The Vici Venous Stent: longterm outcome data

Data from the Arnsberg Venous Registry

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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.

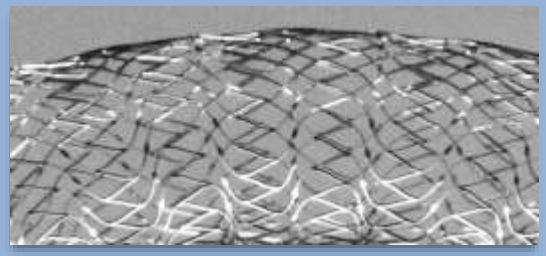
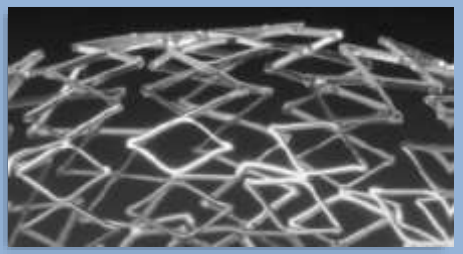
Affiliation/Financial Relationship	**Company**
1. Honoraria for lectures	CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan
2. Honoraria for advisory board activities	Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific
3. Participation 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

Desired Venous Stent Attributes

- Self-expandable
- Crush resistant across length of stent
- Sufficient chronic outward force
- Sufficient wall coverage
- Flexibility sufficient to resist kink at physiological angles
- Durability allowing repeated shortening, twisting, and bending at the groin
- Minimal foreshortening on deployment and balloon dilation
- Predictable, consistent deployment

Goal… Ideal BALANCE strength, flexibility, and lumen quality.

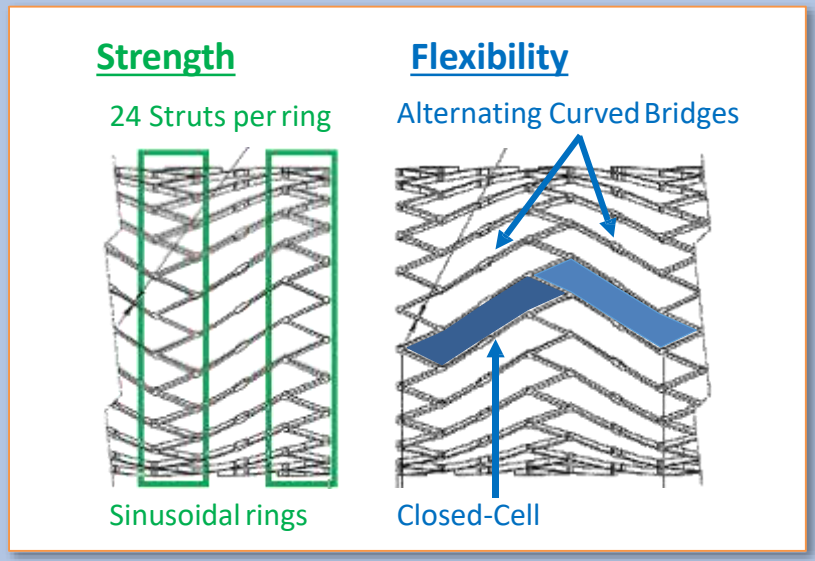
Performance Characteristics

	Closed Cell	Open Cell
		
Design Attributes	• All struts interconnected	• Not all struts interconnected
Performance		
Crush Resistance	++	+
Flexibility	+	++
Coverage	++	+

