Patency Rates and Clinical Results of the SINUS-OBLIQUUS® Venous Stent

Data from the Arnsberg Venous Registry

Michael K. W. Lichtenberg MD, FESC

Arnsberg, Germany

Conflict of Interest Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

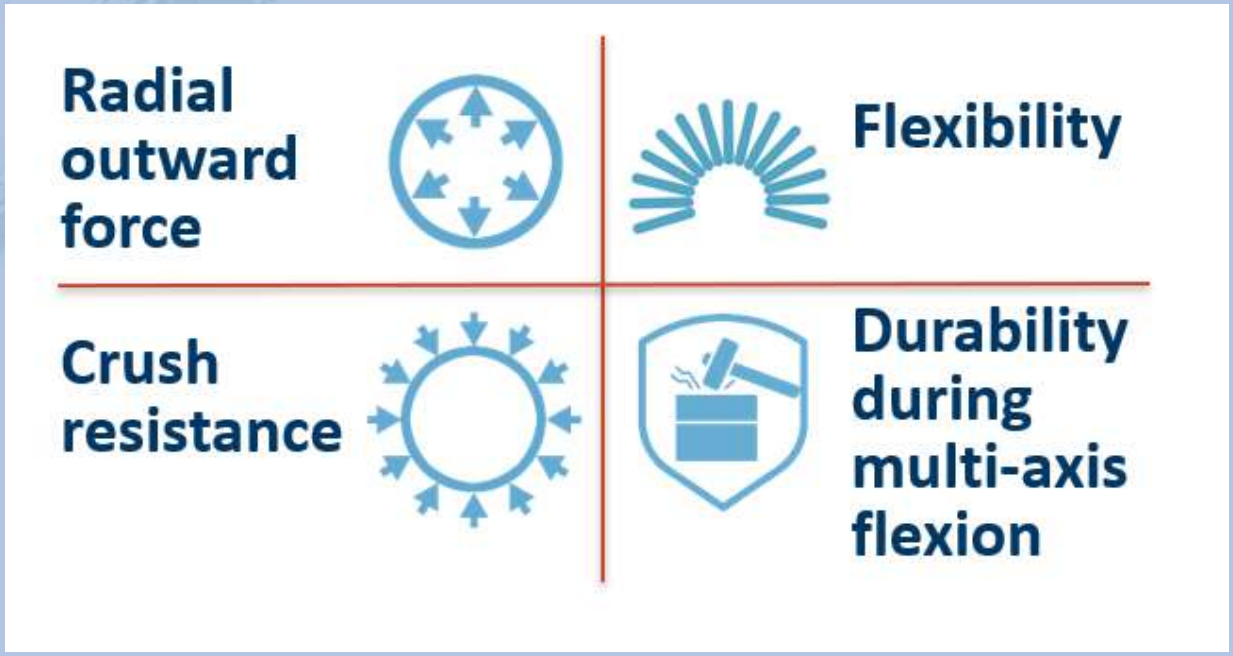
1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan

2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific

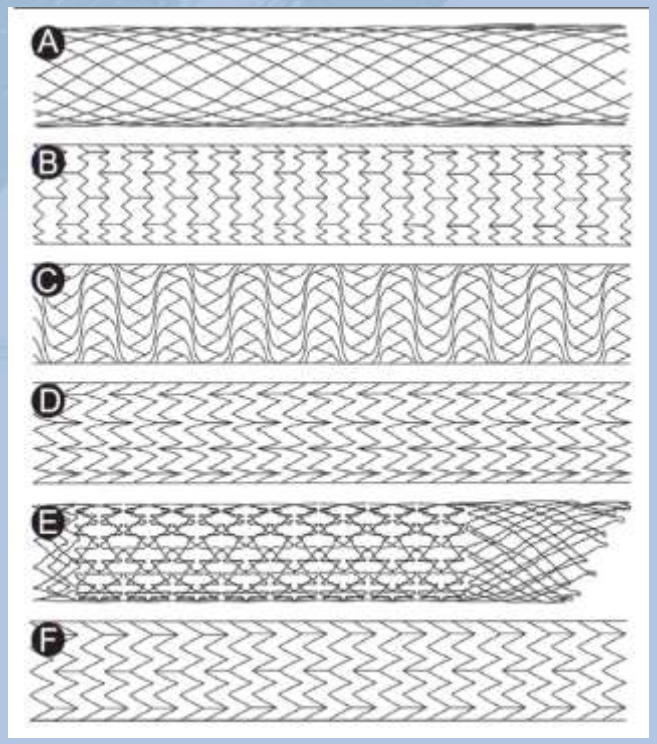
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow

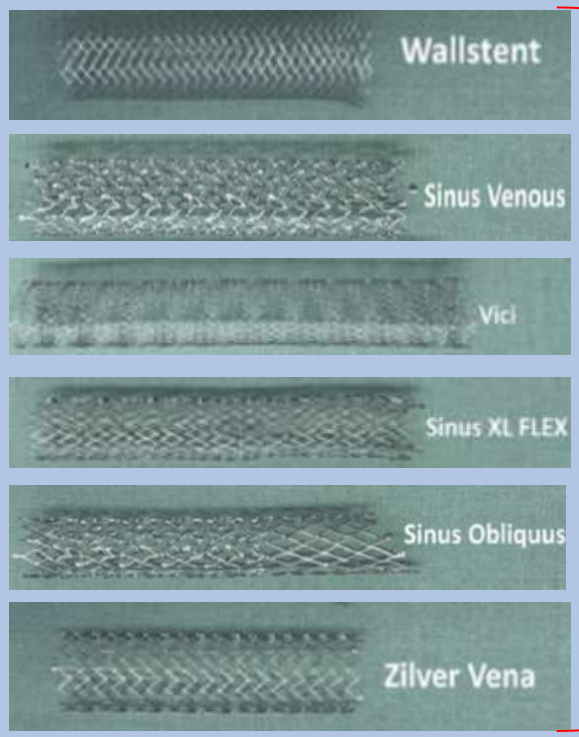
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

