Medical Center Division of Vasular Surgery Paris January 18, 2008 laser ablation contact with the wall
 led to perforations at standard settings
 Leading to increased ecchymosis and possible pain related to wbc extravasation which starts the inflammatory cascade

Jacket-tip fiber

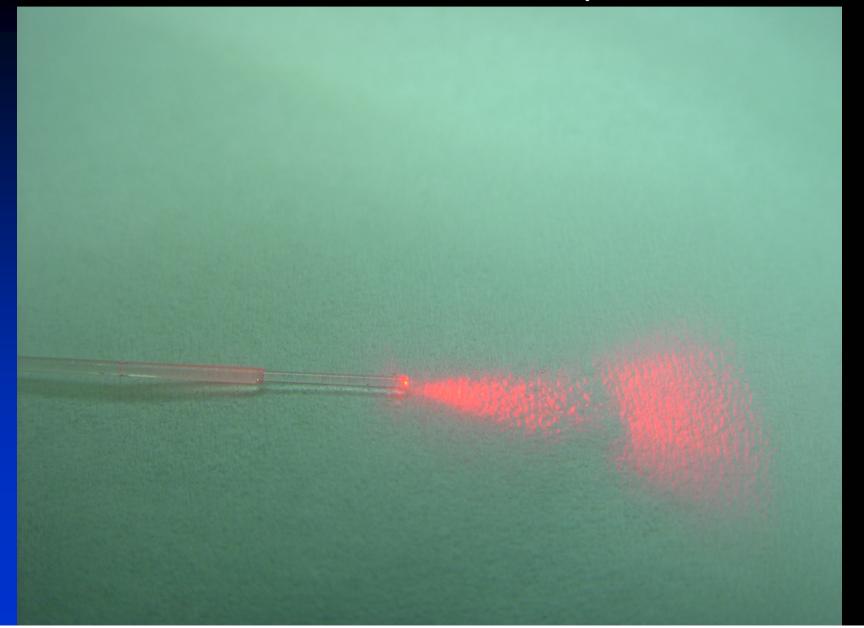




Females/Males Laser Numb Average Average Average Average Average **Total** GSV er of Length Total Age % Pain Bruise J/cm Closed Patien **Treated** ts 980 10 56.50 F=90% 36.25cm 71.57 0.757 1.05 10 NT M=10% <u>+</u>14.2 <u>+</u>10.4 51.70 34.35cm 1.87 10 980 10 F=90% 86.19 1.45 <u>+</u>11.1 <u>+</u>8.1 Bare M=10% Tip

Pain Scores								
	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	TOTAL AVG
Bare- tip fiber	2.7	2.35	2.1	1.4	1.65	1.4	1.5	1.87
Jacket-tip fiber	1.3	1.1	0.7	0.3	0.8	0.6	0.5	0.757
012345678910								