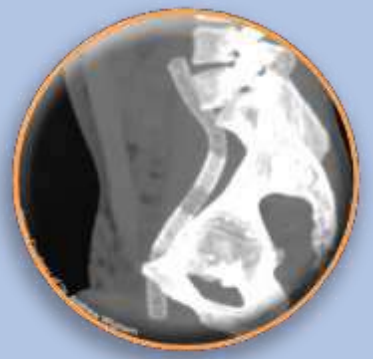
VICI Venous Stent™ System

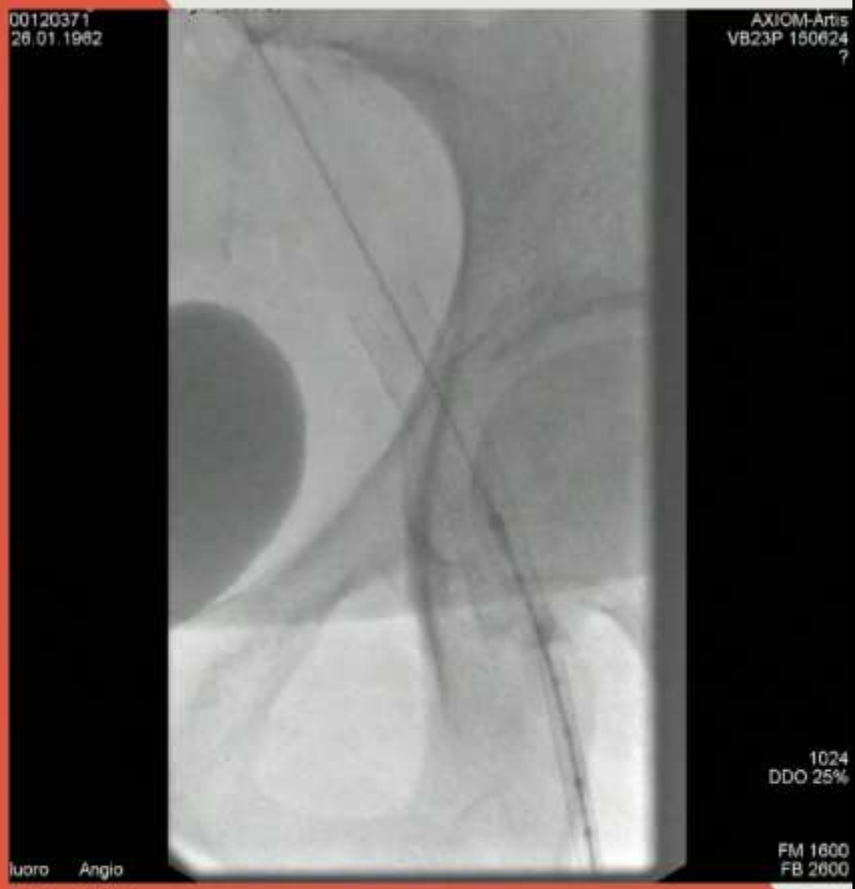
Designed for:

• Strength	High crush resistance
• Flexibility	Multi-directional
• Crush Resistance (end-to-end)	Lumen shape
• Coverage	No gaps, closed-cell
• Deployment	Predictable placement



- Self-expanding Nickel-Titanium (Nitinol)
  - 12, 14, and 16 mm diameter
  - 60, 90, and 120 mm length
- Two delivery systems for controlled stent placement centrally or peripherally





Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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Arnsberg Venous Registry – Subgroup analysis

VICI VENOUS STENT® System

Objective	Assess safety & effectiveness in achieving patency of target venous lesion through 36 months post stent placement (VENITI VICI Stent)
Effectiveness	Primary Patency @ 12-36M // Clincal outcome @ 12-26 -M
Principle Investigators	▪ Dr. Michael Lichtenberg ▪ Dr. Rick de Graaf
Study Design	Ongoing prospective, single arm, single center non-randomized registry FU 1 (4 weeks), FU 2 (6 months), FU 3 (12 months), FU 4 (24 months), FU 5 (36 months)
Patient Population	Subjects with clinically significant chronic non-malignant obstruction of the iliofemoral venous segment

Original communication

Placement of closed-cell designed venous stents in a mixed cohort of patients with chronic venous outflow obstructions – short-term safety, patency, and clinical outcomes

Michael Lichtenberg, Frank Breuckmann, Wilhelm Friedrich Stahlhoff, Peter Neglén, and Rick de Graaf

Vasa (2018), 47 (6), 475–481
https://doi.org/10.1024/0301-1526/a000731

Clinical assessment

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)												

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Demographic / Clinical data 90 patients

Demographic/comorbidity	No. (%)
Age	57.4±16.4
Male	43 (48%)
Female	47 (52%)
Post-thrombotic Syndrome	49 (54%)
Non-thrombotic	41 (46%)
History of venous thromboembolic disease	81 (90%)
Pulmonary embolism	22 (24%)
Deep vein thrombosis	43 (48%)
Coronary Artery Disease	6 (7%)
Myocardial Infarction	1 (1%)
Congestive Heart Failure	7 (8%)
High Blood Pressure	48 (55%)
Renal Disease	6 (7%)
Stroke	3 (3%)
Cancer	13 (14%)
Diabetes	13 (14%)
Smoker (current or previous)[a]	15 (17%)

