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5 years results: endovenous treatment of superficial vein reflux in an outpatient setting

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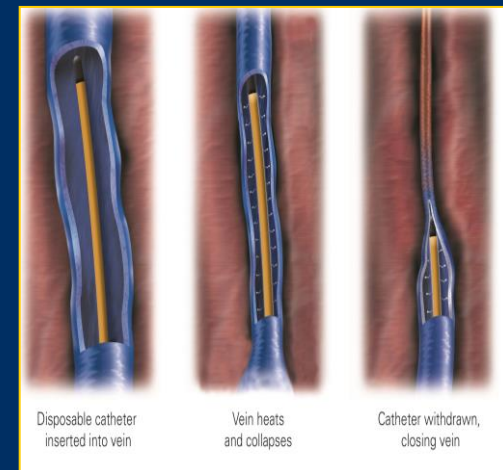
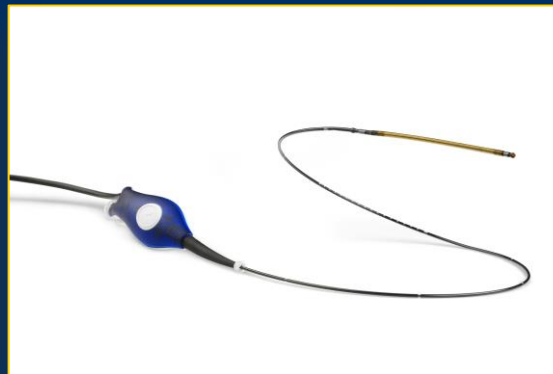
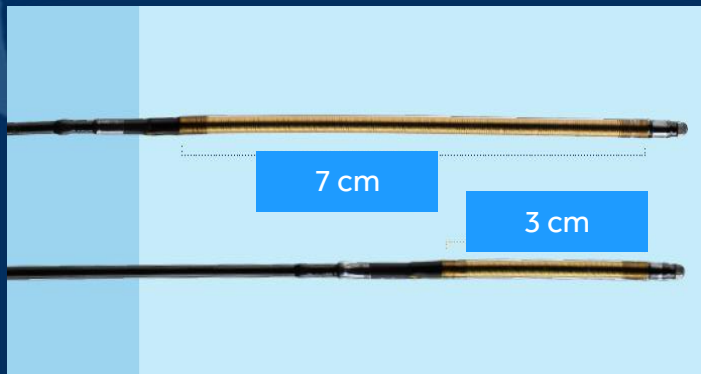
ENDOVENOUS TREATMENT : 5 YEARS RESULTS?

- EVLA (Endovenous laser ablation)
- **RFA (Radiofrequency ablation)**
 - Radiofrequency **segmental** thermal ablation



RADIOFREQUENCY SEGMENTAL THERMAL ABLATION : CLINICAL DESCRIPTION

- The RFA ClosureFast™ system, delivers radiofrequency energy in a controlled fashion
 - segments of veins causing denaturation of the collagen
 - contraction of the vessel
 - no blood can flow through it





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EVOLUTION OF CLOSUREFAST™ TECHNOLOGY

VNUS Medical Technologies
Founded



Covidien acquires VNUS
Medical Technologies



Medtronic acquires Covidien



1995

1999

2005

2006

2009

2014

2015



FDA cleared
Closure™ System

FDA approval
ClosureFast™ System
(segmental ablation)

FDA approval
ClosureRFG™ Generator
(RFG3)

FDA cleared
ClosureRFS™ Stylet





RADIOFREQUENCY SEGMENTAL THERMAL ABLATION : LONG TERM STUDY

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ClosureFAST study

Multicenter, prospective, 5 years f/u

Alan Dietzek. Veith Symposium New York City; November 19, 2013

Rassumussen study

Multicenter, randomized, 3 years f/u

Rasmussen LH, et al., J Vasc Surg Venous Lymphat Disord Oct2013;349-356.