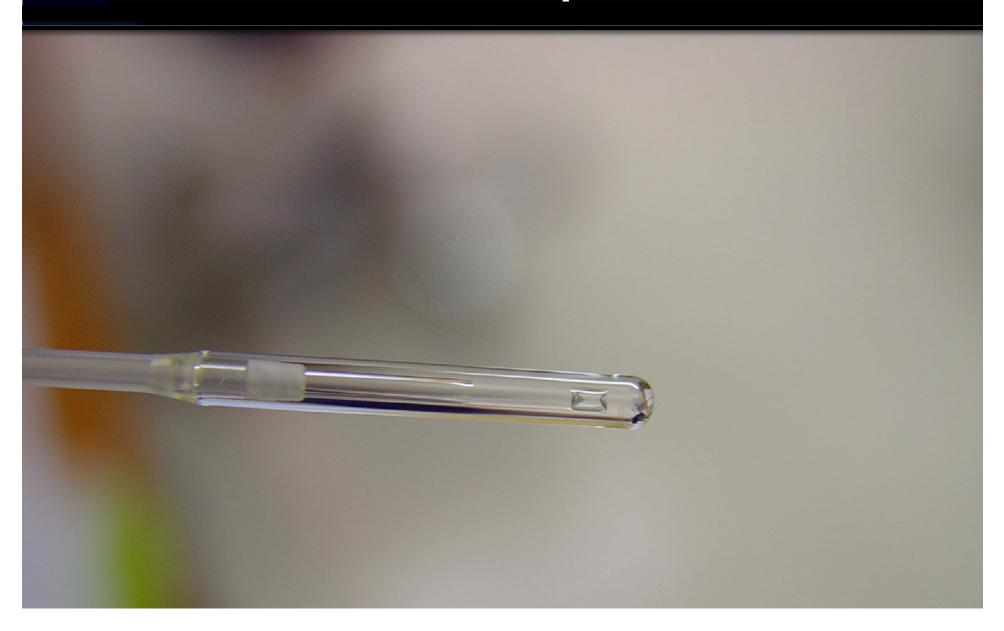
Current fibre :600µ



New fibre : 360 fibre

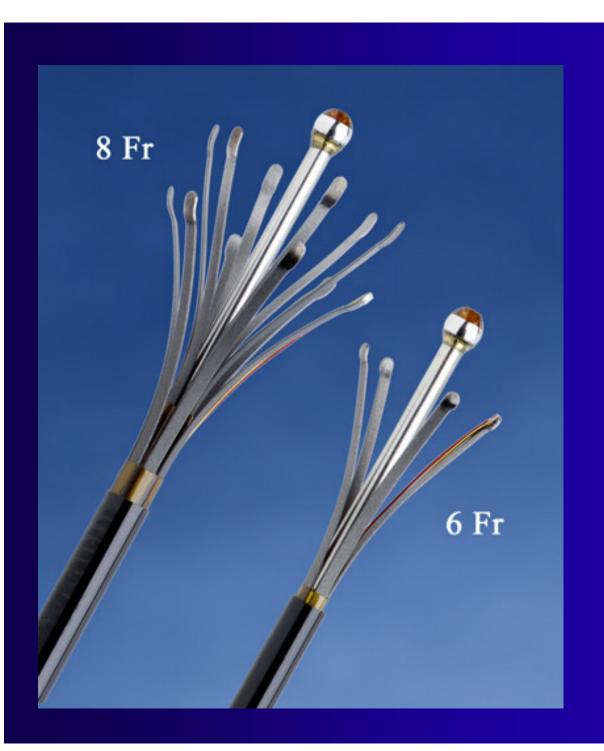
600 μ Tip shape: Hemispherical

360 fibre after procedure



Different catheters in RF ablation





Closure fast



ClosureFAST System



- 7F with a 7cm heating coil
 - 7cm vein length treated at once
 - 6.5 cm index pullback between treatments



Bipolar Radiofrequency-induced Thermotherapy (RFITT)



PRODUCTS APPLICATOR



CELONProCurve 1200-S15Diameter:1.8mmElectrode length:15 mmShaft length:1.200 mmTip shape:Hemispherical



TECHNOLOGY

The endovenous laser principle is based on a thermal process:

A conversion of light into heat

Light energy is targeted, absorbed by the Hemoglobin and water and transformed into heat.

A transfer of heat

Firstly: the blood
Secondly: the vein wall

Result: An alteration of the proteins constructing the entire vein wall (3 layers)

Closure[®] System Technology

Closure system delivers radio-frequency (RF) energy via bipolar electrodes to the vein wall

RF energy creates resistive heating that contracts the vein wall collagen, thereby occluding the vein

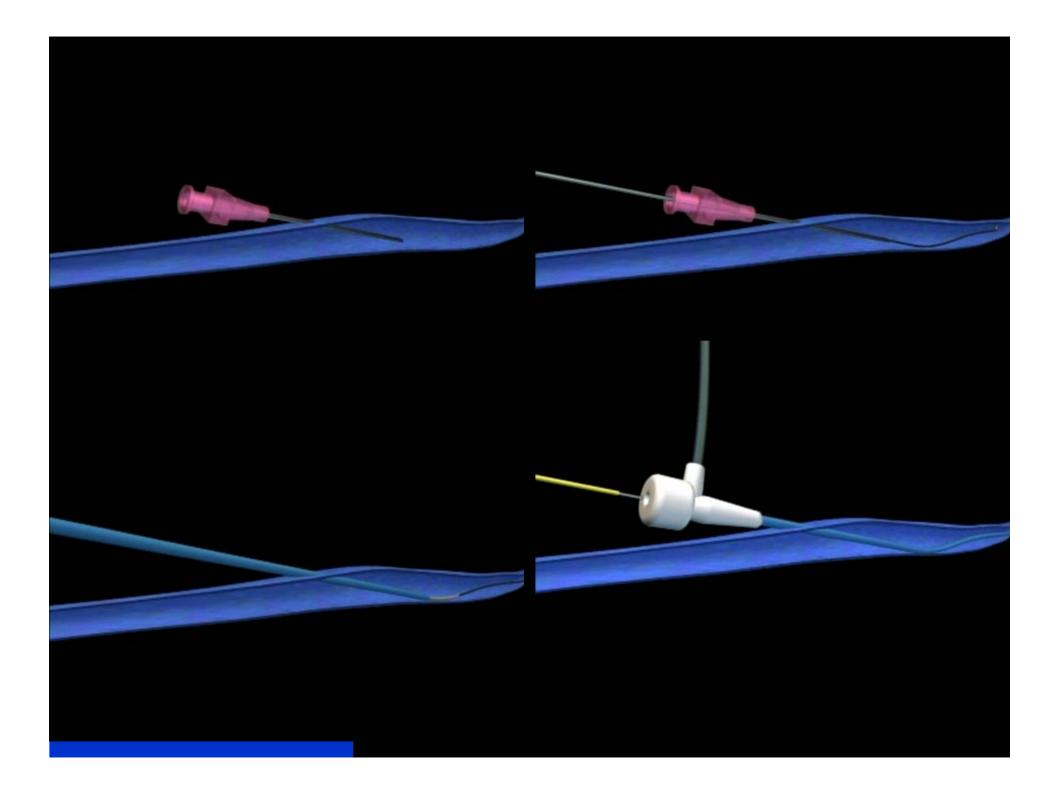
TREATMENT

Using a catheter-based approach

LASER :
• 5Fr with current fibre
• 6Fr with 360 fibre

RF

• 7Fr sheath with RF
• 6 Fr with RFITT



PERIVENOUS ANESTHETIC (tumescent anesthesy) why we need it ?

Not only for anesthetic reason but :

To protect surrounding tissue
To have a spasm of the vein

WHATEVER THE SIZE OF THE VEIN AFTER THE SPASME THE INNER VOLUME HAS TO BE THE SAME

ENERGY

ENERGY (E) in joules POWER (P) in Watt

Energy = power x time(E= P x t) Energy /cm Energy /cm²= Fluence

Minimum Energy /cm = 10 joules /cm /diameter in mm of vein to be treated

(Padova november 2006) (Controversies in varicose desease Paris january 2007)

Calculate the energy before beginning

Minimum energy : SFJ : 12 mm x 10 = 120 joules/cm Thigh: 6mm x 10 = 60 joules /cm

Lenght to be treated 40 cm 60 joules x 40 cm = 2400 joules

red contract of the second s

1470nm Power : 8 watts Continuous mode

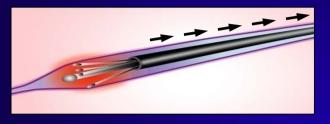
ClosureFAST System

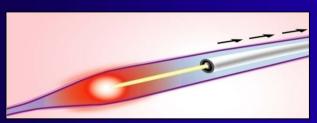


- 7F with a 7cm heating coil
 - 7cm vein length treated at once
 - 6.5 cm index pullback between treatments
- Temperature controlled energy delivery
- Power on/off switch on handle