CEAP score, prior to stenting	
1	0 (0%)
2	1 (1%)
3	56 (62%)
4	20 (22%)
5	8 (9%)
6	4 (4%)
Signs and symptoms, prior to stenting[b]	
Pain (inc. venous claudication)	89 (99%)
Varicose veins	83 (92%)
Edema	89 (99%)
Pigment Changes	41 (46%)
Ulcers	10 (11%)
Use of compression stockings	88 (98%)

Lesion location

Table II. Anatomical sites of stent placement in 82 limbs.

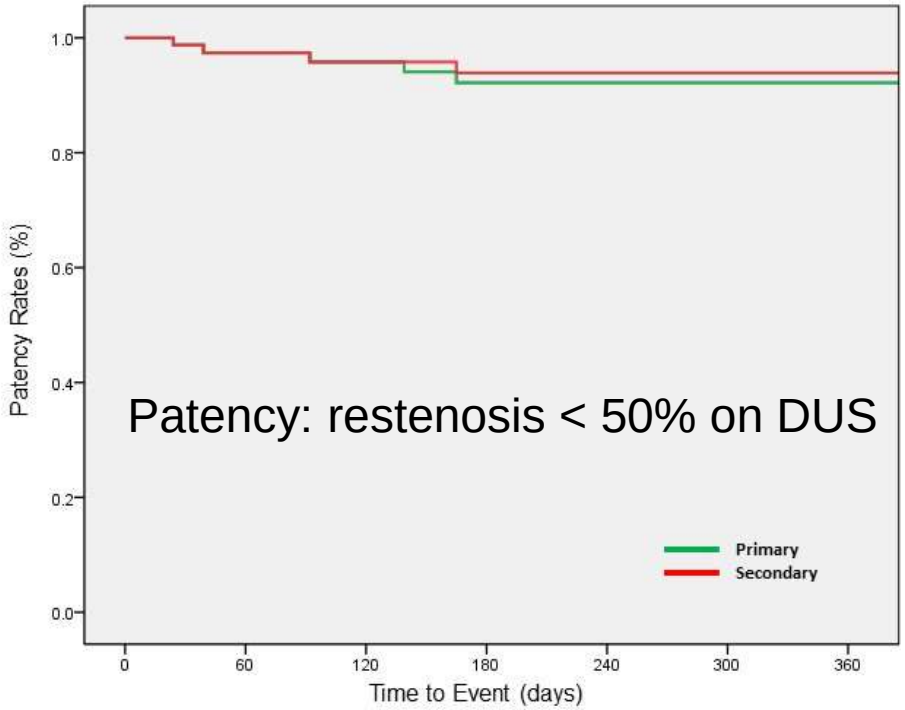
	All limbs (n = 82)	Left (n = 61)	Right (n = 21)
Isolated CIV	34 (42 %)	29 (47 %)	5 (24 %)
Isolated EIV	11 (13 %)	4 (7 %)	7 (33 %)
Isolated CFV	2 (2 %)	1 (2 %)	1 (5 %)
CIV + EIV	19 (23 %)	17 (28 %)	2 (10 %)
EIV + CFV	7 (9 %)	3 (5 %)	4 (19 %)
CIV + EIV + CFV	9 (11 %)	7 (11 %)	2 (10 %)

CFV: Common femoral vein; CIV: common iliac vein; EIV: external iliac vein.

Adverse events

Adverse Event	No. (%)
Access-site complications	1 (1%)
Hematoma	1 (1%)
Stent reocclusion	5 (6%)
Stent migration	0 (0%)
Pulmonary embolism	0 (0%)
Venous rupture	0 (0%)
Infection	0 (0%)
Blood transfusion	0 (0%)