Proebstle study

Multicenter, prospective, 5 years f/u

TM Proebstle , et al., BJS 2015 Feb;102(3):212-8



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CLOSUREFAST STUDY

: Dietzek A et al. 2013

Study Features:

- International multi-center study (8 Europe, 5 US)
- Prospective, longitudinal, single arm
- 326 patients and 396 limbs treated
- 278 limbs followed to 5 years (70.2%)



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CLOSUREFAST STUDY

: Dietzek A et al. 2013

■ Primary Endpoints

- Vein occlusion rate
- Absence of reflux rate

■ Secondary Endpoints

- Presence of complications and side effects
- Quality of life (QOL)



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CLOSUREFAST STUDY

: Dietzek A et al. 2013

BASELINE CHARACTERISTICS

	Enrolled Subjects (N=326)
Age mean (SD) Age range	50.8 (13.3) 18 - 79 years
Gender	73.3% Female 26.7% Male
BMI mean (SD) BMI range	26.5 (5.6) 16.2 - 48.5

BMI = Body mass index



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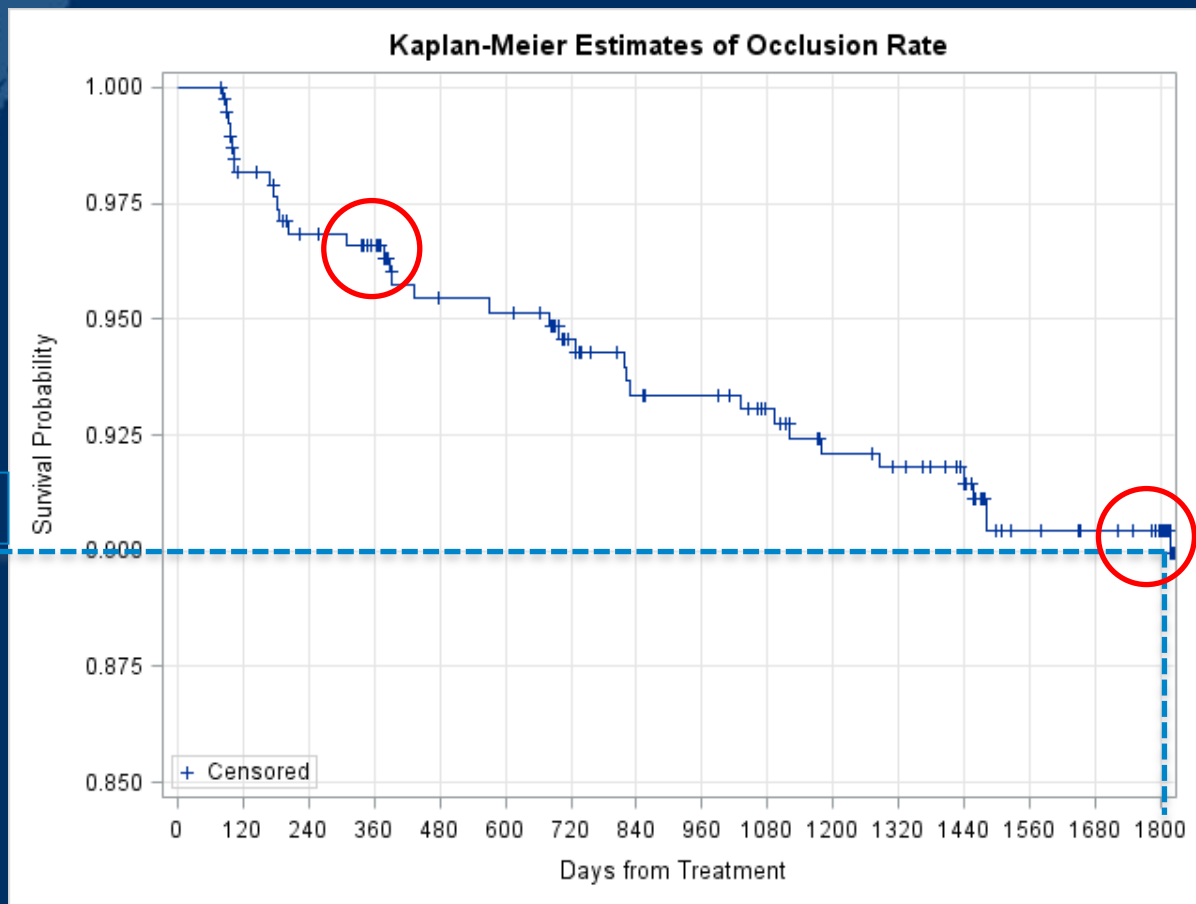
CLOSUREFAST STUDY

: Dietzek A et al. 2013

OCCLUSION RATES AT 1 & 5 YEARS

96.6% success at 1 year

90.0% success at 5 years





CLOSUREFAST STUDY

: Dietzek A et al. 2013

OCCLUSION & REFLUX FREE RATES

Time	Occlusion Rates %*	Std Error
1 Year	96.6%	0.9%
2 Year	94.3%	1.2%
3 Year	92.8%	1.4%
4 Year	91.1%	1.5%
5 Year	90.0%	1.7%

Time	Reflux free Rates %*	td Error
1 Year	98.9%	0.5%
2 Year	97.8%	0.8%
3 Year	95.7%	1.1%
4 Year	94.0%	1.3%
5 Year	93.7%	1.3%

*Product limit occlusion estimates.