Critical venous stent design considerations are



Different stent types





Crush resistance

Radial resistive Force

Flexibility

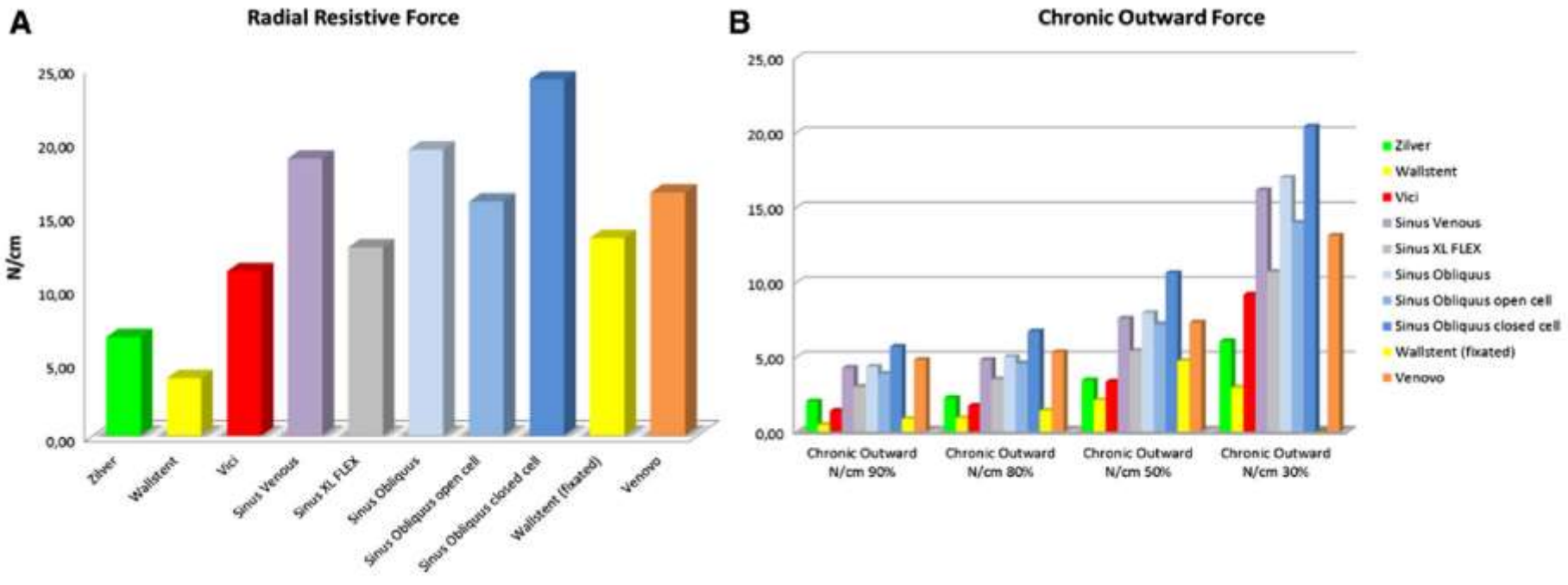
Cardiovasc Intervent Radiol
https://doi.org/10.1007/s00270-018-1916-1

CIRSE CrossMark

LABORATORY INVESTIGATION

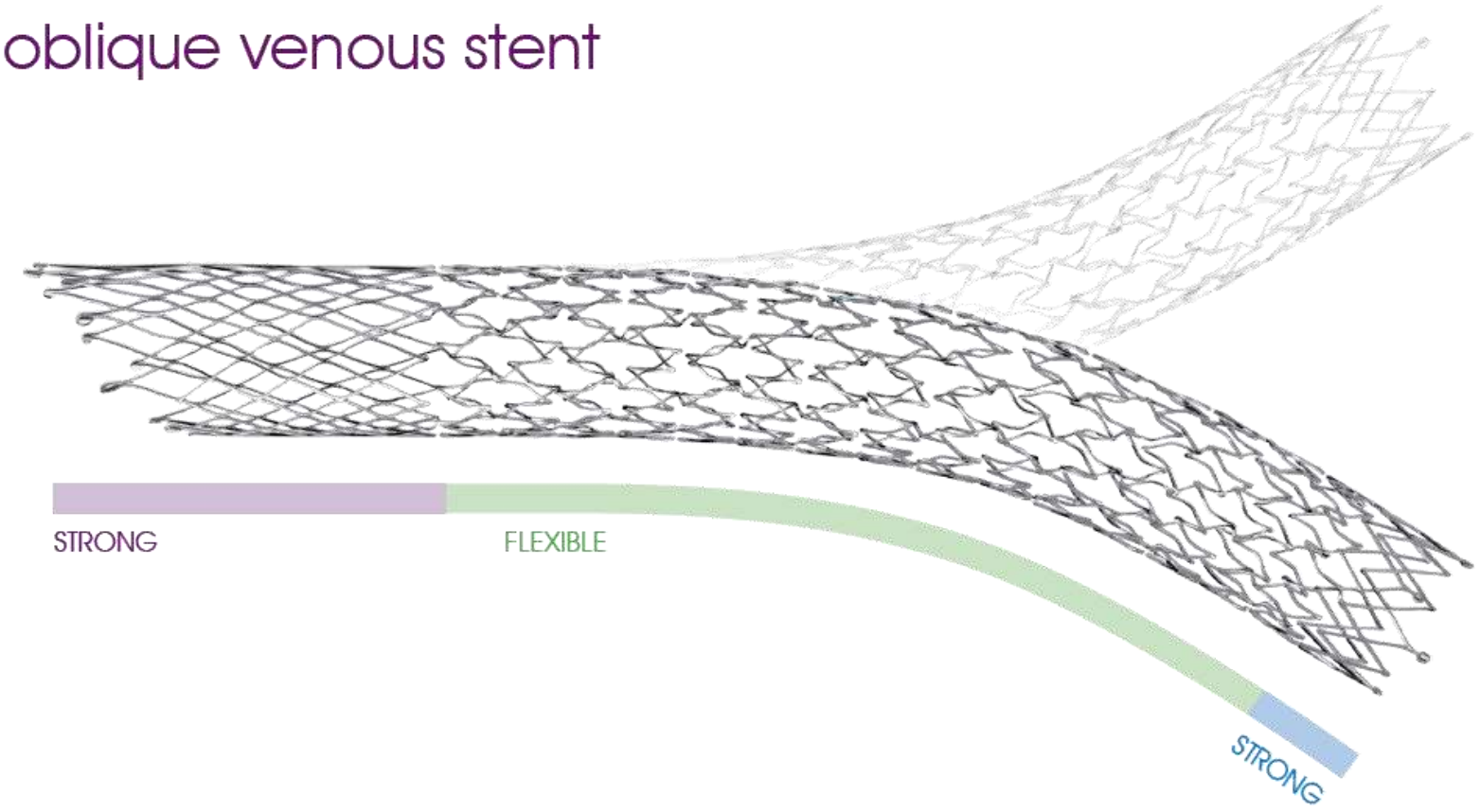
Physical Properties of Venous Stents: An Experimental Comparison

