Beyond Venous Registry

12-months data report from a real world PMCF registry and single centre analysis

Michael Lichtenberg, MD, FESC
Arnsberg Vascular Center

Klinikum Hochsauerland

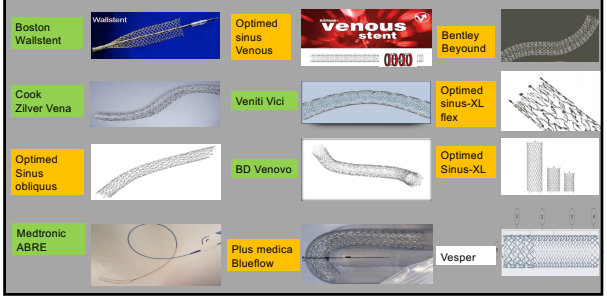
Disclosure

Speaker name:
Michael Lichtenberg
I have the following potential conflicts of interest to report:

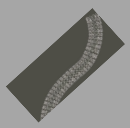
- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

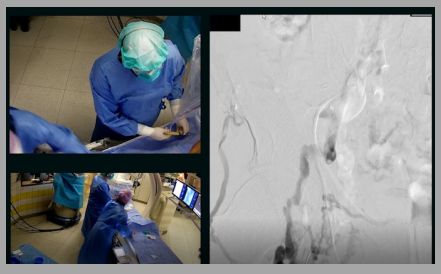
Venous Stent Options (US)

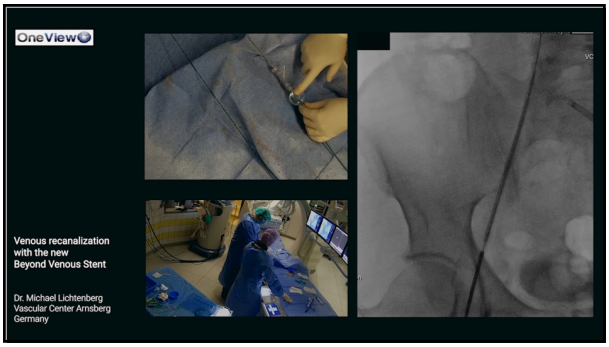


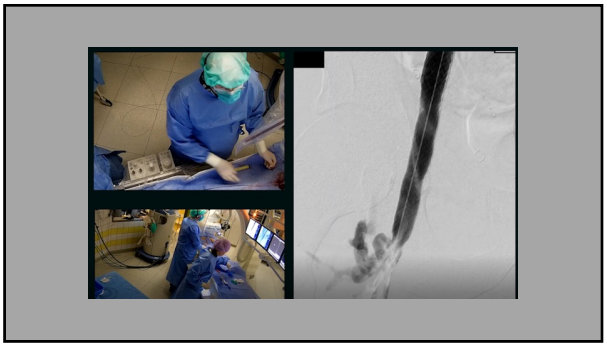
The Bentley BeYond Venous



- Self-expanding nitinol Stent System
- Hybrid stent design
- 10 F for all sizes: Ø 10 - 18 mm, length 60 – 150 mm
- Market introduction in 2020
- Indicated for endovascular treatment of symptomatic obstructions of the femoral or iliac veins such as:
  - acute DVT
  - PTS
  - May-Thurner
  - Tumor

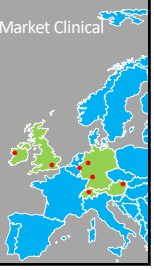






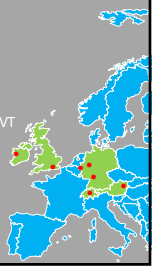
The BeYond Venous PMCF Study

- Prospective, international multicentre, single-arm Post-Market Clinical Follow-Up study to evaluate Safety and Performance
- 7 Centers: Arnsberg, Aachen, Heidelberg, Zurich, Vienna, London, Galway
- 112 Patients included
- Primary Endpoint: 12 m patency rate
- Secondary Endpoint: Clinical performance
  Clinical safety
  at 3 m, 6 m, 24 m … 60 m



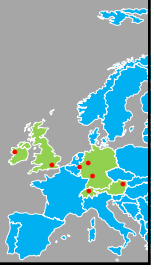
The BeYond Venous PMCF Study

- Main Inclusion Criteria:
  - Life expectancy ≥ 1 y
  - Clinically significant symptomatic venous outflow obstruction with at least CEAP score ≥ 3 or VCSS pain score ≥ 2 or suspected DVT
  - ≥ 50 % obstruction in target vessel
  - Obstructive lesions able to be treated with stent coverage