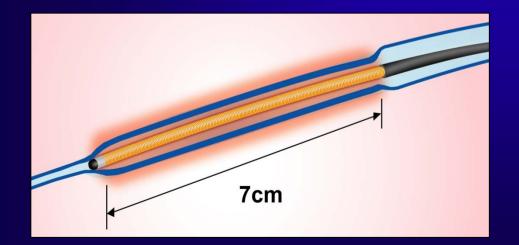


Segmental Ablation replace Old Continuous Pullback Concept



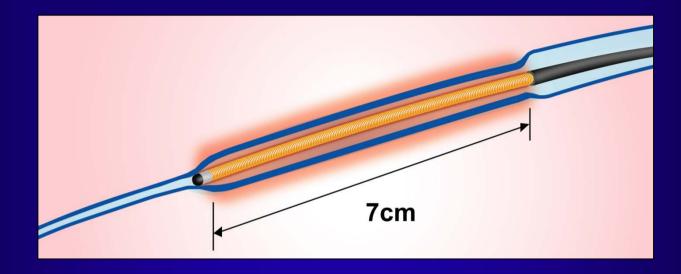


- Used by both Closure Plus and laser
- Amount of energy delivered is dependent on speed of pullback.
- Small area is being treated at any given time.



- 7 cm length treated all at once in 20 sec.
- Energy delivery does not vary by pullback speed.
- Treatment Device (set) temperature: 120°C.

ClosureFAST Segmental Ablation



- 7 cm length treated all at once in 20 seconds
 - Device (set) temperature: 120° C
 - Tissue temperature: 100 110° C
- No energy delivery during repositioning
- Uniform energy dose not dependant on pullback speed

Ablation Time Comparison (45cm GSV Segment)

Current Closure $- 85^{\circ}$ C18Current Closure $- 90^{\circ}$ C10ClosureFAST3 - 5 mins810nm laser10 - 14 W31320nm laser6 - 10 W>

18 - 24 mins 10 - 12 mins

 $3 - 5 \text{ mins}^1$ >7.5 mins²

References:

1 - EVLT® – Compare Alternatives; Diomed website 8/14/06

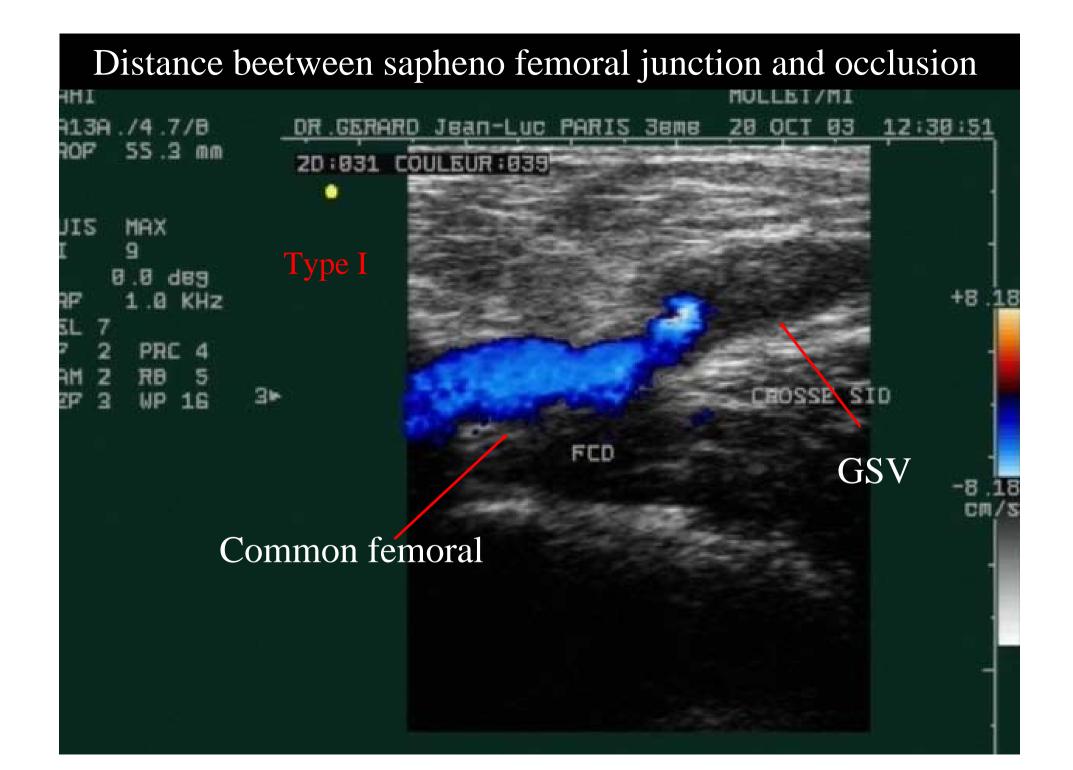
2 - Proebstle; ACP2004 abstract

RESULTS to the junction

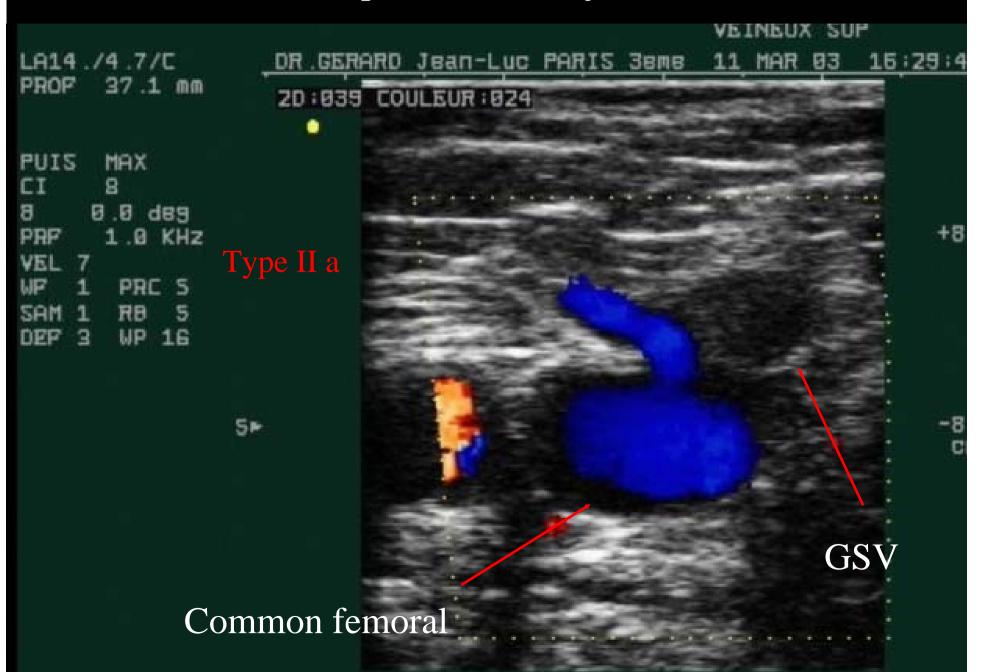
Sapheno-femoral junction duplex scan patterns after endovenous laser