Darius Dabir[1] · Andreas Feisst[1] · Daniel Thomas[1] · Julian A. Luetkens[1] · Carsten Meyer[1] · Ana Kardulovic[2] · Matthias Menne[2] · Ulrich Steinseifer[2] · Hans H. Schild[1] · Daniel L. R. Kuetting[1]

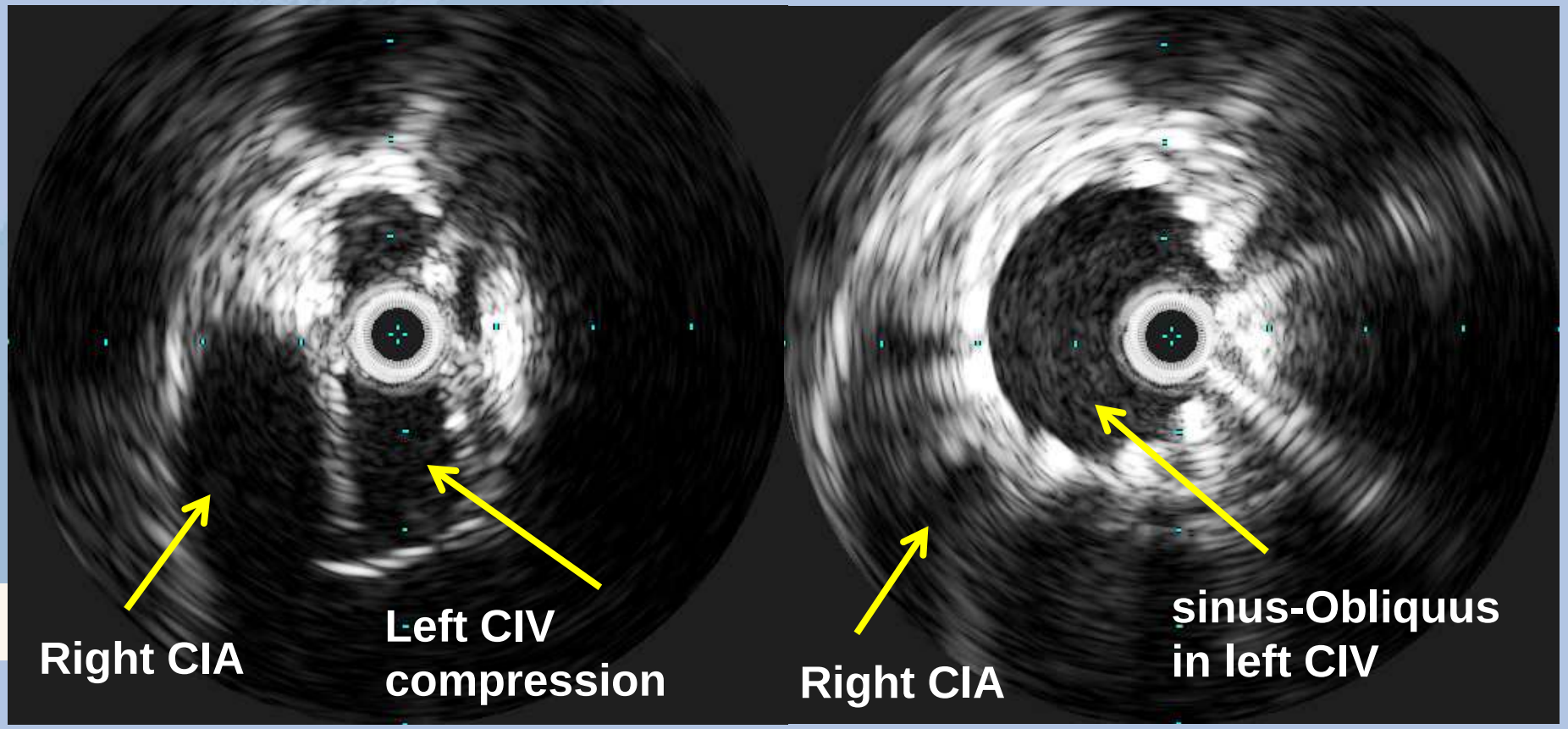


sinus-Obliquus

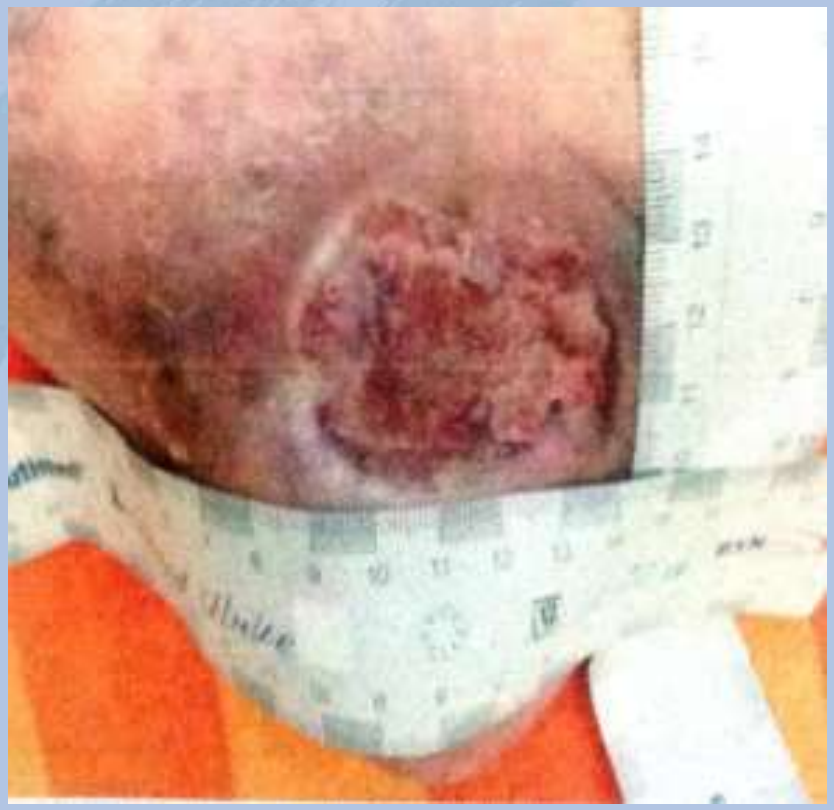
the first oblique venous stent



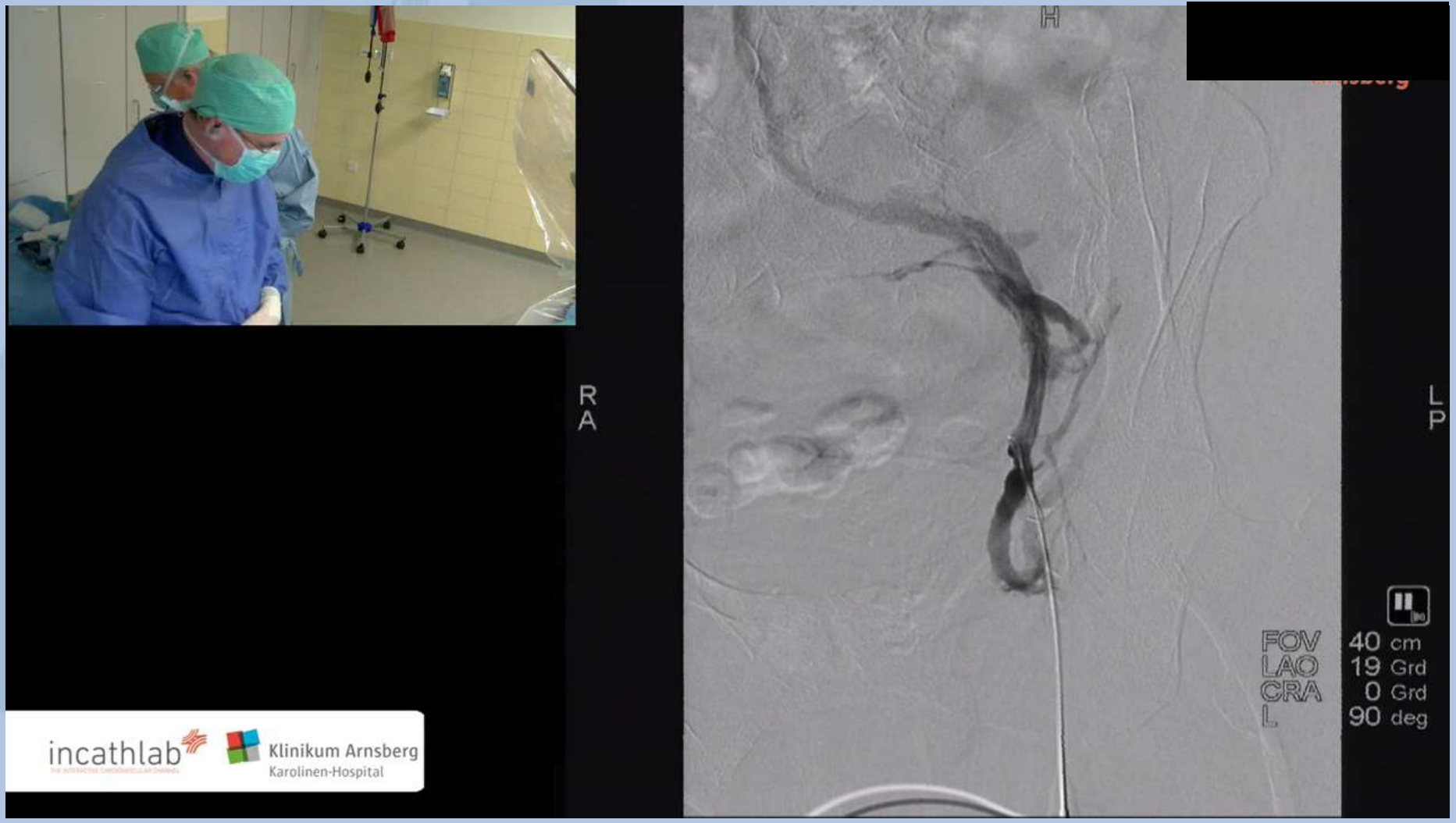
sinus-Obliquus

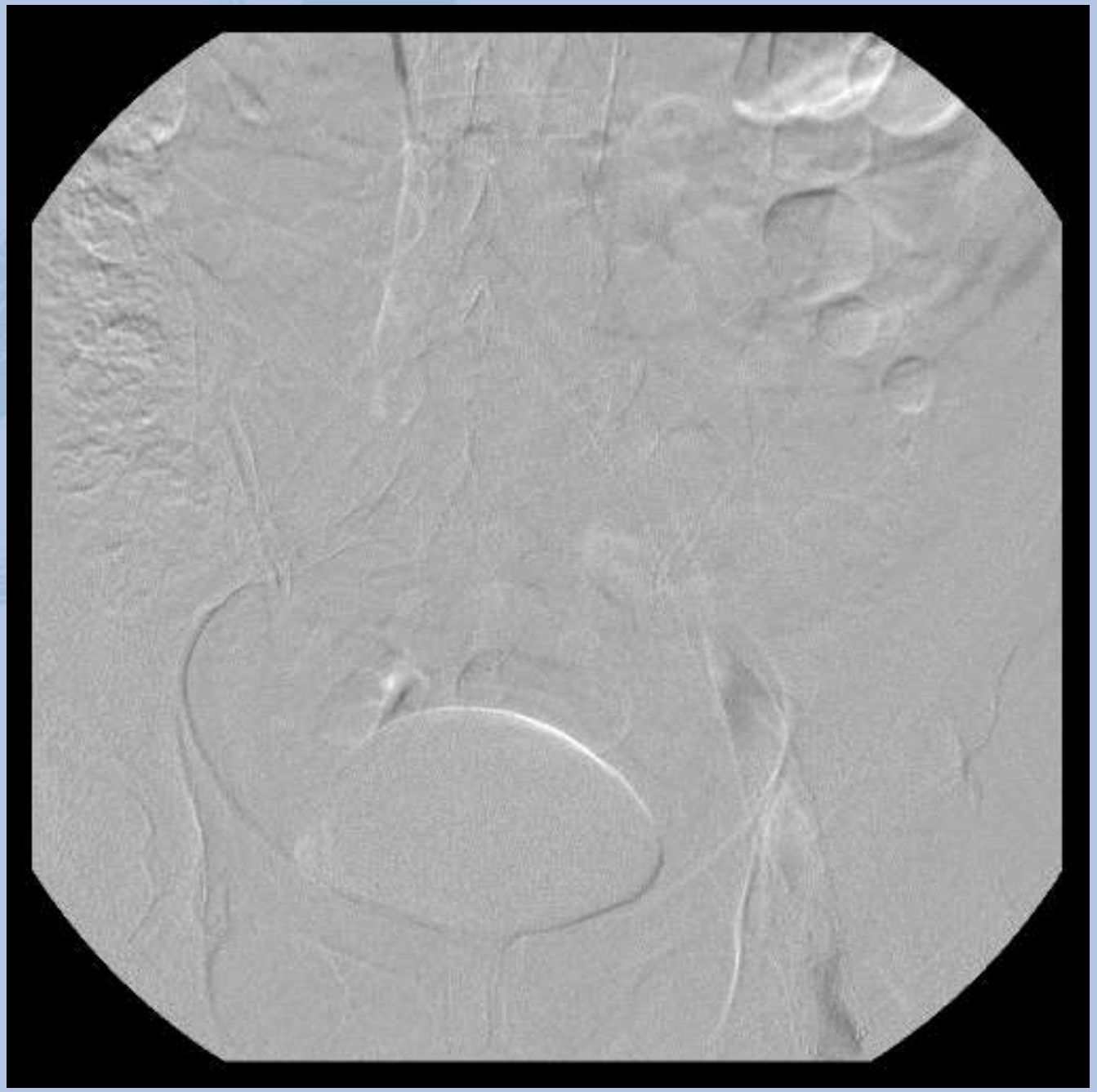


47 y, female, descending iliofemoral DVT 2008, C6

