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6-months Follow-Up of a Polyglycolic-Acid Yarn Implantation for Abolition of Saphenous Vein Reflux

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Disclosure

Thomas Proebstle

- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ I do not have any potential conflict of interest

Objective

Feasibility and Safety of
Non-Thermal / Non-Tumescent abolition of
Saphenous Vein Reflux by ultrasound-controlled
insertion of a Polyglycolic-Acid Yarn implant.

- Blocking reflux
- Eliciting an inflammatory response leading to permanent occlusion and fibrosis of the vein

Methods

Two consecutive cohort studies, total N=81

Tahoe I: multicenter, n=51, Europe

Tahoe II single center, n=30, Dom. Rep.

n = 77 available for 6 months follow-up

Table II. Baseline Demographics and CEAP category

Baseline Demographics and CEAP Category			
Subject Characteristics	TAHOE I	TAHOE II	TAHOE I/II Combined
Age (yrs.)			
Mean \pm SD (N)	49.6 \pm 12.8 (51)	47.7 \pm 10.0 (30)	48.9 \pm 11.8 (81)
Range (min, max)	(26.0, 78.0)	(31.0, 74.0)	(26.0, 78.0)
Female	76.5% (39/51)	80.0% (24/30)	77.8% (63/81)
Height (cm)			
Mean \pm SD (N)	170.5 \pm 8.5 (51)	160.3 \pm 8.5 (30)	166.7 \pm 9.8 (81)
Range (min, max)	(150.0, 195.0)	(141.0, 180.0)	(141.0, 195.0)
Weight (kg)			
Mean \pm SD (N)	72.6 \pm 16.8 (50)	71.6 \pm 10.3 (30)	72.2 \pm 14.6 (80)
Range (min, max)	(50.0, 130.0)	(49.0, 92.0)	(49.0, 130.0)
BMI			
Mean \pm SD (N)	25.0 \pm 5.7 (50)	27.9 \pm 4.2 (30)	26.1 \pm 5.3 (80)
Range (min, max)	(17.9, 45.0)	(18.5, 35.5)	(17.9, 45.0)
CEAP Clinical Classification			
C0	0.0% (0/51)	0.0% (0/30)	0.0% (0/81)
C1	0.0% (0/51)	0.0% (0/30)	0.0% (0/81)
C2	58.8% (30/51)	46.7% (14/30)	54.3% (44/81)
C3	31.4% (16/51)	20.0% (6/30)	27.2% (22/81)
C4a	5.9% (3/51)	13.3% (4/30)	8.6% (7/81)
C4b	2.0% (1/51)	10.0% (3/30)	4.9% (4/81)
C5	2.0% (1/51)	3.3% (1/30)	2.5% (2/81)
C6	0.0% (0/51)	6.7% (2/30)	2.5% (2/81)

Methods: key features of study protocol

Tahoe I :

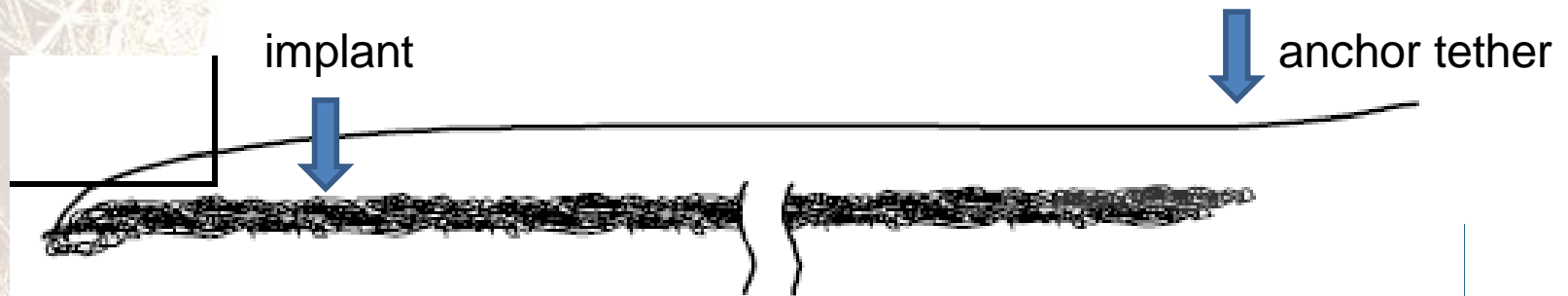
- LMWH s.c. for 2 weeks,
- excentric compression over GSV for 3 days
- compression stockings for 14 days

Tahoe II:

- no LMWH, no compression

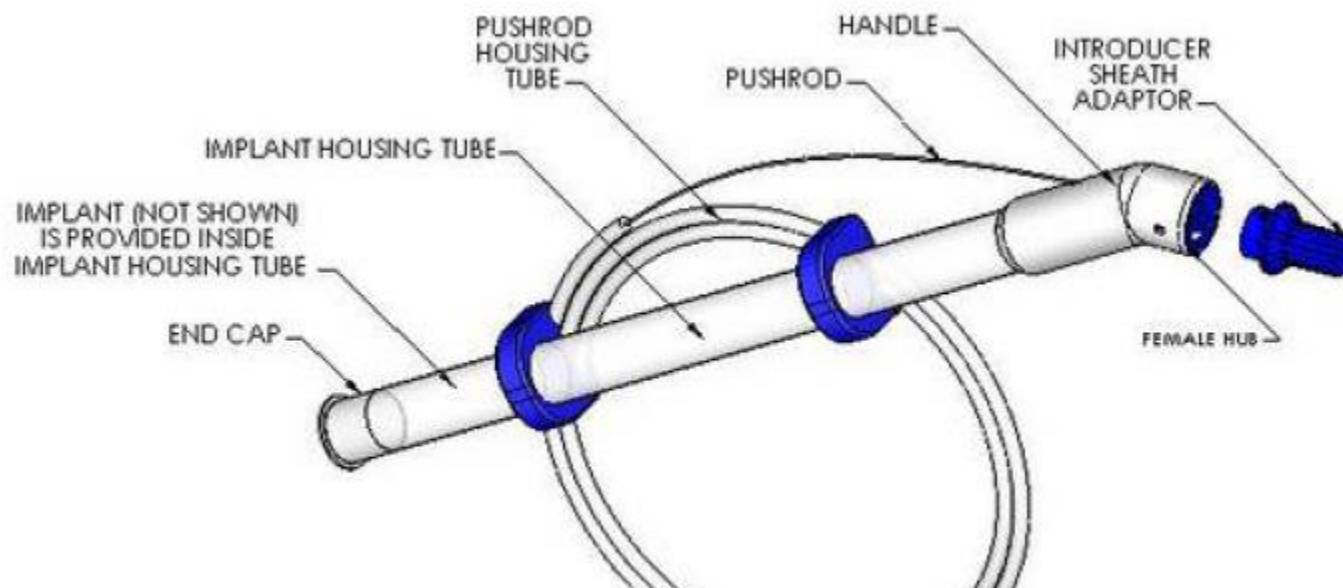
Methods

Device : Polyglycolic-Acid Yarn Implant



Hidden inside implant: Pushrod with nitinol release wire





Results

- Ultrasound appearance
- Side effects
- Occlusion rates

Venous

P

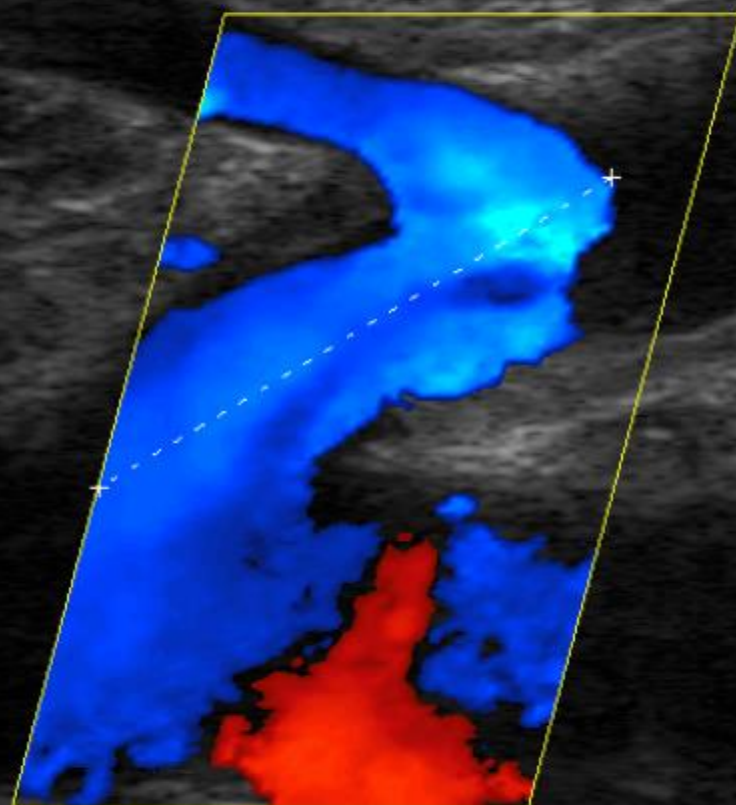
07-Dec-2009

04:48:35 AM

5/1



SFJ R TAHOE 7D



5.81



5.81

TIB = 1.4

TIS = 1.4

TIC = 1.8

12L5

E/3/C/H/SV2

4 cm

Farbe

PRF 0.90kHz

WF 67Hz

Freq 6.0MHz

+ Durchmesser 2.05 cm

A



45 von 45

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Venous

P

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6 / 1

SFJ R TAHOE 7D

MI:

TIB = 0.8

TIS = 0.8

TIC = 0.8

12L5

E/3/C/H/SV2

4 cm

1 cm

+ Durchmesser 2.90 cm

A



69 von 69

Venous

P

07-Dec-2009

04:51:46 AM

9/1

SFJ R TAHOE 7D D3

MI:

TIB = 0.8

TIS = 0.8

TIC = 0.8

12L5

E/3/C/H/SV2

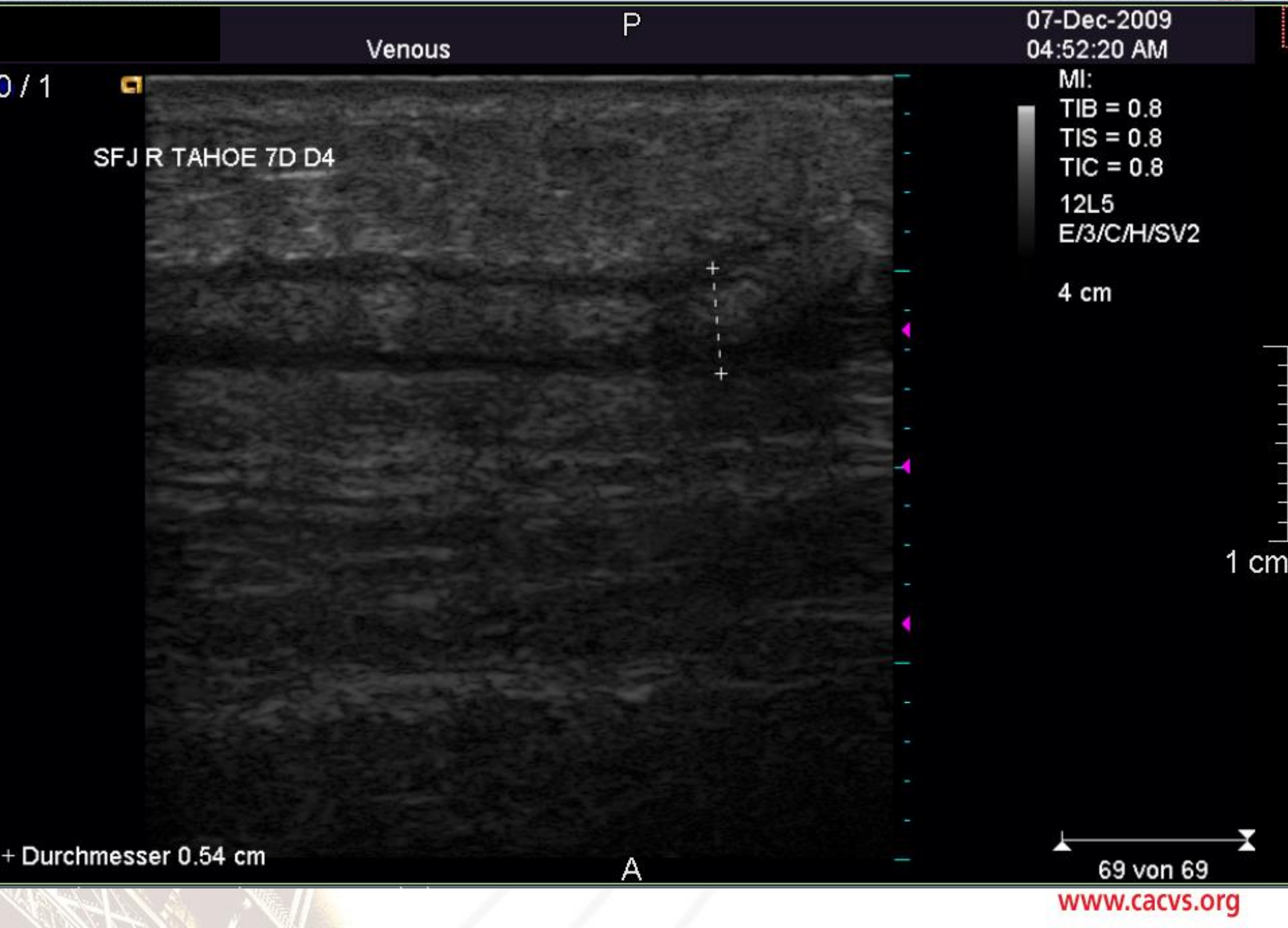
4 cm

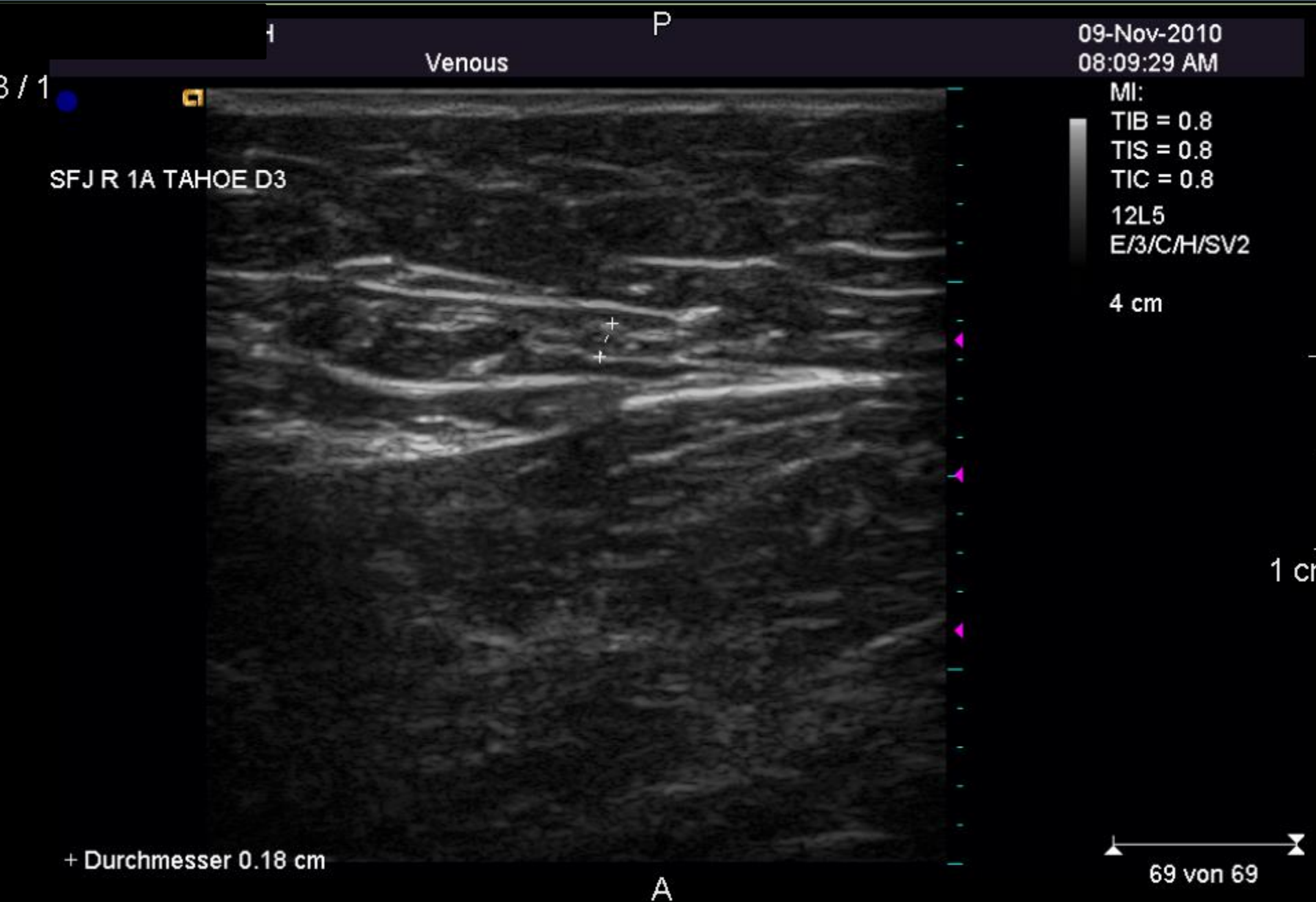
1 cm

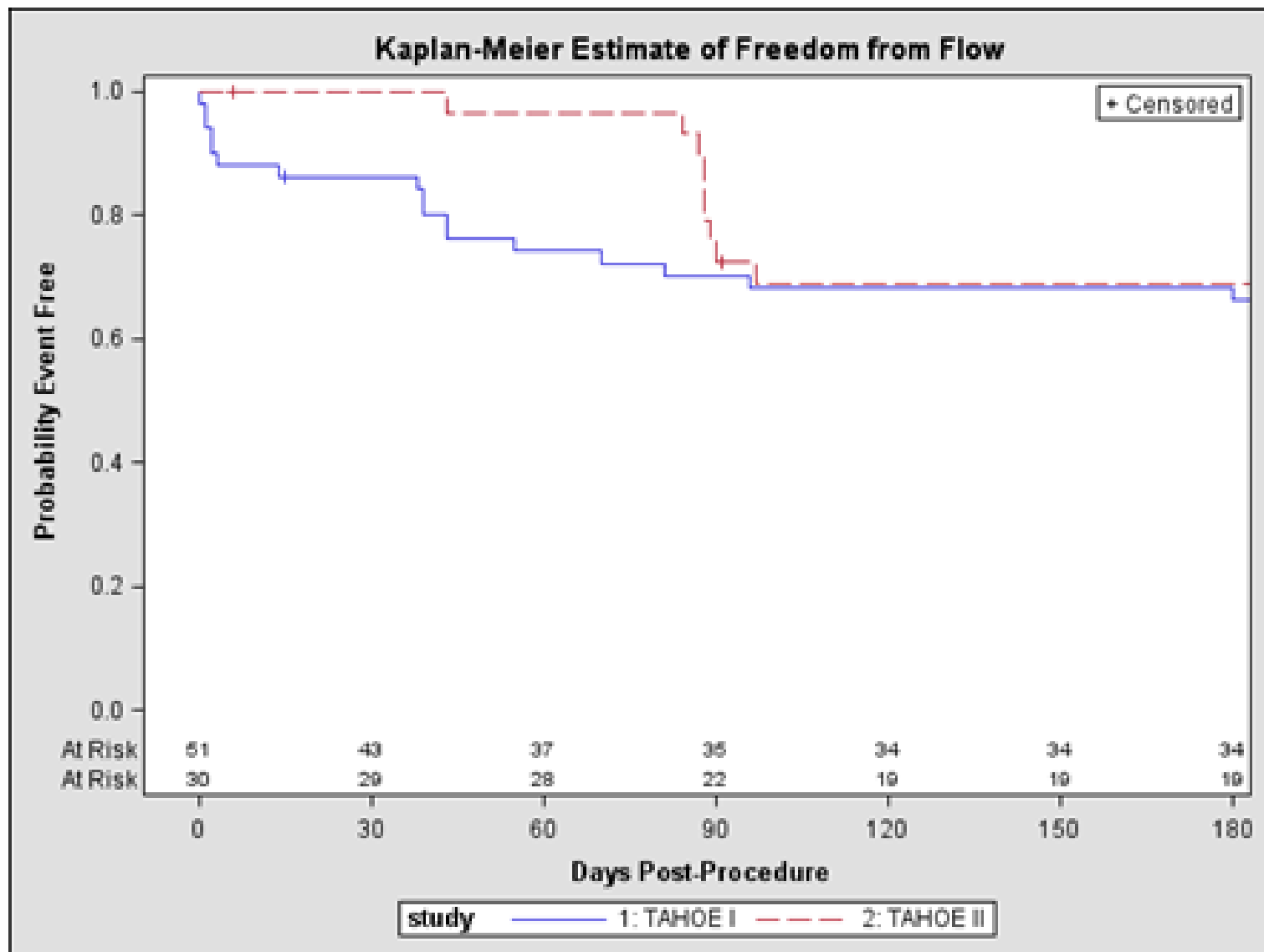
+ Durchmesser 0.69 cm