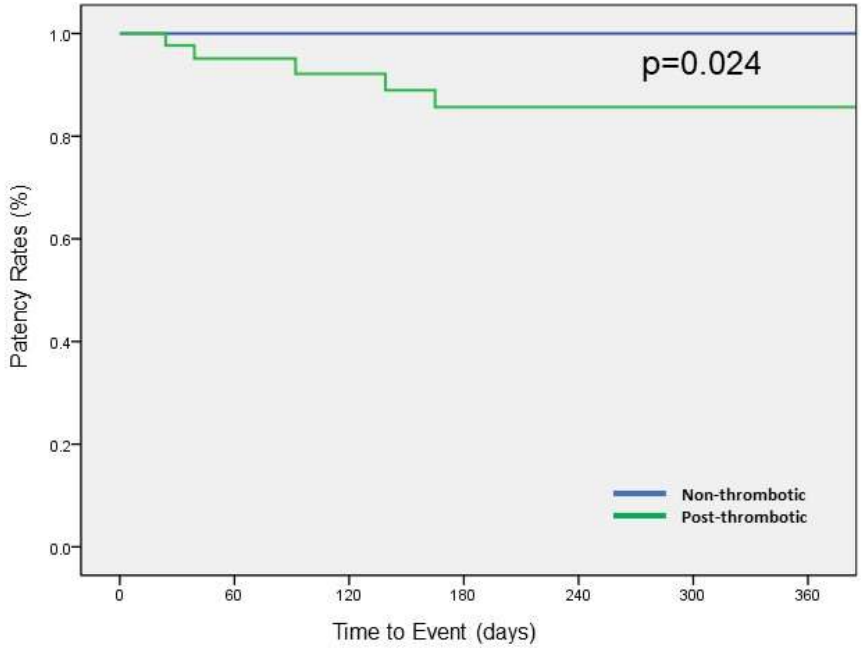
Primary patency @ 12 months



Primary	89	63	59	46	32	28	21
Primary-asst	89	63	59	46	32	28	21
Secondary	89	63	59	46	32	28	21

92.2% @ 12 months

Patency rates non-thrombotic vs. post-thrombotic



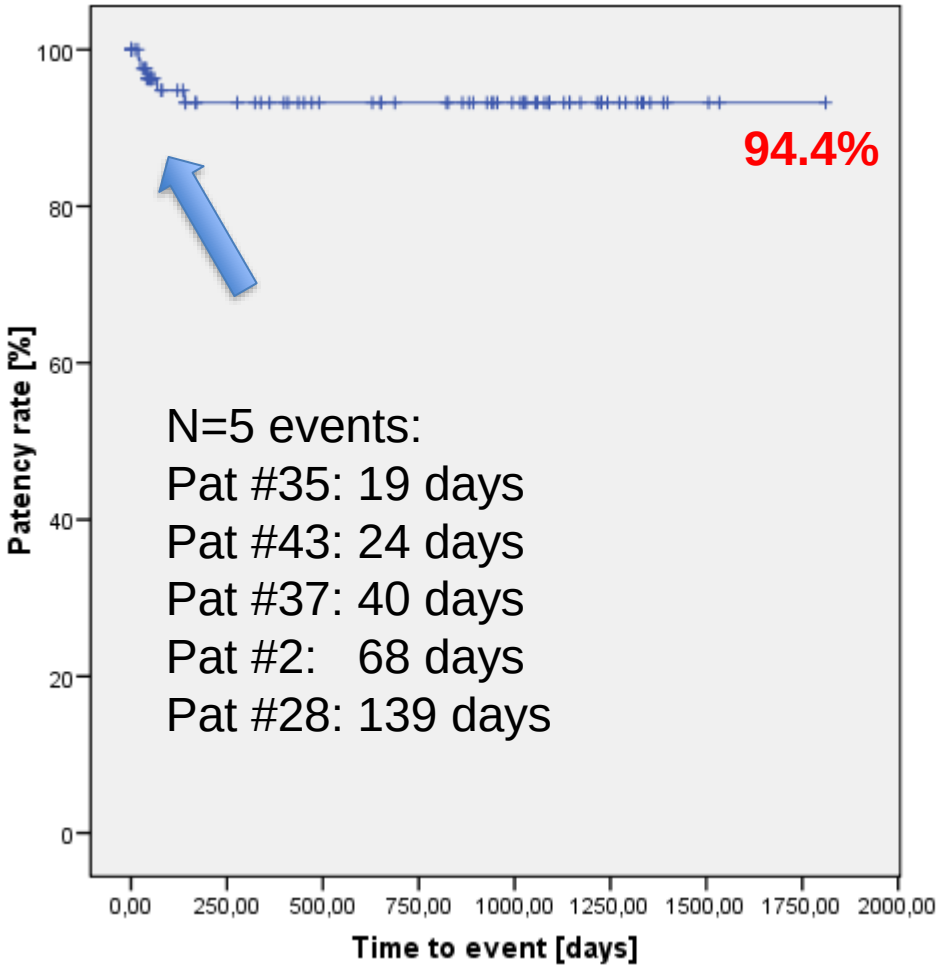
Non-thrombotic	41	30	29	21	15	13	9
Post-Thrombotic	48	33	30	25	17	15	12