The BeYond Venous PMCF Study

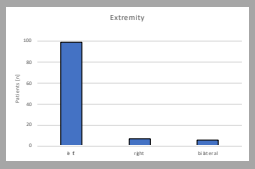
- Main Exclusion Criteria:
  - Patients with contraindications as listen in IFU
  - Target limb symptoms caused by peripheral arterial disease
  - Presence of inferior vena cava obstruction
  - Intended concurrent adjuvant procedure
  - Prior surgical or endovascular procedure of target vessel
  - Presence of venous stents from different manufacturers in the same extremity

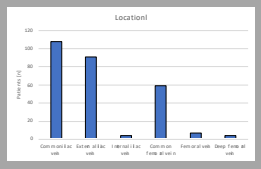


The BeYond Venous PMCF Study

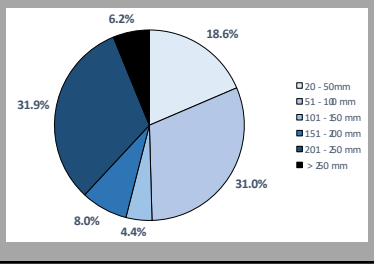
Patients enrolled	**n = 112**	
3 m FU	**n = 91**	91.3 days (14.5)
6 m FU	**n = 77**	185.3 days (21.0)
12 m FU	**n = 57**	374.5 days (16.8)
Mean Age		43.8 (15.5)
Gender	Male	36
	Female	76
Smoking Status	Never	66
	Current	15
	Former	27
	No remark	4

BeYond PMCF Study



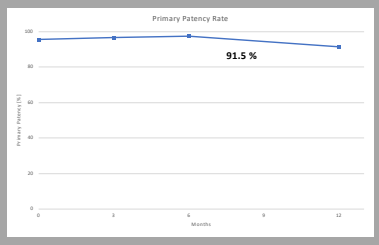


BeYond PMCF Study



Primary Patency after 12 months

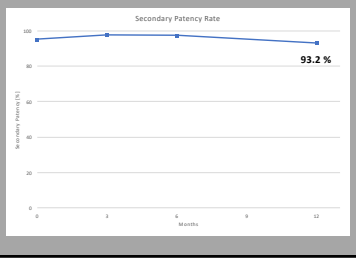
91.5 % primary patency after 12 m



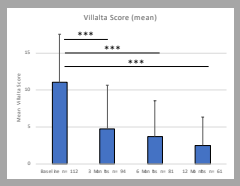
Technical success ≥ 98.2 %

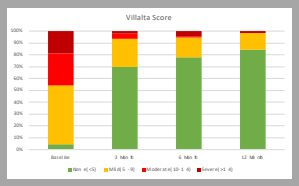
Secondary Patency after 12 months

93.2 % secondary patency after 12 m

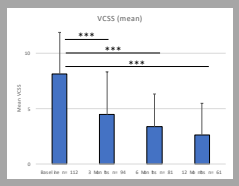


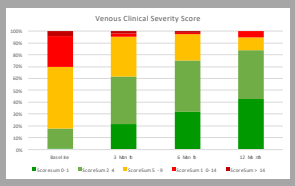
Villalta Score





Venous Clinical Severity Score (VCSS)





The Arnsberg Venous Registry

Real-World Results with the Beyond Venous Stent

Arnsberg® VenousStentRegistry

Study	Assess safety and effectiveness of venous stent placement through 36 months in patients with non-thrombotic iliac vein lesions (NIVL) and post-thrombotic (PTS) iliac vein lesions
Design	**Investigator-initiated**, ongoing prospective, single arm, single center, non-randomized registry
Endpoints	Primary patency at 12 months; Clinical outcome at 12 months
Primary Investigators	Dr. Michael Lichtenberg
Subjects	59 subjects; 19 (32%) PTS and 40 (68%) NIVL

Michael Lichtenberg et al. Venous venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions- short-term results from the Arnsberg venous registry. *Vasa* (2019); *48* (2), 1–6.