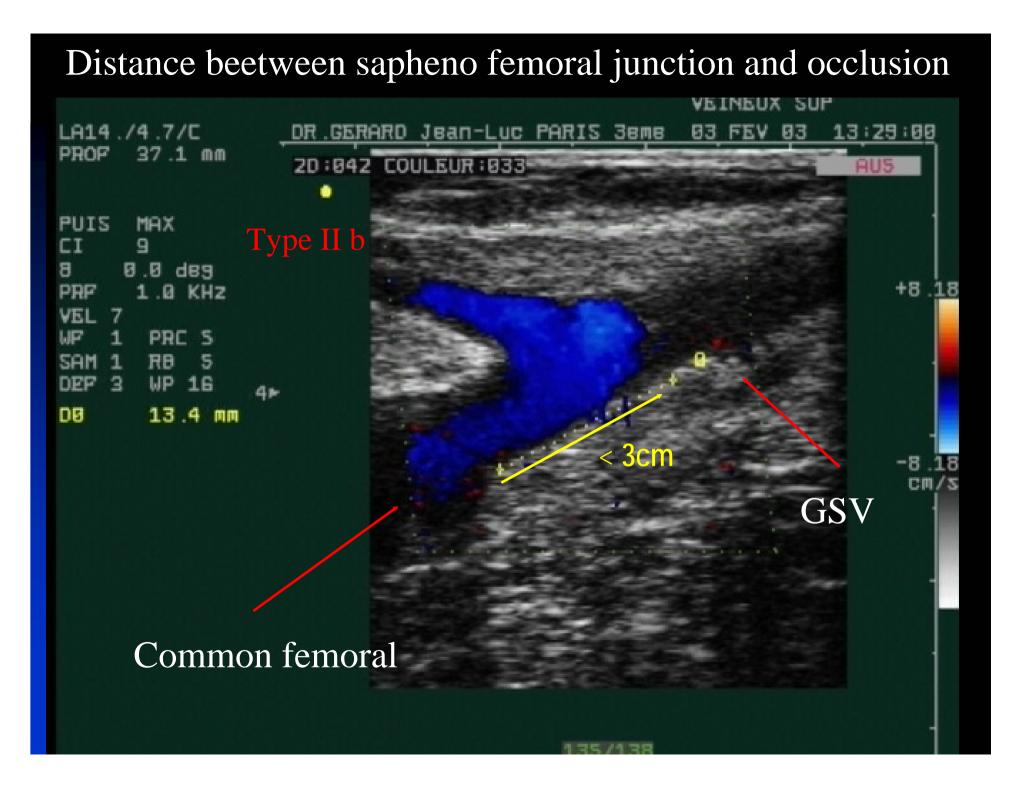
Pichot O, Kabnick L, Perrin M

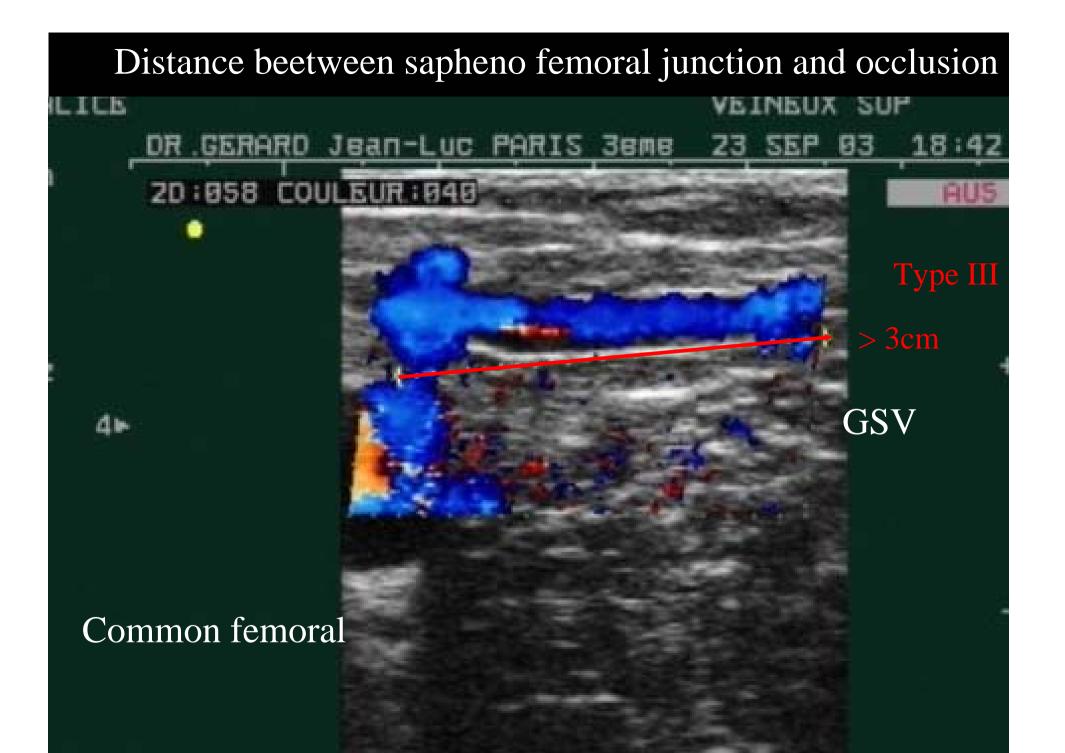
 Aspects échographiques de la jonction saphénofémoral après oblitération de la grande veine saphène par Radiofréquence (Closure)
 (phlébologie 2002,55,N°4,329-334)