100% @ 12 months

85.7% @ 12 months

Patency: restenosis < 50% on DUS

Overall primary patency @ 24 and 36 months



Case Processing Summary

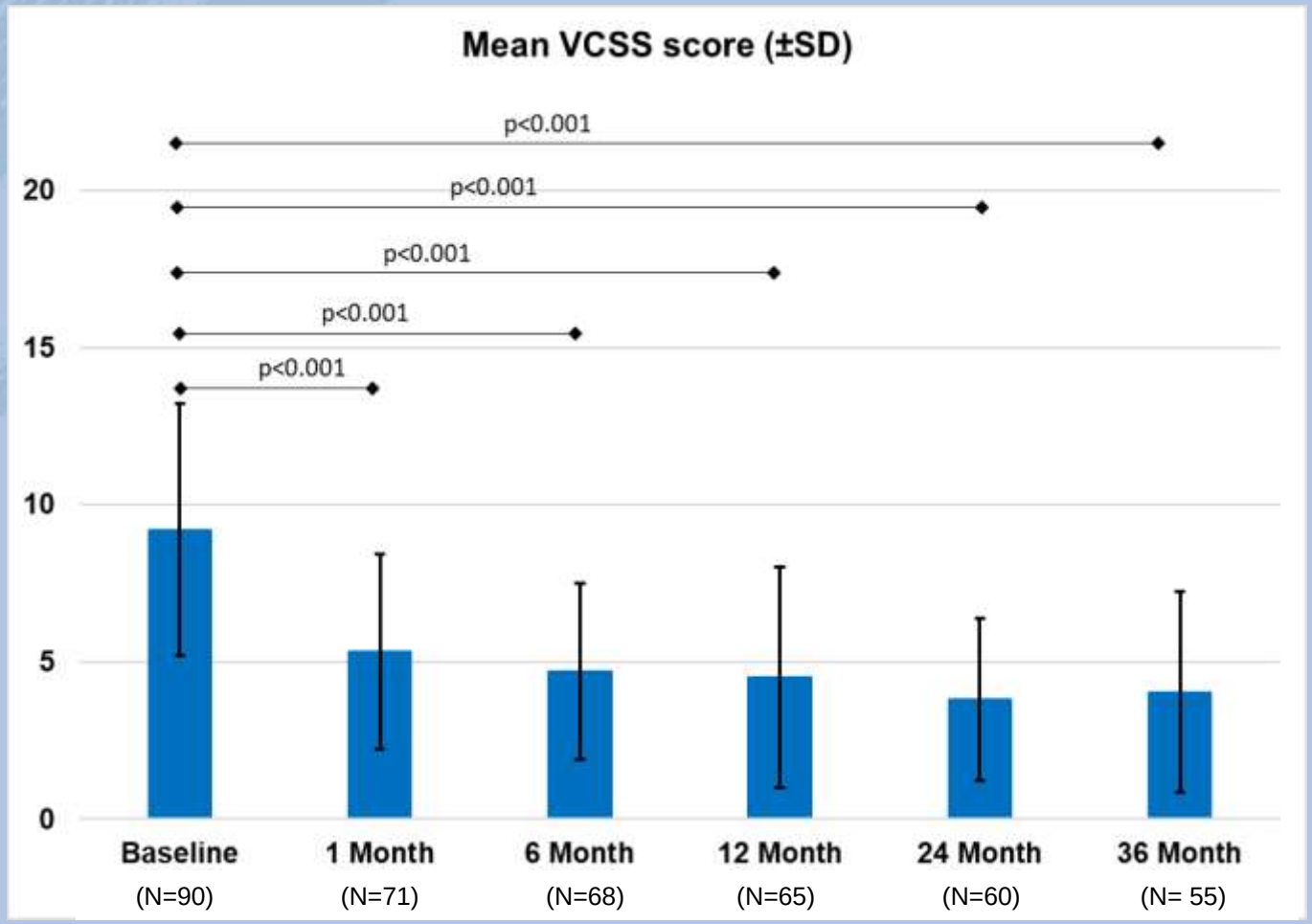
Total N	N of Events	Censored	
		N	Percent
90	5	85	94,4%