Demographics

female	50	84,7%
male	9	15,3%

Tab. 2 Age of the patients (years)

mean	41
standard deviation	15
minimum	17
25% percentile	29
median	39
75% percentile	55
maximum	73
patients	N=59

Tab. 4 Medical history

		n	%
VTD	Yes	23	39,0%
pulmonary embolism	Yes	7	11,9%
deep vein thrombosis (DVT)	Yes	26	44,1%
high blood pressure	Yes	12	20,3%
high blood pressure control	Yes	12	20,3%
renal disease	Yes	3	5,1%
PVD	No	45	76,3%
coagulopathy	Yes	5	8,5%
CVA	Yes	0	,0%
cancer	Yes	2	3,4%
diabetes	Yes	2	3,4%
diabetes control	Yes	2	3,4%
patients		59	100,0%

Tab. 5 Details on DVT legs

Base: Only patients with DVT in history

	n	%
left	16	61,5%
right	10	38,5%
patients	26	100,0%

Target vessel information

	n	%
no (PTO)	19	32,2%
yes (NIVL)	40	67,8%
patients	59	100,0%

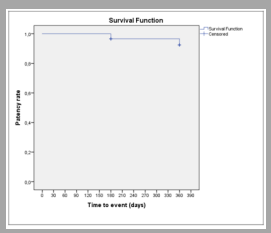
Tab. 10 Target vessel location

	n	%
left limb	49	83,1%
right limb	10	16,9%
patients	59	100,0%

	left limb		right limb		total	
	n	%	n	%	n	%
CIV	19	38,8%	2	20,0%	21	35,6%
EIV	0	,0%	0	,0%	0	,0%
CFV	0	,0%	0	,0%	0	,0%
CIV + EIV	15	30,6%	3	30,0%	18	30,5%
CIV + CFV	0	,0%	0	,0%	0	,0%
EIV + CFV	1	2,0%	1	10,0%	2	3,4%
CIV + EIV + CFV	14	28,6%	4	40,0%	18	30,5%
patients	49	100,0%	10	100,0%	59	100,0%

Stented length 127 mm

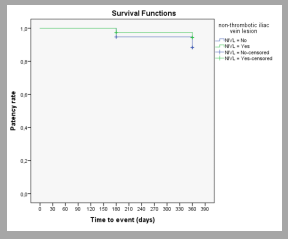
Patency analysis (overall)



	n	%
(0) freedom from loss of patency	55	93,2%
(1) loss of patency	4	6,8%
patients	59	100,0%

	FU 1 (6 months)		FU 2 (12 months)	
	n	%	n	%
freedom from CDTLR	4	80,0%	5	100,0%
no freedom from CDTLR	1	20,0%	0	,0%
patients	5	100,0%	5	100,0%

Patency by subgroup

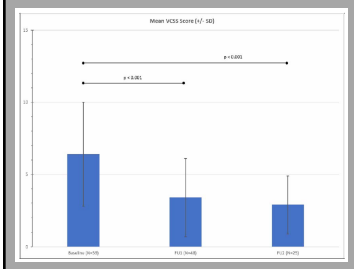


	non-thrombotic iliac vein lesion			
	NIVL = No		NIVL = Yes	
	PTS		NIVL	
(0) freedom from loss of patency	17	89,5%	38	95,0%
(1) loss of patency	2	10,5%	2	5,0%
patients	19	100,0%	40	100,0%

Tab. 20 Secondary stent patency depending on NIVL

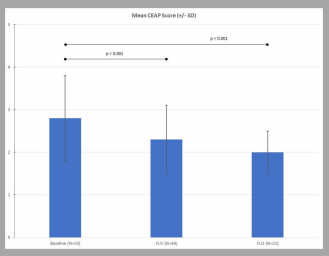
	non-thrombotic iliac vein lesion			
	PTS		NIVL	
	n	%	n	%
(0) freedom from loss of patency	19	100,0%	39	97,5%
(1) loss of patency	0	,0%	1	2,5%
patients	19	100,0%	40	100,0%

VCSS during follow-up period



	Baseline	FU 1 (6 months)	FU 2 (12 months)
mean	6,4	3,4	2,9
standard deviation	3,6	2,7	2,6
minimum	2,0	,0	,0
25% percentile	4,0	1,0	1,0
median	6,0	3,0	3,0
75% percentile	8,0	5,0	4,0
maximum	19,0	14,0	7,0
patients	N=59	N=48	N=25

CEAP score during follow-up period



Thank You