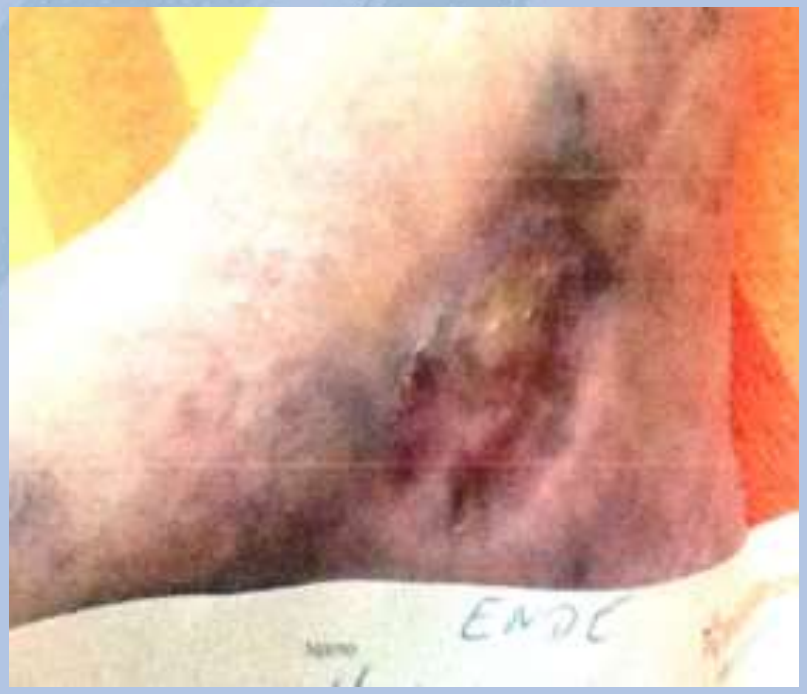


Pain	**3**
VV	2
Edema	2
Pigmentation	3
Inflammation	3
Induration	3
Ulcers	1
Size	3
Duration	3
Compression	3
VCSS	26
CEAP	6


H
R
A
L
P
FOV
LAO
CRA
L
40 cm
19 Grd
0 Grd
90 deg
incathlab
Klinikum Arnsberg
Karolinen-Hospital



FU 7 months later



Pain	**0**
VV	1
Edema	0
Pigmentation	1
Inflammation	0
Induration	1
Ulcer	0
Size	0
Duration	0
Compression	2
VCSS	5
CEAP	5

Arnsberg Venous Registry

48 patients in the Sinus obliquus cohort analysis

The aim of this retrospective study is to assess the performance and safety of the SINUS-OBLIQUUS Stent System in a single centre population of patients representative of a real-world situation. Data were collected relating to the performance and safety of the SINUS-OBLIQUUS stent from the index procedure through 12 months post-procedure. All procedures for patient preparation and follow-up, including medication and vascular access, were according to Angiology departmental standard of care.