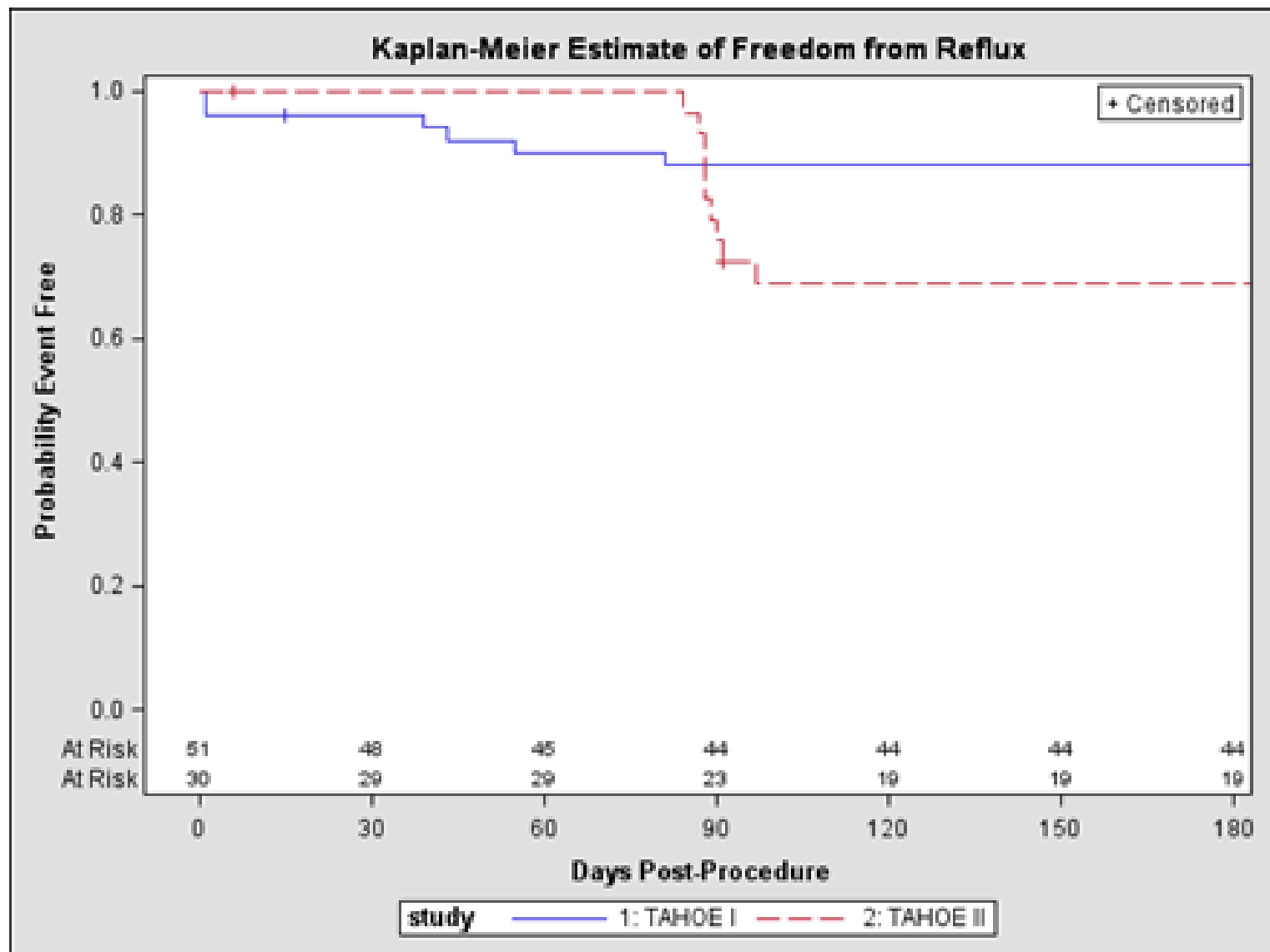
A

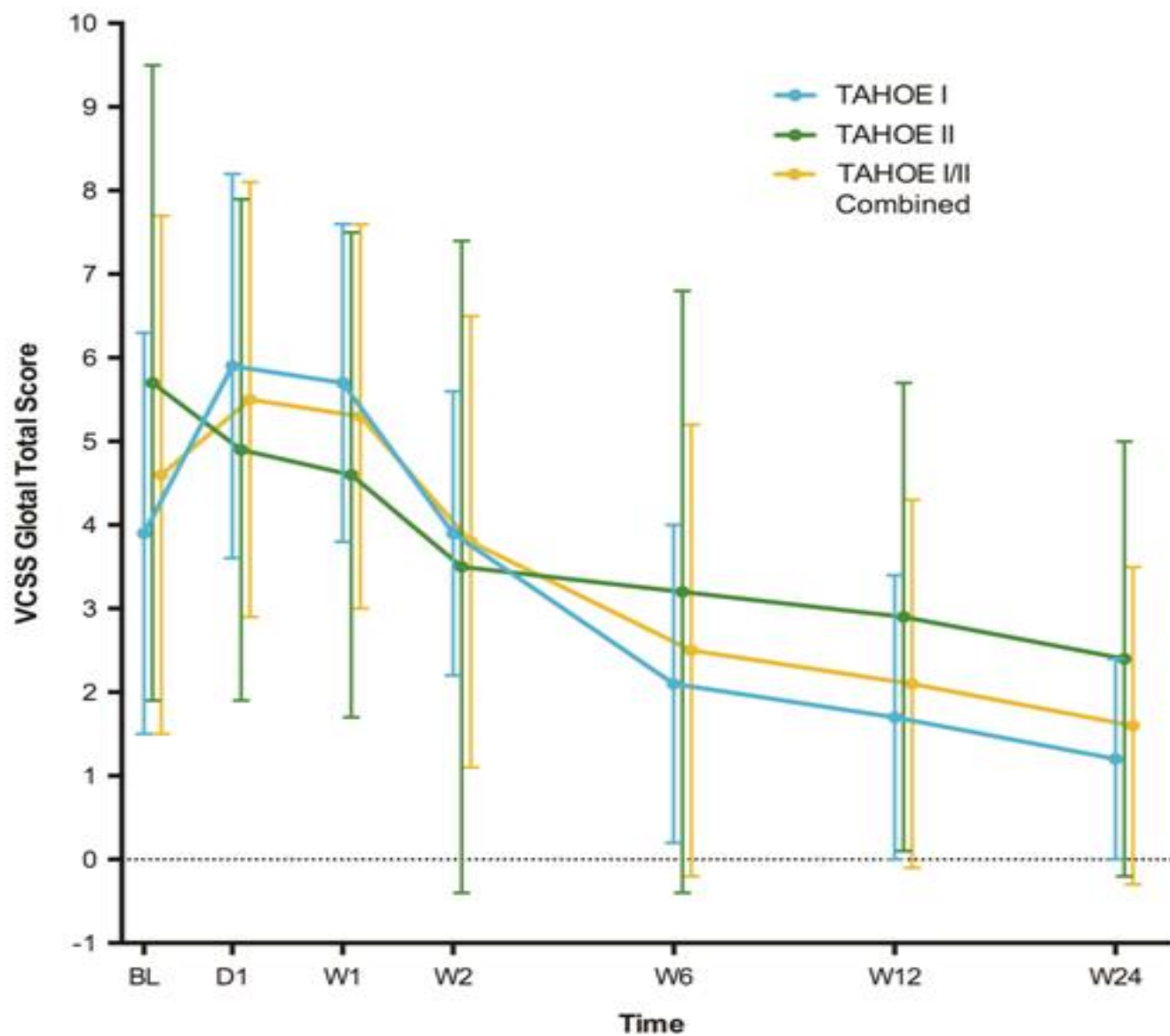
69 von 69

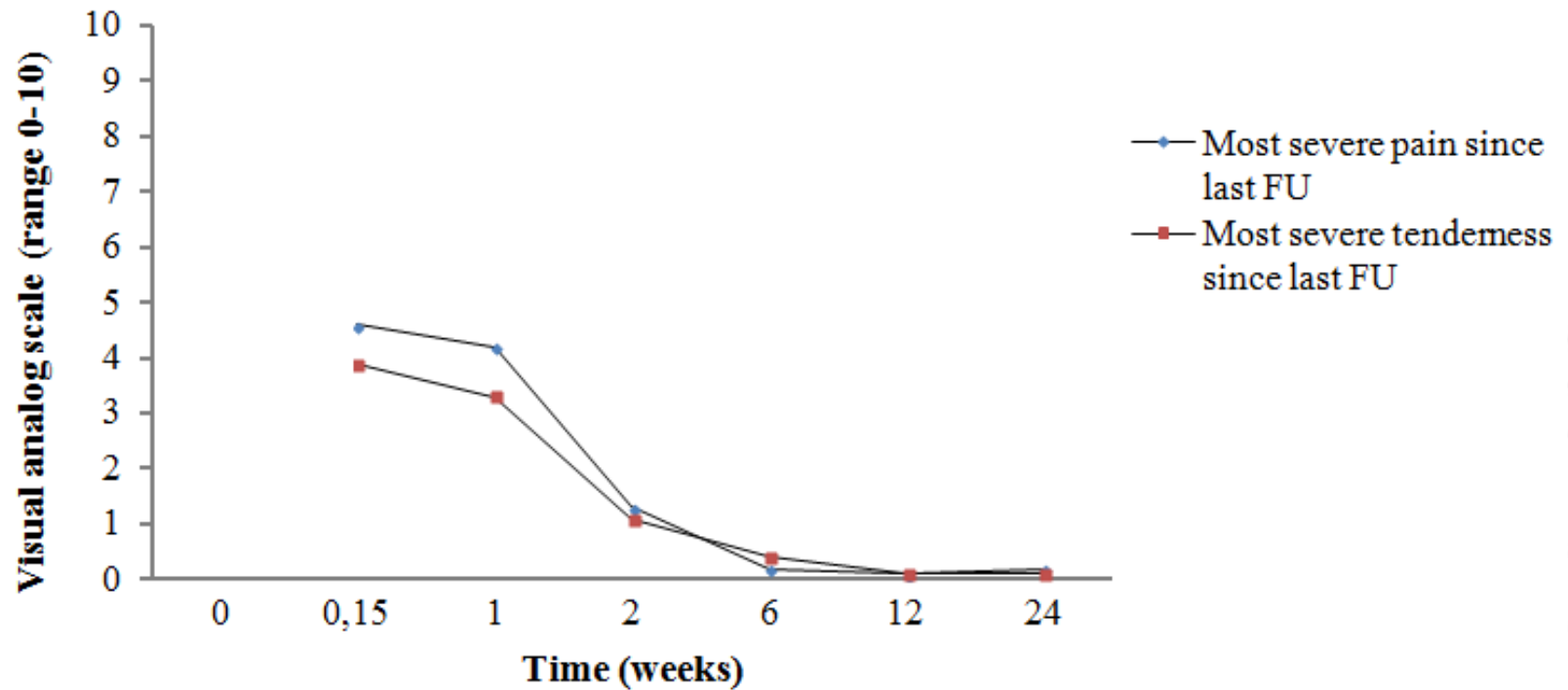












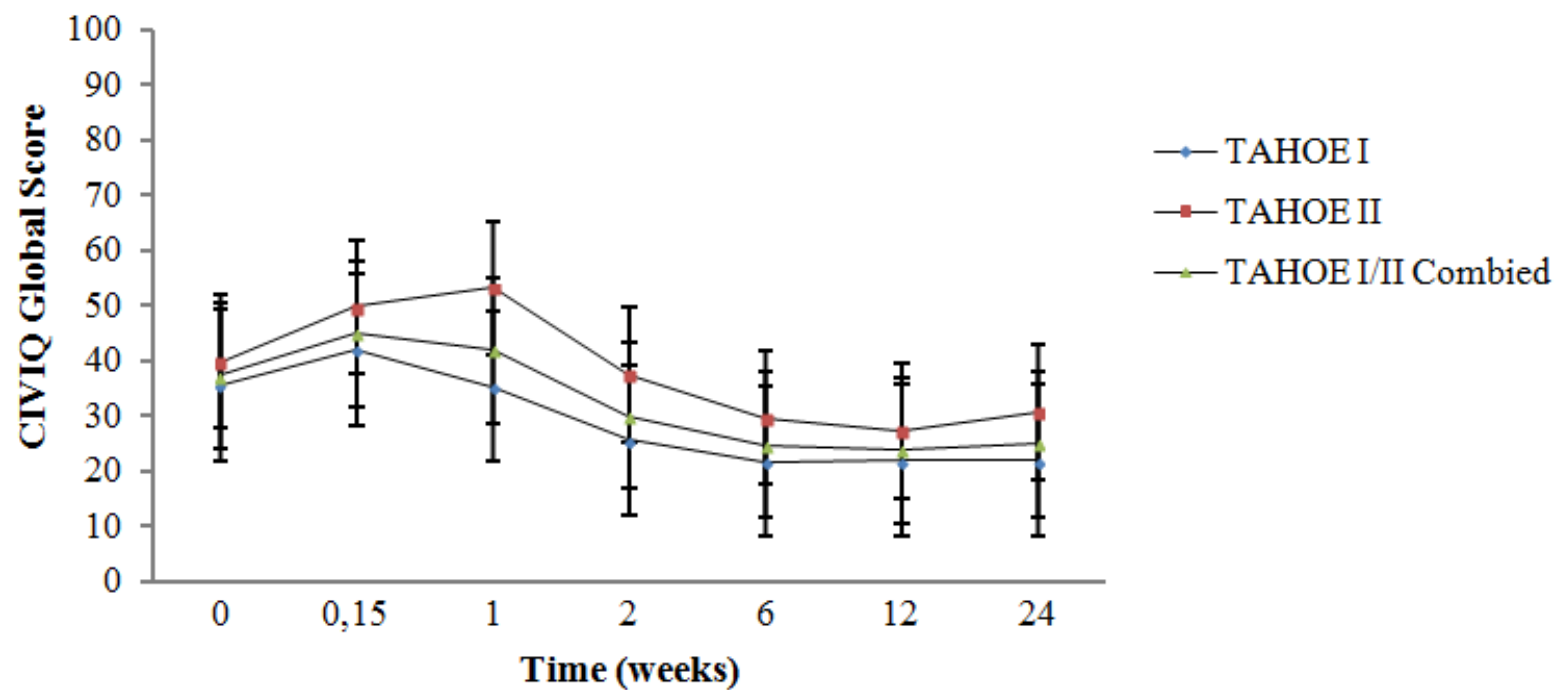


Table V. Post-Procedure Treatment Related Complications. NR = not recorded

	Day 1			Week 1			Week 2			Week 6		
Side Effects	TAHOE I	TAHOE II	TAHOE I/II Combined	TAHOE