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RASMUSSEN STUDY

: Rasmussen et al. 2013

Study Features :

- Randomized, prospective trial, two sites Denmark
- 500 subjects (580 legs)
- Patients assessed at 3, 30 and 1 & 3 years (intended 5 year follow-up)

Compared 4 treatments :

- EVLA (980 nm and 1470 nm) – 125(144)
- RFA ClosureFast™ catheter – 125(148)
- Ultrasound guided sclerotherapy (UGSF) – 125(144)
- Surgical stripping – 124(142)



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RASMUSSEN STUDY

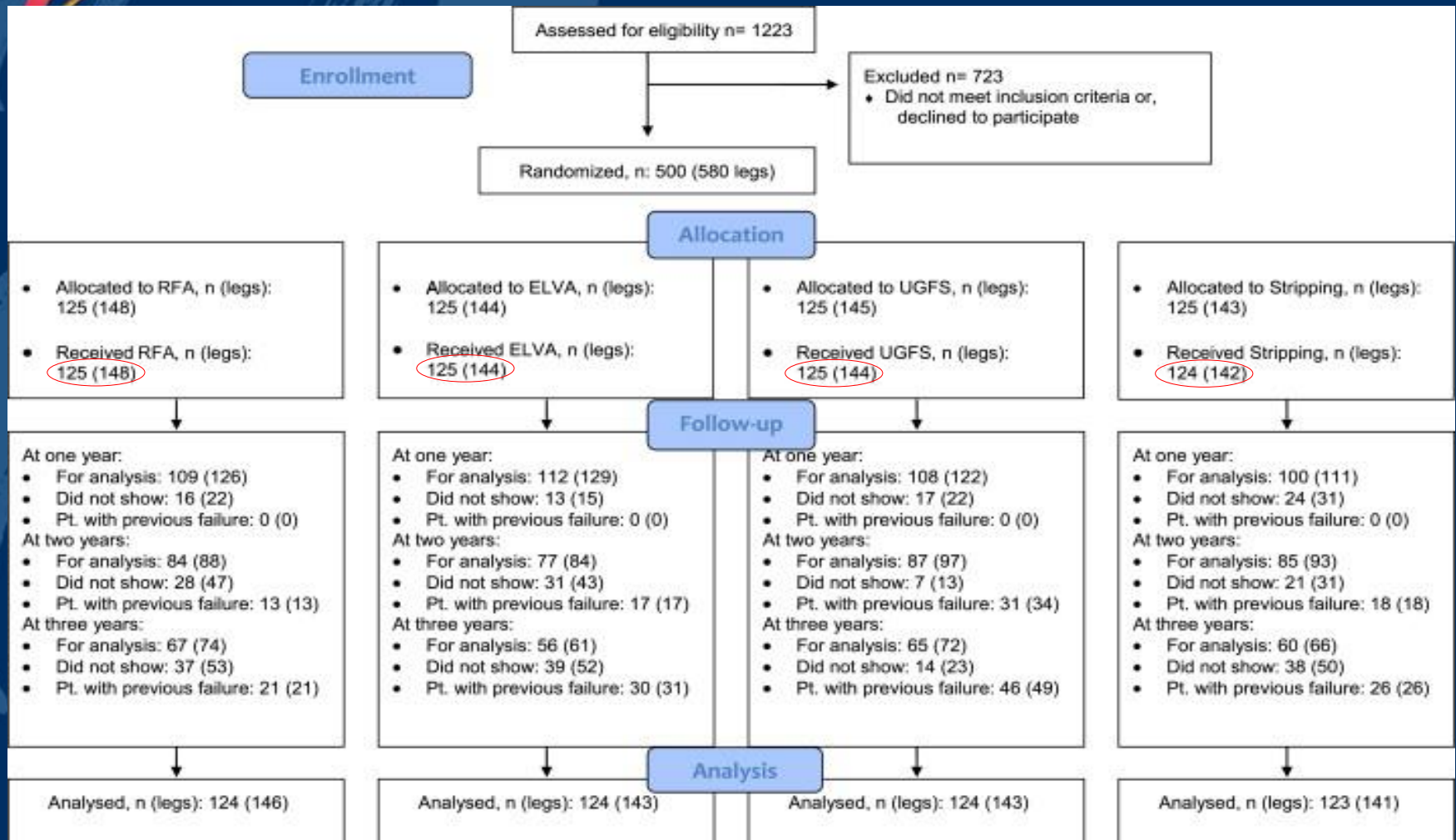
: Rasmussen et al. 2013

- **Primary endpoint**
 - Closed or absent GSV
(Refluxing segment 10cm or more considered failure)

- **Secondary endpoints**
 - Presence of varicose veins, reoperations, VCSS and QOL



RASMUSSEN STUDY



EVLA: Endovenous Laser Ablation 980-nm diode laser 17 legs & 1470nm diode laser 127 leg;;GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.



RASMUSSEN STUDY BASELINE CHARACTERISTICS

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: Rasmussen et al. 2013

	RFA	EVLA	UGFS	Stripping
No. of patients	125	125	125	124
No. of legs	148	144	144	142
Bilateral	23	19	19	18
Age (range)	51 (23-77)	52 (18-74)	51 (18-75)	50 (19-72)
Female (%)	70	72	76	77
CEAP C2-C3 (%)	92	95	96	97
CEAP C4-C6 (%)	8	5	4	3

EVLA: Endovenous Laser Ablation 980-nm diode laser 17 legs & 1470nm diode laser 127 leg,;GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. *JVS Venous Lymphat Disord* 2013;349-356.