Distance beetween sapheno femoral junction and occlusion



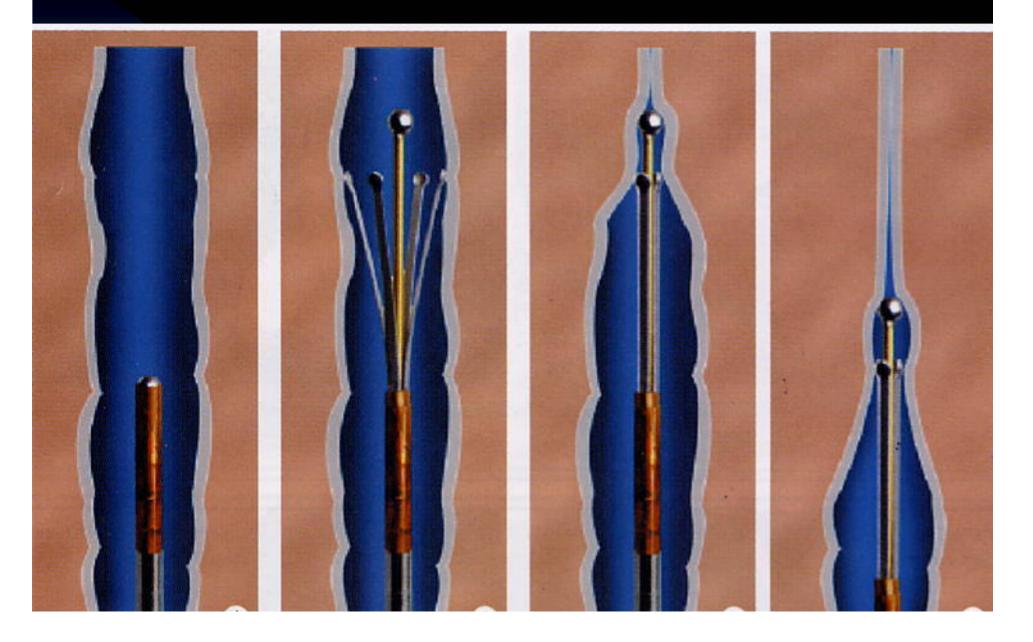


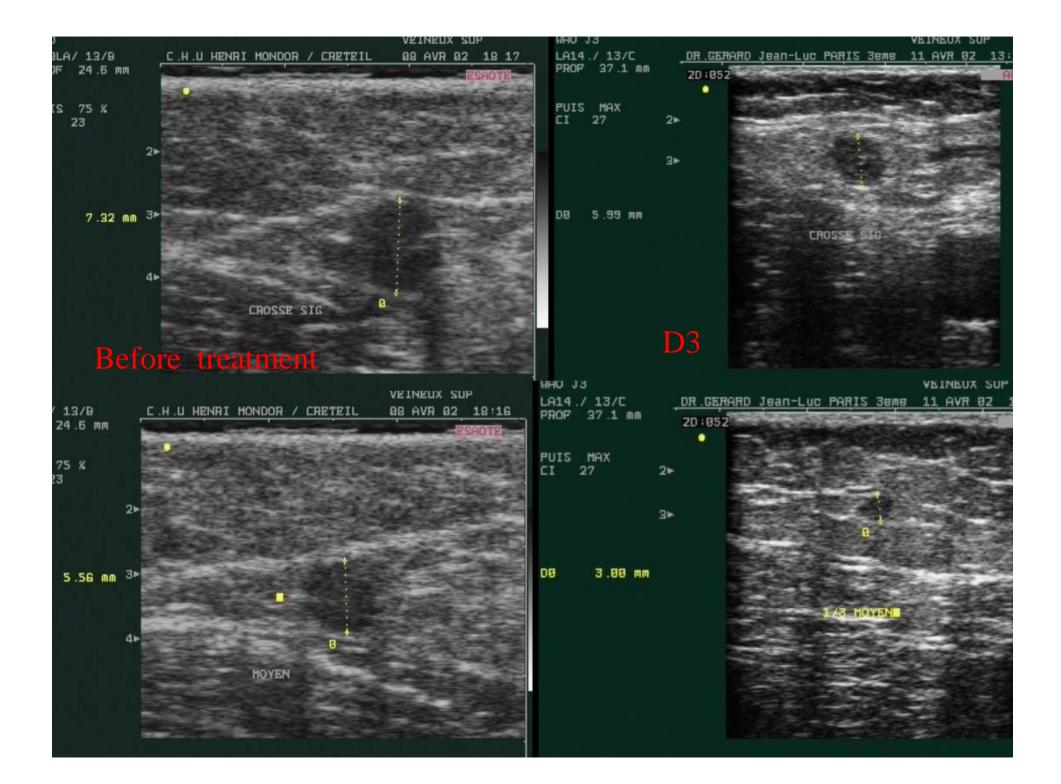


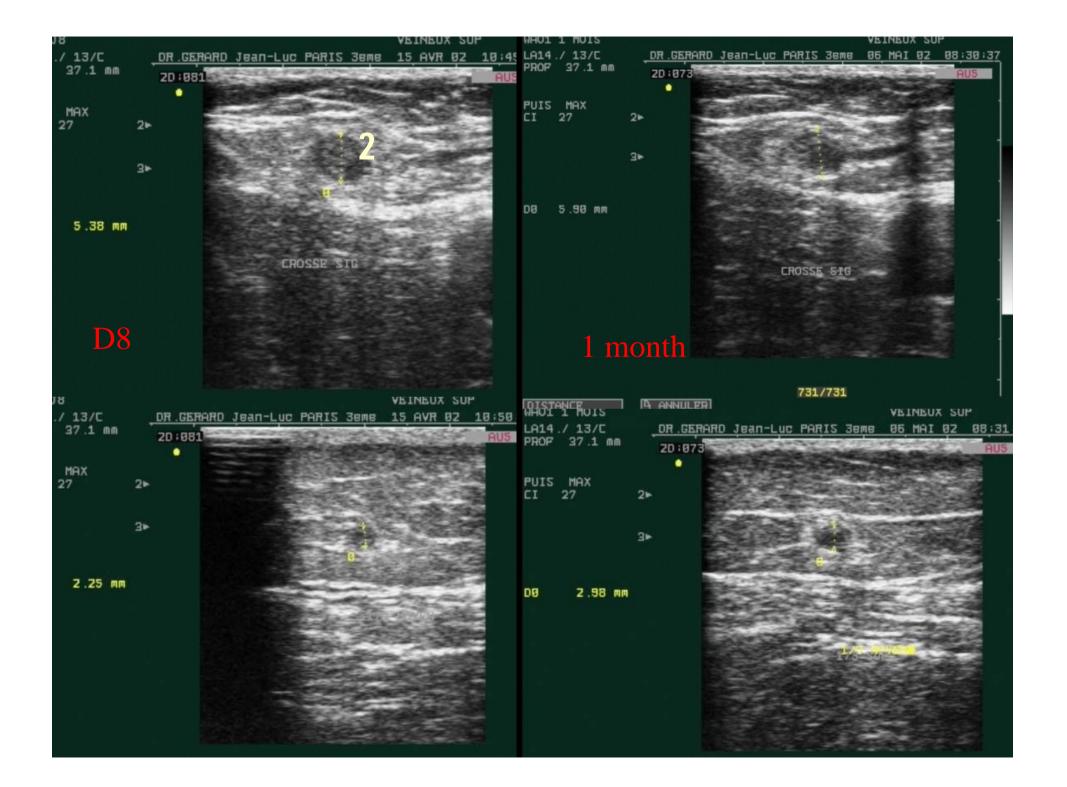
Immediate results

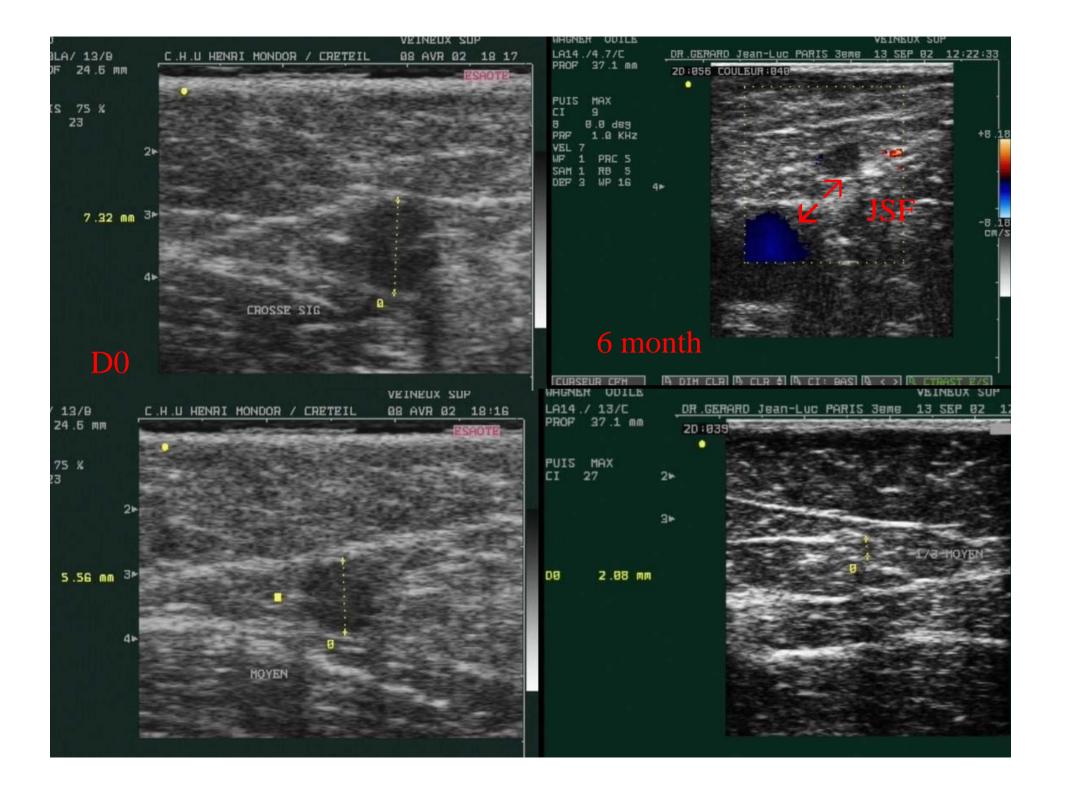
Progressive Shrinkage of the vein

Progressive shrinkage



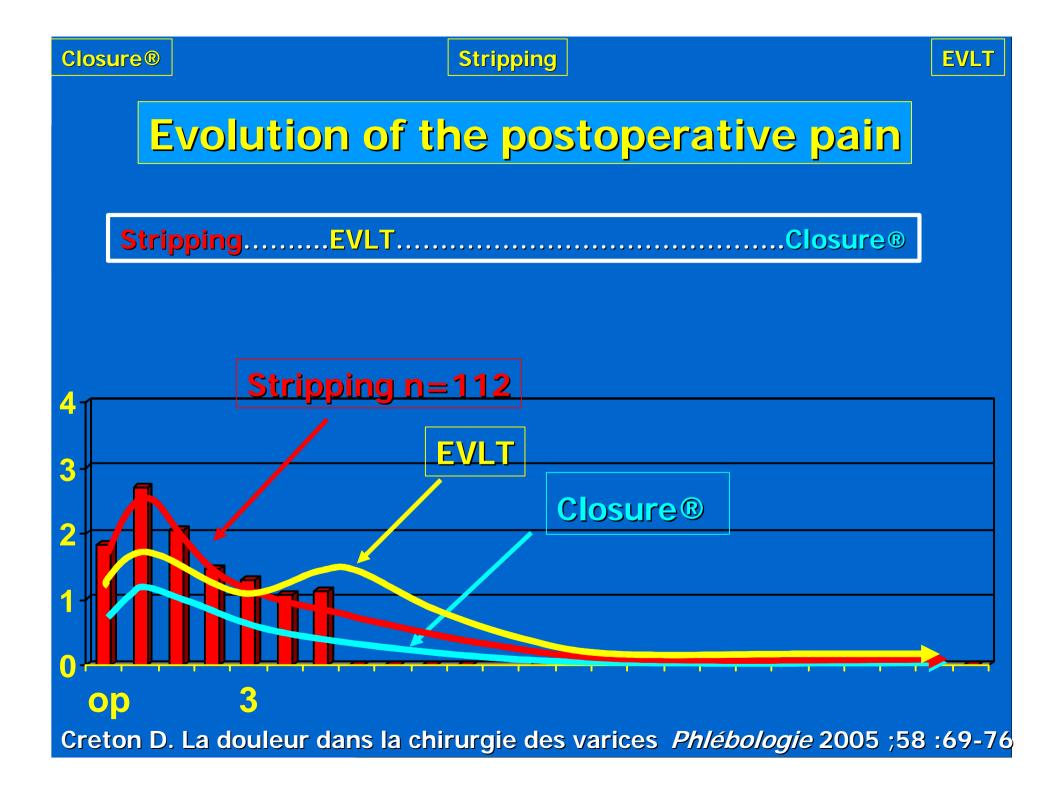






Pain during the procedure

No pain



Litterature Review

Currently 82 articles have been published in English (68) and French (14) on RF obliteration for treating varicose veins.

Nineteen of them compared **RF** versus **EVL** but no **RCT**.