Primary Endpoints	Freedom from clinically-driven target lesion revascularization (CDTLR) through 36 months
Secondary Endpoints	• Primary patency at 6 months • Secondary patency at 6 and 12 months • MAE at 6 and 12 months • Compare pain rating scale scores and venous clinical severity scores (VCSS, CEAP) between baseline and 6 and 12 months post-index procedure.

Study is sponsored by German Venous Center Arnsberg

Klinikum Arnsberg
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster

Clinical Assessment

http://www.veinforum.org/uploadDocs/1/Revised-VCSS---June-2010.pdf

NAME:

		LEFT						RIGHT				
	Initial	Pre-Op	3-4 Days	3-4 Weeks	3-4 Months	1 Year	Initial	Pre-Op	3-4 Days	3-4 Weeks	3-4 Months	1 Year
DATE:												
CEAP (0-6)												
Fatigue: (Y/N)												
VCSS (0-3 Each)												
Pain												
Varicose Vein												
Venous Edema												
Pigmentation												
Inflammation												
Induration												
Active Ulcers												
Ulceration Duration												
Active Ulcer Size												
Compressive Therapy												
Total												
Complications: Blank (none) to 3 (severe)												
Hyperpigmentation												
Phlebitis												
Paresthesia												
Erythema												
Ecchymosis												
Infection												
Thermal Injury												
Other												
Patient Satisfaction: (None/Partly/Very)												
Varicose Veins:(None/ Residual/New/Recur)												
Outcome:(Not successful/ Successful/N/A)												

www.veinforum.org

Demographics/Medical History

Demographics/ Comorbidity	No. (%)
Age	57 (19-89)
Male	18 (38%)
Female	30 (62%)
Post-thrombotic	**22 (46%)**
Non-thrombotic	**26 (54%)**
Prev. PE	6 (13%)
Prev. DVT	22 (46%)
Renal Disease (GFR < 50 ml/min)	3 (6%)
Cancer	1 (2%)
Diabetes	4 (8%)
Smoker	10 (21%)

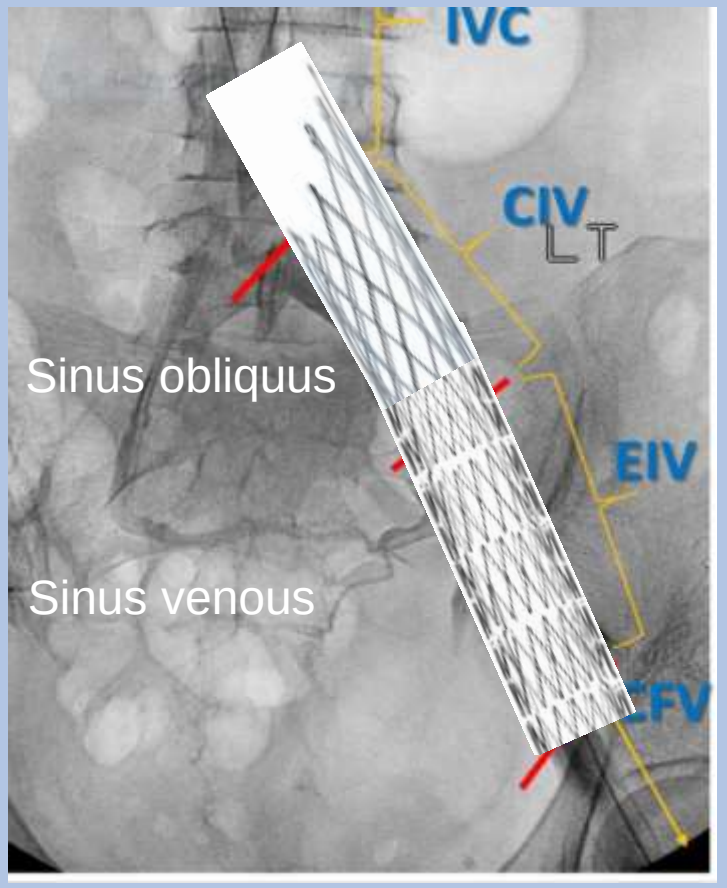
CEAP Score, prior stent	No. (%)
1	0 (0%)
2	1 (2%)
3	27 (56%)
4	13 (27%)
5	5 (10%)
6	2 (4%)
Signs/Symptoms prior stent	**No. (%)**
Pain (incl. venous claudication)	39 (81%)
Varicose Veins	32 (66%)
Edema	29 (60%)
Pigment Changes	20 (42%)
Ulcers	10 (21%)
Use Compression Stockings	39 (81%)