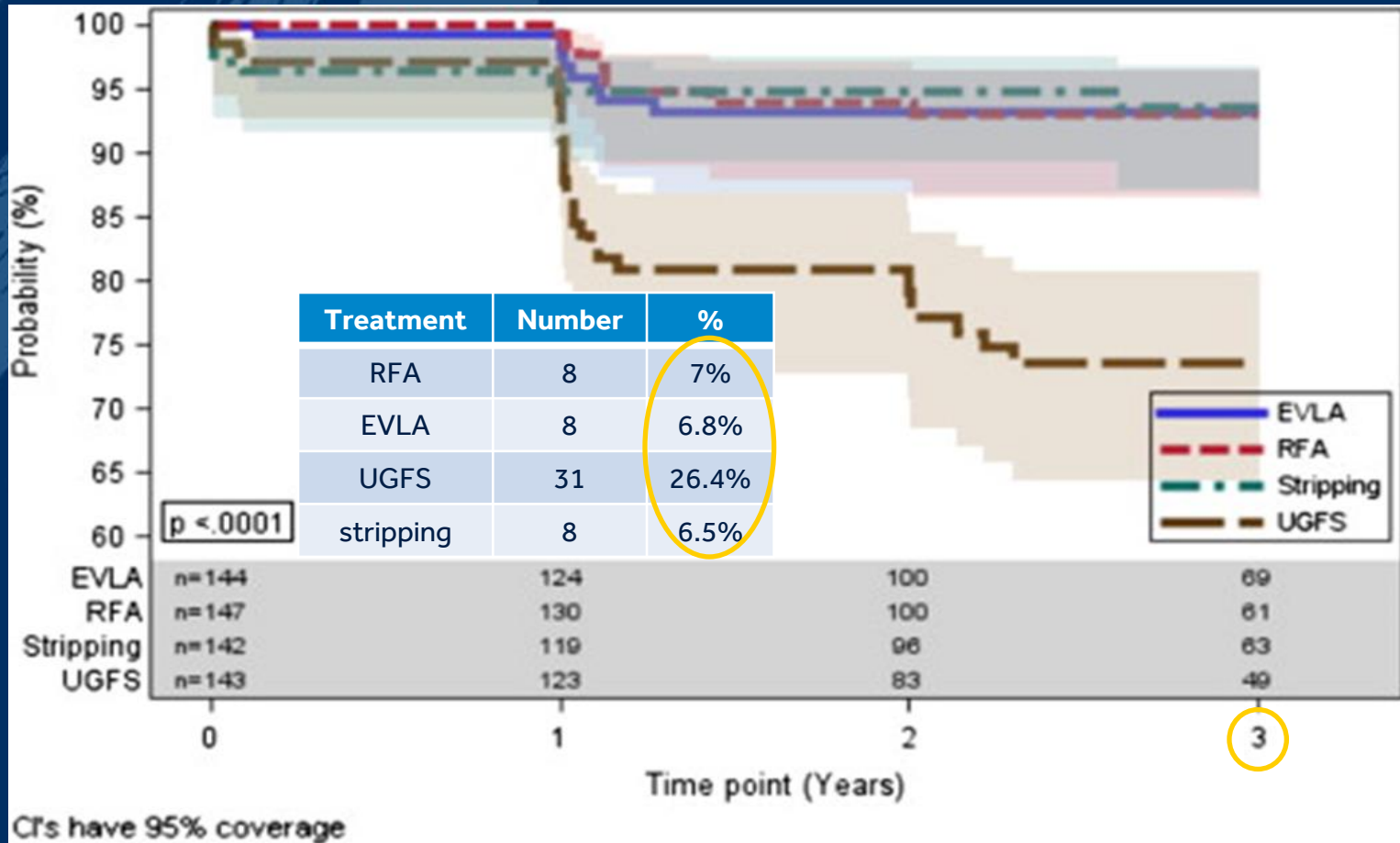


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OPEN OR REFLUXING GSV'S

RASMUSSEN STUDY

: Rasmussen et al. 2013



EVLA: Endovenous Laser Ablation ;GSV, Great Saphenous Vein; RFA, Radiofrequency Ablations; USGS, Ultrasound-guided Foam Sclerotherapy.

Kaplan-Meier (KM) plot of reoperations. The KM figures represent time to the event.

Rasmussen LH et al., Randomized clinical trial comparing EVLA, RFA, FS, and stripping for GSV with 3 yr follow-up. *JVS Venous Lymphat Disord* 2013;349-356.



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RASMUSSEN STUDY

: Rasmussen et al. 2013

▪ **VCSS (Venous Clinical Severity Score) :**

Improved significantly in all groups ($p < .0001$), no significant difference between groups at any given point in time and continued throughout the 3 year follow-up.

▪ **AVVSS (Aberdeen Varicose Vein Symptom Severity Score)**

Improved significantly in all groups from day 3 through year 3 ($p < .0001$), no significant difference between groups throughout.

▪ **SF-36 Scores (Quality of Life)**

Significant improvements made over baseline in the following categories; physical, bodily pain, vitality, and social functioning, in addition to emotional and physical component summary in all groups at all times.



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PROEBSTLE STUDY

: Proebstle et al., 2015

Study Features:

- European multi-center (8 sites in Germany, France)
- Prospective, cohort study
- Between April 2006 ~ March 2007
- 225 patients and 295 limbs treated
- 177 patients and 236 limbs followed to 5 years (78.7%)