Seven compared RF versus HL + Stripping +/Stab Avulsion including 4 RCT

One compared RF, EVL, HL+stripping



RAPID and MILD PATIENT RECOVERY

VERY FEW ADVERSE EFFECTS

Multi-centre retrospective study EVLA of saphenous veins outside operating theatre

DESIGN OF THE STUDY

Multi-centre (19 centres), retrospective study

Participants in France :

Allouche Boitelle Bracon Cales Desnos Delafoulhouze Galland Gérard Hamel-Desnos Hévia Landon Magnaval Mussard Neaume Thirifays Participants in Switzerland :

Ducrey Favre Kern Merminod

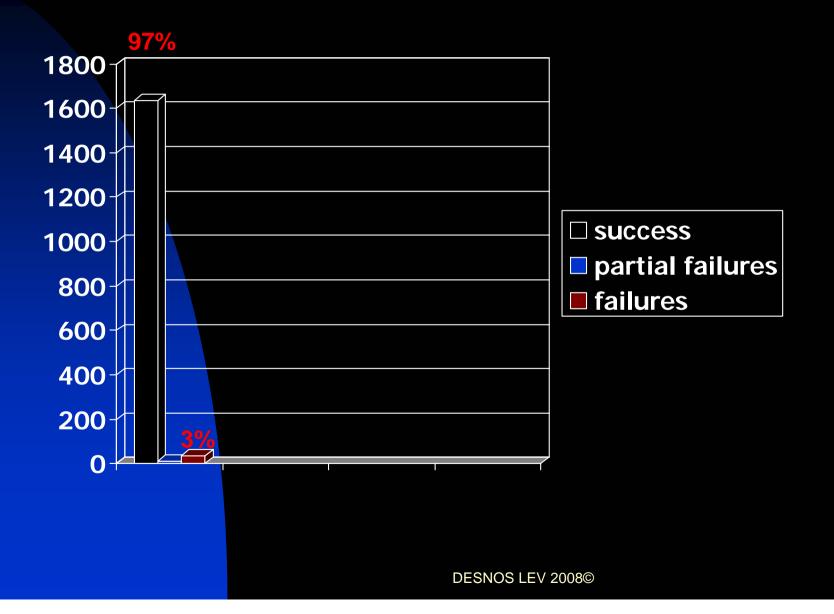
Population included : <u>1703</u> saphenous veins; <u>1422</u> patients