I	TAHOE II	TAHOE I/II Combined	TAHOE I	TAHOE II	TAHOE I/II Combined	TAHOE I	TAHOE II	TAHOE I/II Combined
Echymosis	10.2% (5/49)	6.7% (2/30)	8.9% (7/79)	11.8% (6/51)	13.8% (4/29)	12.5% (10/80)	3.9% (2/51)	0.0% (0/29)	2.5% (2/80)	0.0% (0/49)	0.0% (0/28)	0.0% (0/77)
Erythema	2.0% (1/51)	6.7% (2/30)	3.7% (3/81)	11.8% (6/51)	48.3% (14/29)	25.0% (20/80)	3.9% (2/51)	10.3% (3/29)	6.3% (5/50)	0.0% (0/50)	3.6% (1/28)	1.3% (1/78)
Fever	NR	26.7% (8/30)		NR	34.5% (10/29)		NR	3.4% (1/29)		NR	0.0% (0/28)	
Nausea	NR	33.3% (10/30)		NR	34.5% (10/29)		NR	3.4% (1/29)		NR	0.0% (0/28)	
Thrombus extension into CFV	NR	6.7% (2/30)		NR	10.3% (3/29)		NR	3.4% (1/29)		NR	0.0% (0/28)	
Induration	0.0% (0/51)	10.0% (3/30)	3.7% (3/81)	19.6% (10/51)	31.0% (9/29)	23.8% (19/80)	13.7% (7/51)	41.4% (12/29)	23.8% (19/80)	10.0% (5/50)	0.0% (0/27)	6.5% (5/77)
Other	2.0%** (1/51)	3.3%* (1/30)		7.8%** (4/51)	6.9%* (2/29)		0%** (0/51)	3.4%* (1/29)	1.25% (1/80)	6.0%** (3/50)	0.0%* (0/28)	

* Includes: "Patient fainted last night" at Day 1; "Bleeding" and "Inflammation and edema" at Week 1; "Episodes of hypotension" at Week 2

** Includes: Access point red/brown spot or Granuloma, Chilling, Fever, and Nausea

Conclusion

Non-Thermal / Non-Tumescent Abolition of Saphenous Vein Reflux with a Polyglycolic-Acid Yarn implant at present is not ready for routine use.

Systemic and local side effects are too severe and anatomical success rate is too low

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