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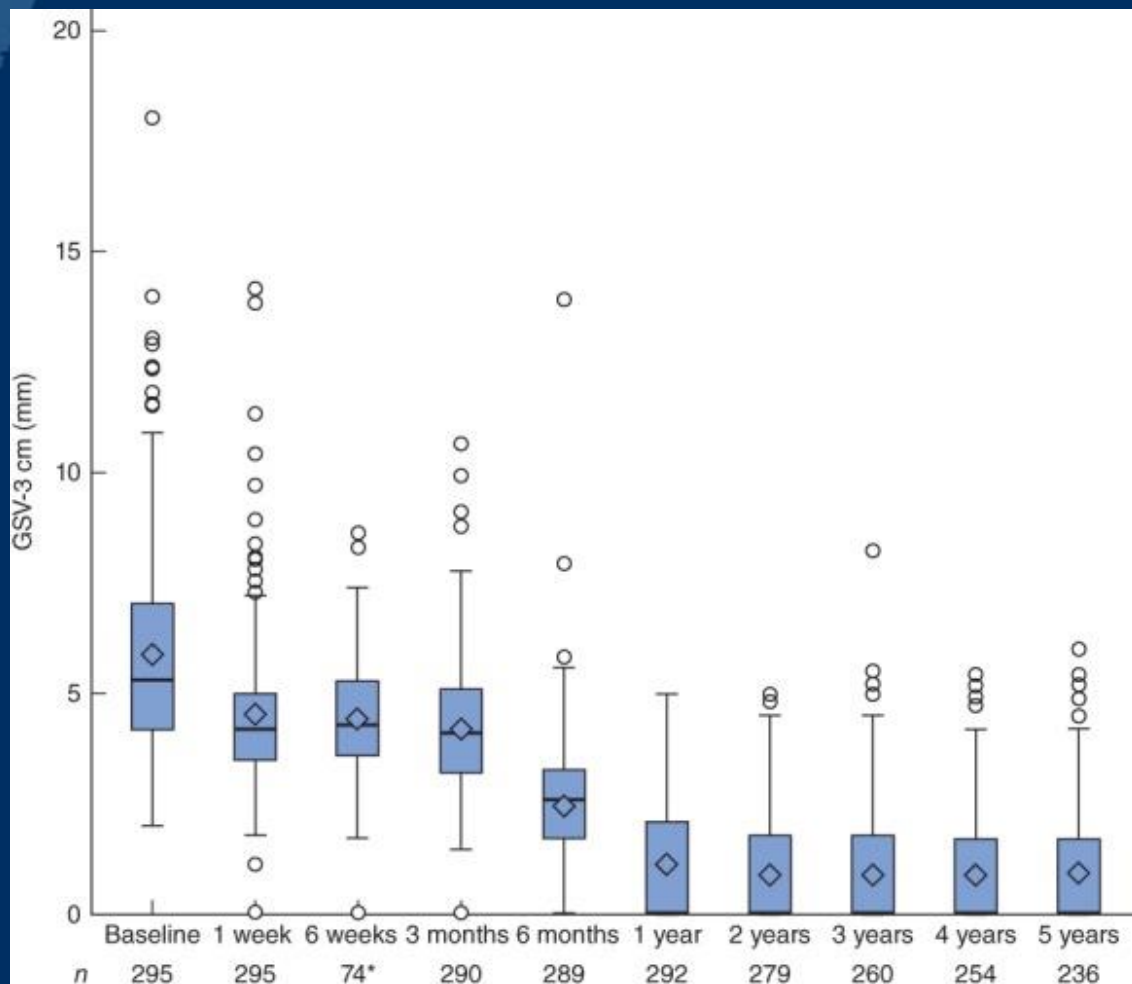
PROEBSTLE STUDY

: Proebstle et al., 2015

- **Primary endpoint** : Vein occlusion
Absence of flow in the treated vein using distal augmentation
- **Secondary endpoints** :
CEAP, VCSS, VAS for pain, complications etc.



- Mean diameters of GSV 3cm distal to the SFJ
- Not visible in 53.4% at 5 years
- Fibrotic cord mean 2.0mm (preOP mean 5.8mm)