Gender	Female 74% (1300)
	Male 26% (403)
Age	Average 57
	Median 57
	(Extremes 15 and 92)
BMI	Average 25
	Median 24
	(Extremes 15 and 64)
CEAP	Average 2.8
	Median 2
	(Extremes 2 and 6)

Veins treated, main features of treatment

Type of vein (n)	GSV <u>1394</u>	SSV <u>309</u>
Diametre (mm)	Average 7.21	Average 6.41
Standing (large majority of cases)	Median 7	Median 6
	(Extremes 2 and 23)	(Extremes 3 and 17)
Length treated (cm)	Average 40	Average 21
	Median 40	Median 20
	(Extremes 3 and 85)	(Extremes 5 and 60)
Energy released (Joules / cm)	Average 64	Average 65
	Median 64	Median 64
	(Extremes 25 and 153)	(Extremes 38 and 100)

Effectiveness of treatment carried out



Comparative results

	EMC Perrin (2007) (encyclopédie médico- chirurgicale)	EVLT study outside operating theatre
Effectiveness	About 95 %	■ 97%
DVT	■ 0 to 2.7 %	■ 0.3% (n = 5) PE 0.06% (n = 1)
SVT	■ 1.7 to 10%	■ 0.2% (n = 4)
Dysesthesia	■ 0 to 36.5%	■ 0.7% (n = 12)
Hematoma	■ 0.8 to 46%	■ 0.3% (n = 5)
Infections	■ 0	■ 0.1% (n = 2)
 Sick leave (average number of days) 	4 (under LA)	often 0 sometimes 3 or 4 depending on centre ESNOS LEV 2008© (4)

Bipolar Radiofrequency induced Thermotherapy (RFITT[®])

A minimally invasive procedure for applications in phlebology

Bipolar Radiofrequency-induced Thermotherapy (RFITT) for the efficient and gentle treatment of insufficient veins -Results of the BRITTIV* Multicenter-Study –

(* Bipolar Radiofrequency-Induced Thermotherapy (RFITT) for the Treatment of Insufficient Veins)

(results presented by Dr. M. Camci at the German Congress of Phlebology in Mainz 2007) M Camci¹, B Harnoss², G Akkersdijk³, B Braithwaite⁴, L Hnatek⁵, E Roche⁶, P Santoro⁷, M Sarlija⁸, Y Sezgin², D Nio³, M Ajduk⁸, D Koios²

¹Mediapark Klinik, Cologne/Germany; ²Martin-Luther Clinic, Berlin/Germany; ³Spaarne Ziekenhuis, Hoofddorp/The Netherlands; ⁴Mapperley Park Clinic, Nottingham/UK; ⁵Atlas Hospital, Zlin/Czech Republic; ⁶Platón Clinica, Barcelona/Spain; ⁷Angiomedica, Rom/Italy; ⁸Klinicka Bolnica Dubrava, Zagreb/Croatia

Intermediate results – clinical data (06/07)

• N:	273 legs in 230 patient	
• Ø age:	53 years	
• Gender ratio:	30% men; 70% women	
• Treatment area:	VSM = 97%, VSP = 3%	
• Anaesthesia:	General $= 70\%$,	
<i>Spinal</i> = 23%, <i>Local</i> = 7%		
	additional Tumescence = 81%	
• Ø Power setting:	24 Watt	
• Ø Vein length:	42 cm	
• Ø Treatment time:	46 s	
• => Ø time per cm:	1,1 s	
 Patient satisfaction*: 	>99%	

*were satisfied with the treatment and would recommend it to friends and/or family

IN TOTAL in RF ablation

• ADVANTAGES RF Fast

- Efficient : more than 95%
- Uniform energy dose not dependant on pullback speed
- Less painful, less ecchymosis comparing surgery and laser ablation

• DISAVANTAGES

- Is it still RF with Closure Fast ?
- Parameters are fixed (120 ° Celsius) whatever size of the vein
 - Risk of paresthesia: SSV and GSV below knee
 - Burn: superficial veins
- Possible inefficacy
 - Lack of spasm after tumescent anesthesia (perforator between the 7cm catheter)
- 7Fr sheath with RF

IN TOTAL in LASER ablation

DISAVANTAGES

- Different wavelengths
- Energy dose
 - By your own
 - Dependant on pullback speed

ADVANTAGES

- Efficient : more than 95%
- Adapt energy according size of the vein
- Adapt energy according depth of the vein
- Less painful less ecchymosis with 360 and 1470 nm

COST

LASER : 150 to 200 euros

RF Fast: 400 euros

RFITT : 285 euros

CONCLUSION

RF or EVLT ablation Ambulatory technique or mini invasive procedure Efficient but necessitating

Ultrasound skill (surgeon or vascular physician)
 Minimum training

Systematic review of foam Sclerotherapy for varicose veins. X. Jia^{1*}, G. Mowatt¹, J. M. Burr¹, K. Cassar², J. Cook¹, C. Fraser¹ British Journal of Surgery 2007 Août (*Br J Surg 2007; 94: 925-36*)

Sixty-nine studies were included.

- Security
 - Serious adverse events (PE, DVT): less 1%
 - ♦ Visual disturbance : 1.4%
 - ♦ Headache: 4.2%
 - ◆ Thrombophlebitis (SVT): 4.7%
 - matting/skin staining/pigmentation: 17.8 %
 - ◆ pain at the site of injection: 25.6 %
- Efficacy
 - Complete occlusion of treated veins: 87 %
 - developpment of new veins: 8.1 %

FOAM THERAPY

ADVANTAGES

- Cheeper, easy
- Adapt dose according size of the vein
- Adapt dose according depth of the vein
- Best treatment for recurrency

DISAVANTAGES

- Less efficient big veins
- Disappearance of vein longer than RF or LASER (30% 3M, 85% 2Y)
- Adverse effects : 0,3 % neurologic complications including visual disturbance (transient and reversible)