41% ≥ CEAP C4

Target Lesion Location

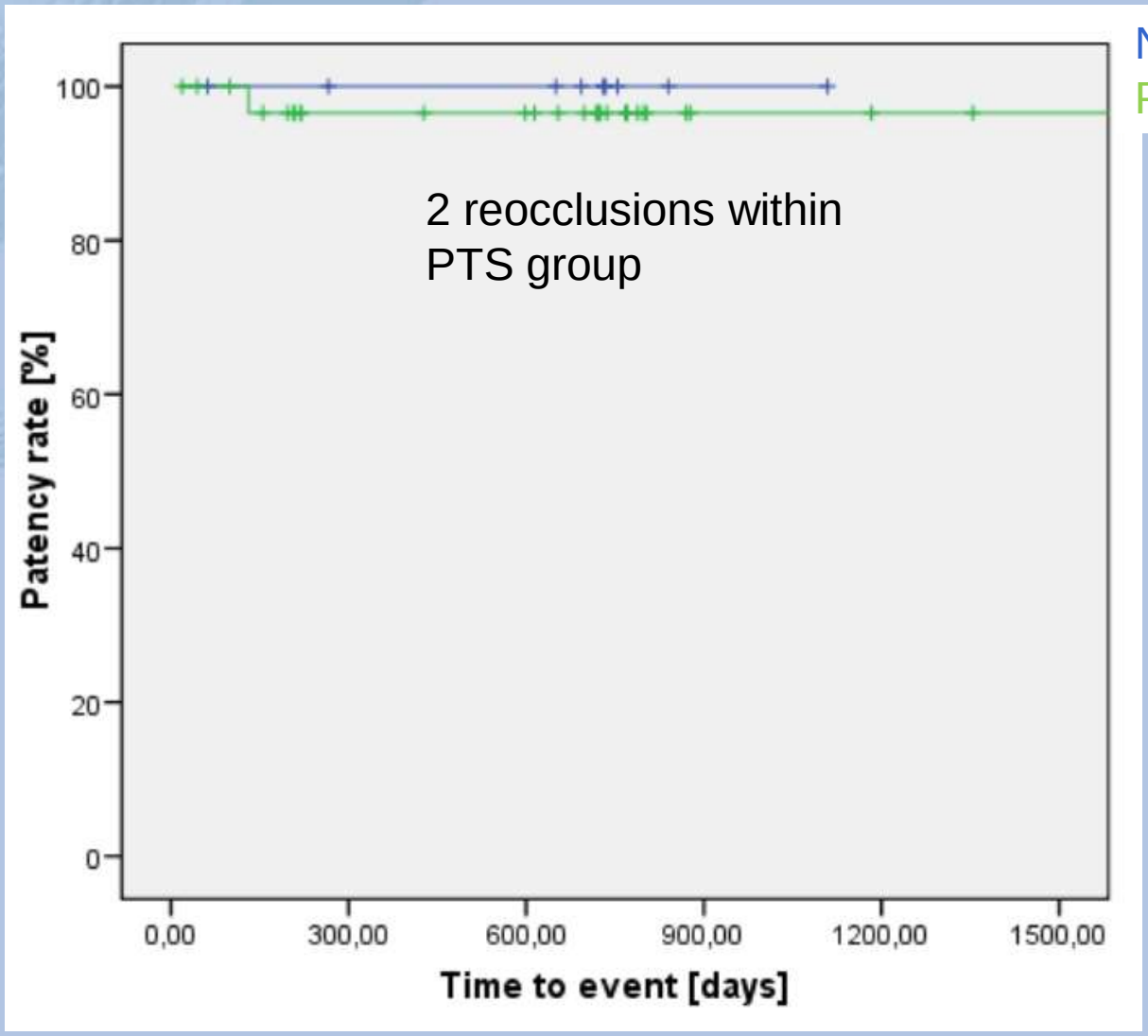
Target Limb	N=48 (100 %)
Left	43 (90%)
Right	5 (10%)

Left	43 (90%)
CIV	22 (51%)
CIV + EIV	16 (37%)
CIV + EIV + CFV	5 (12%)
Right	**5 (10%)**
CIV	5 (100%)