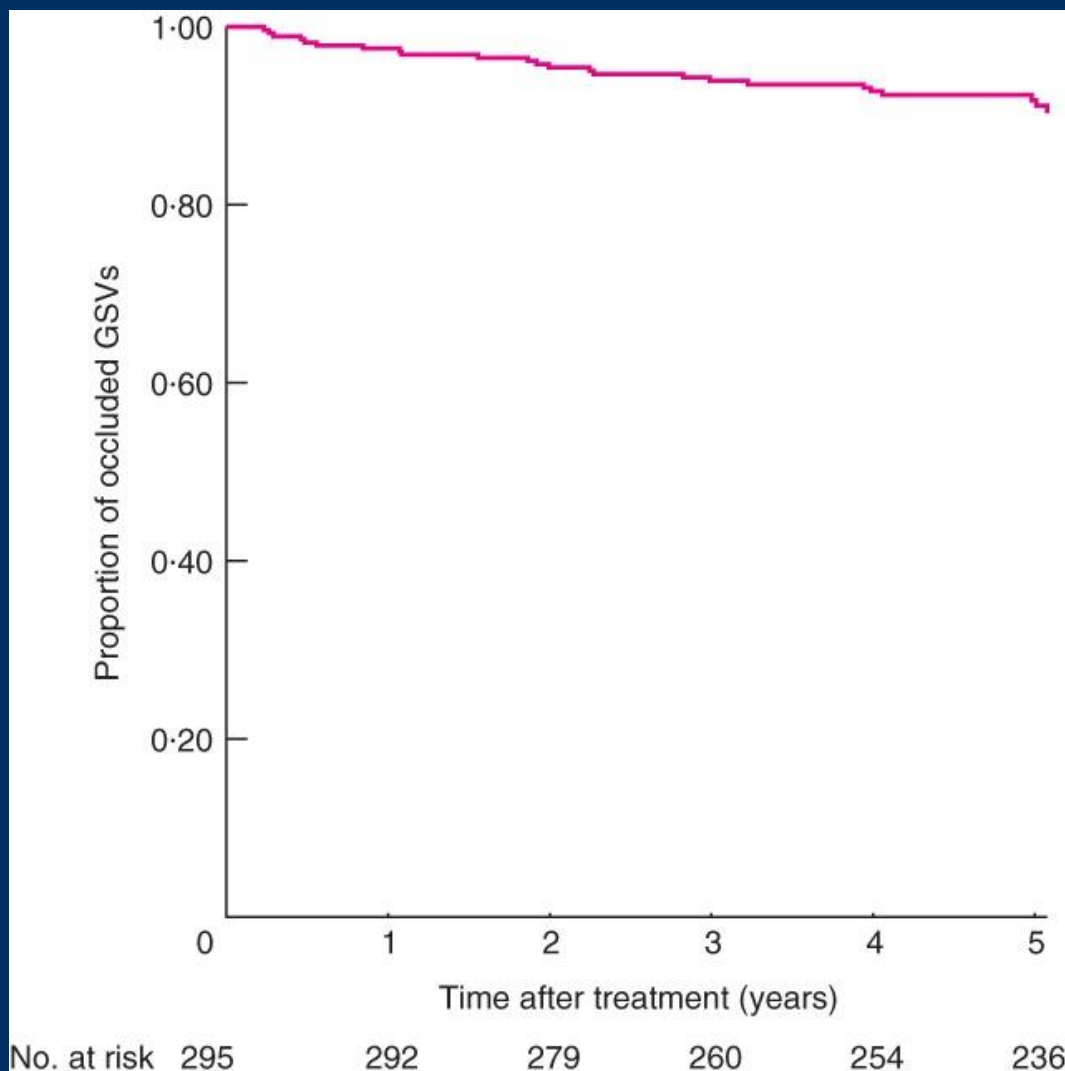
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PROEBSTLE STUDY

: Proebstle et al., 2015

- GSV occlusion rate at 5 years : 91.9%

(complete occlusion with absence of any reflux up to 3cm below SFJ)



Proebstle et al., 5 yr results from the prospective European multicenter cohort study in RF segmental thermal ablation for incompetent GSV BJS 2015 Feb;102(3):212-8