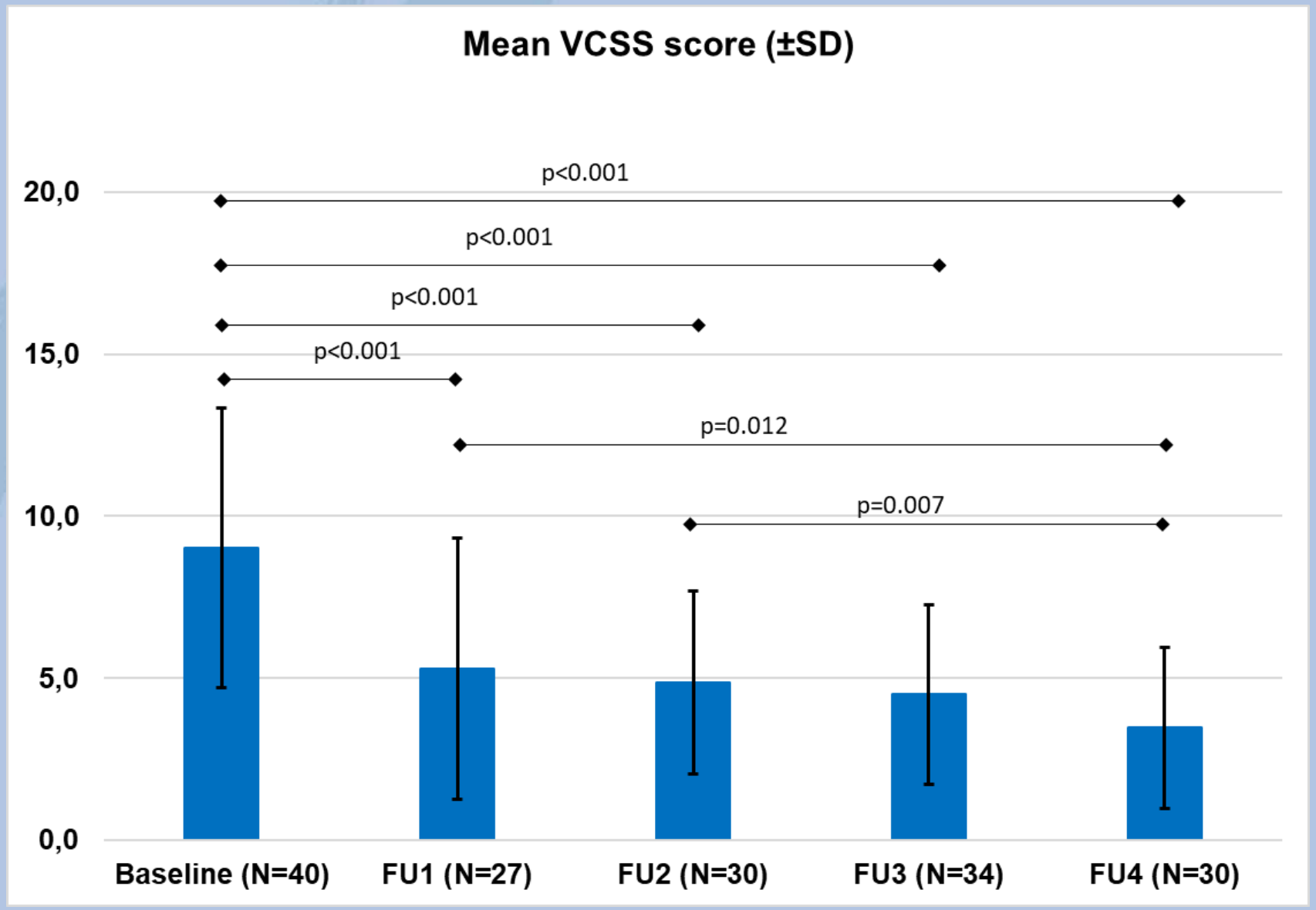
Patency Analysis

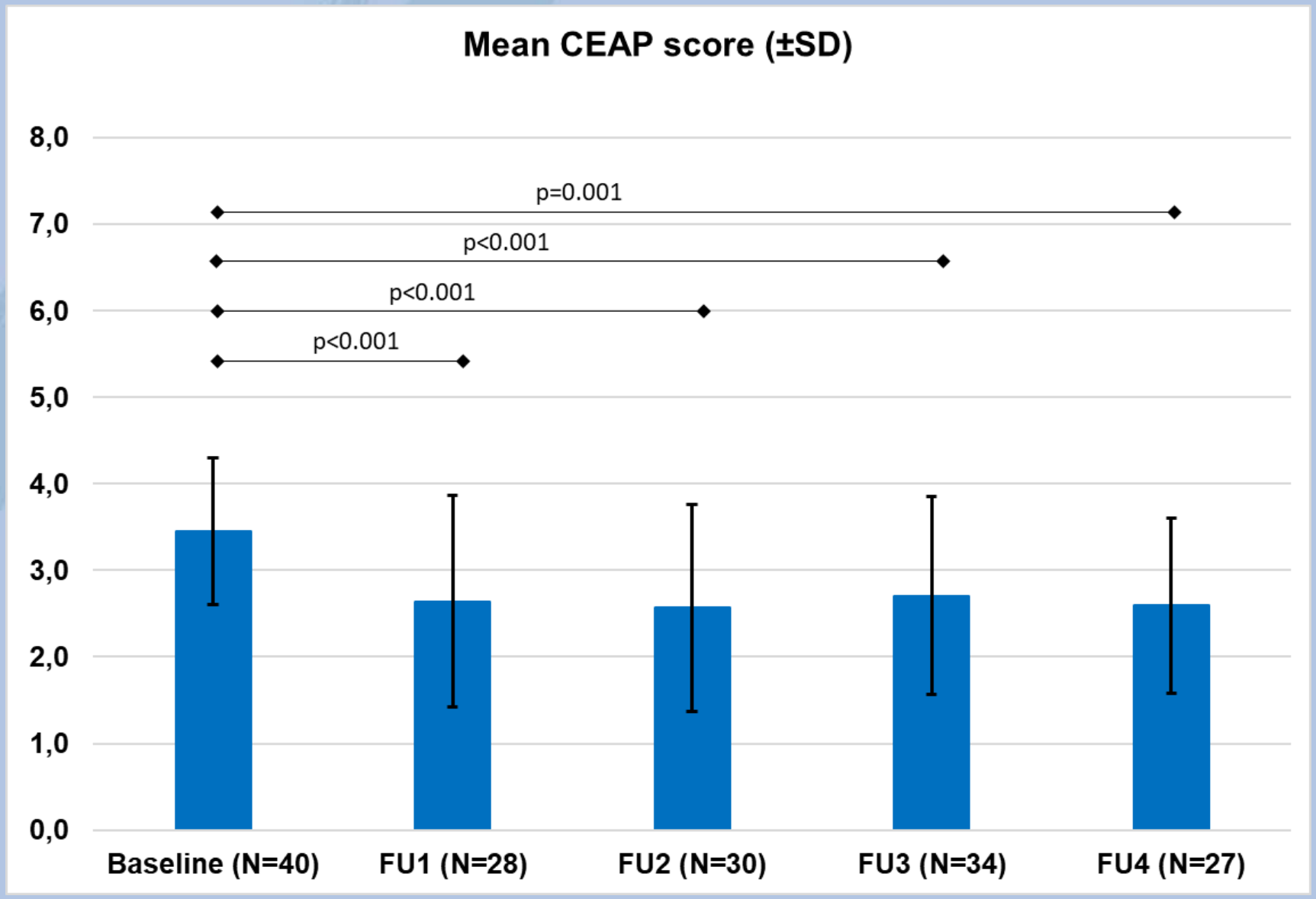
(restenosis > 50% by duplex)



NIVL: 100%

PTS: 96.7%


Mean VCSS score (±SD)
20,0
15,0
10,0
5,0
0,0
p<0.001
p<0.001
p<0.001
p<0.001
p=0.012
p=0.007
Baseline (N=40)
FU1 (N=27)
FU2 (N=30)
FU3 (N=34)
FU4 (N=30)


Mean CEAP score (±SD)
8,0
7,0
6,0
5,0
4,0
3,0
2,0
1,0
0,0
p=0.001
p<0.001
p<0.001
p<0.001
Baseline (N=40)
FU1 (N=28)
FU2 (N=30)
FU3 (N=34)
FU4 (N=27)

Registered Complications

Adverse Event	No. (%)
Access-site complications	2/48 (4%)
Hematoma	1/48 (2%)
Infection	1/48 (2%) After AV fistula
Stent early reocclusion (within 3 days)	1 (2%)
Stent migration	0 (0%)
Clinical sig. pulmonary embolism	0 (0%)
Venous rupture	0 (0%)
Blood transfusion	1/48 (2%)

Conclusions

- 24 months long term efficacy data in the Arnsberg Sinus obliquus registry are very promising:

	NIVL	PTS
Primary patency:	100%	96.7%

- Safety data raise no concerns
- Patients feel substantially better
  - VCSS dropped from 9.0 to 3.4 , CEAP from 3.45 to 2.59 after 24 months
  - Especially improvement of venous claudication and ulceration (8/10)
- Venous anatomy and disease require dedicated venous stents

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