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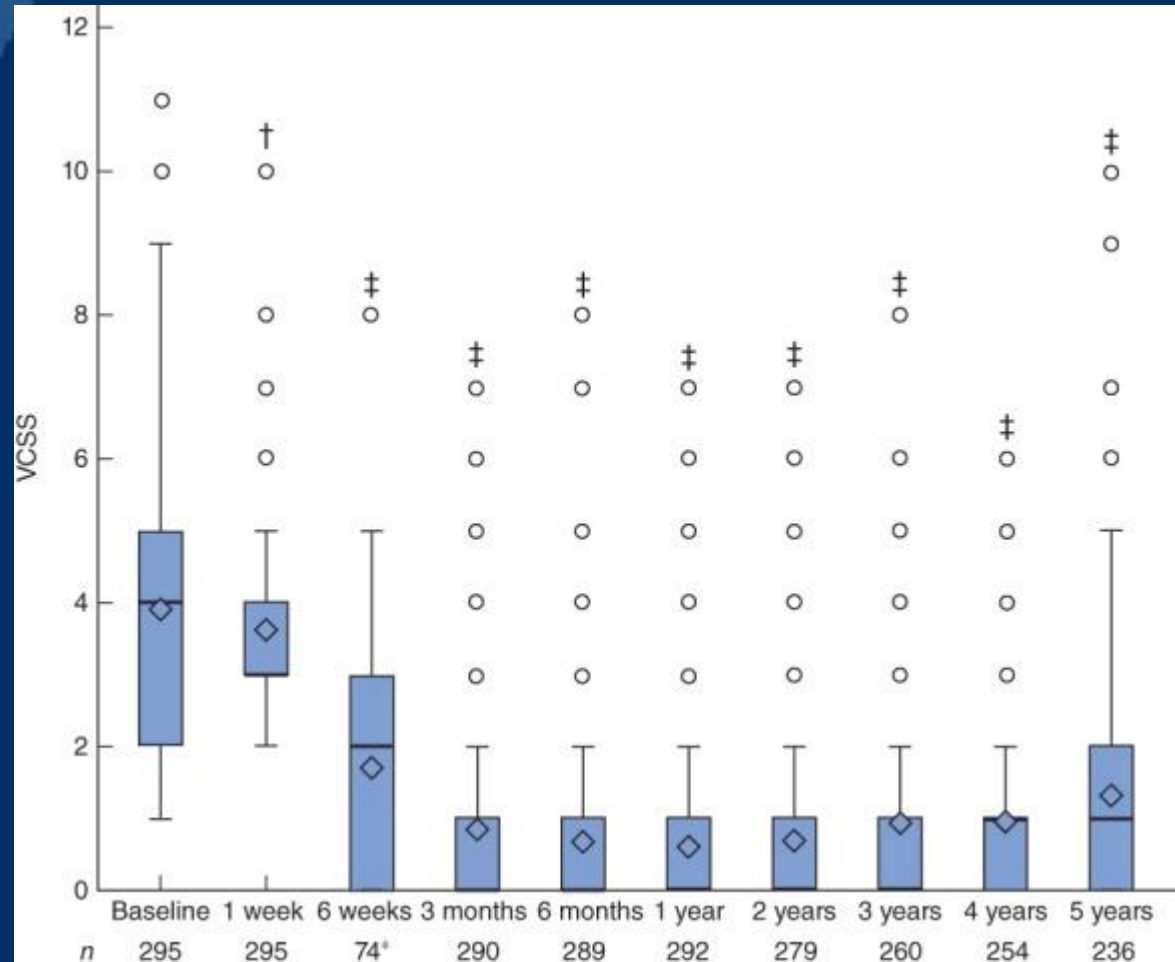
PROEBSTLE STUDY

: Proebstle et al., 2015

VCSS

Baseline mean 3.9(2.1)

reaching 1.3(1.7) at 5 years



Proebstle et al., 5 yr results from the prospective European multicenter cohort study in RF segmental thermal ablation for incompetent GSV BJS 2015 Feb;102(3):212-8



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RFA CLOSUREFAST™ CATHETER : SUMMARY

- Occlusion rate :

3-yr follow up 93% (Ramussen et al.)

5-yr follow up 90% / 91.9% (Dietzek / Proebstle et al.)

- Significant improvements

: VCSS, AVVSS, SF-36, pain VAS



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My experience of RF segmental ablation (ClosureFast™)

- 1st case on 11 Nov 2014

	Subjects (N=291)
Age mean (SD)	43.3 (15.4)
Age range	18 - 76 years
Gender	80.8% Female 19.2% Male
BMI mean	23.5 (3.5)
BMI range	15.8 - 42.7

No. patients

More than 3 mo	More than 6 mo	More than 1 yr
224	150	50



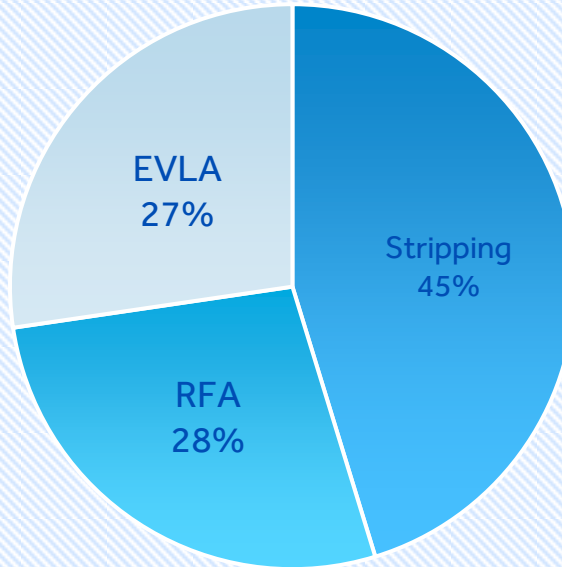


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My experience of RF segmental ablation (ClosureFast™)

- 50 patients reached u
- 32/50 patient followe
- 1 patient showed rec
- Occlusion rate 96.8 % at 1 year

My procedures





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Thank you

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