Statistics

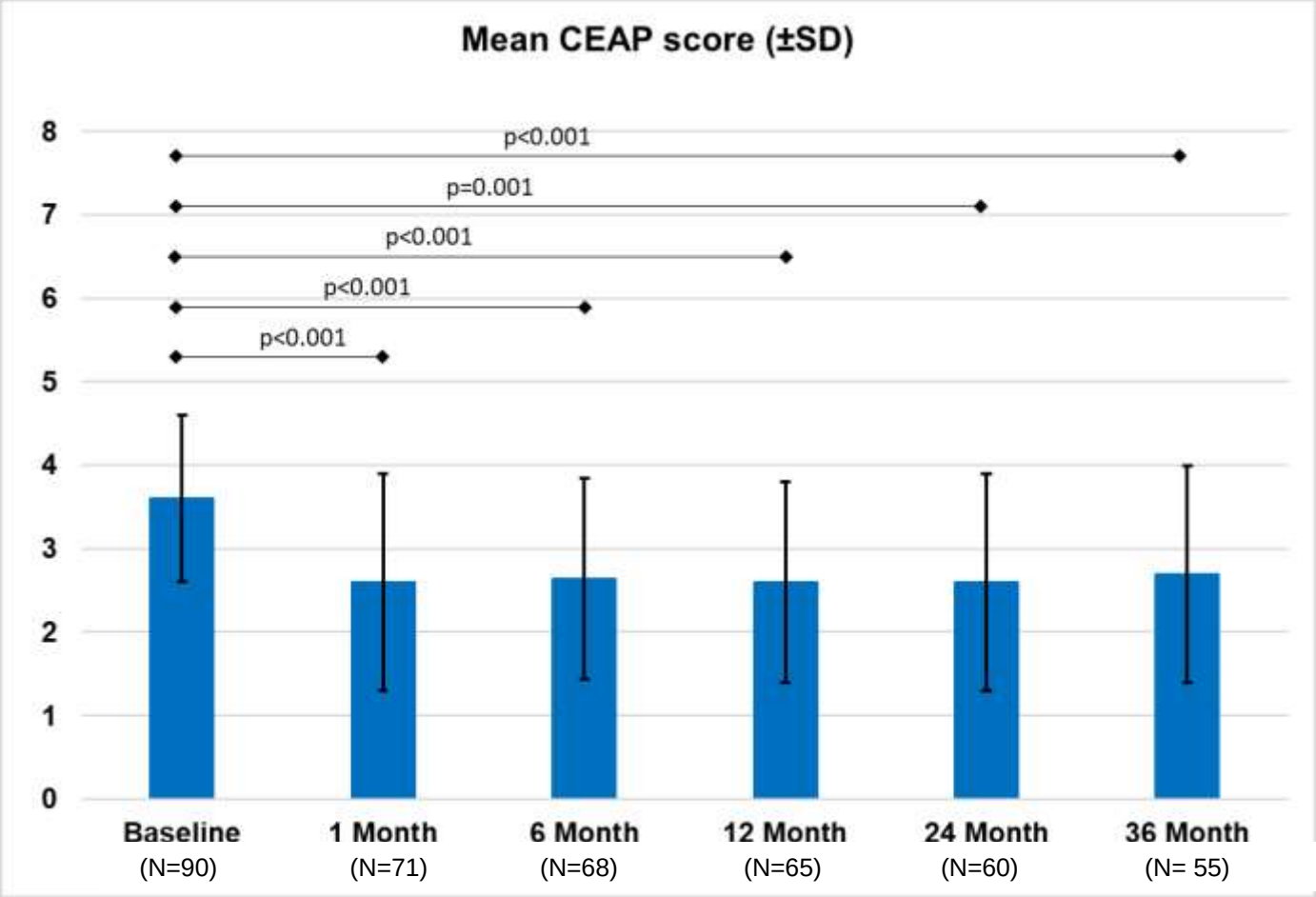
Time_to_Event

N	Valid	90
	Missing	0
Mean		616,5889
Median		559,5000
Minimum		,00
Maximum		1811,00

Clincal outcome: VCSS analyis

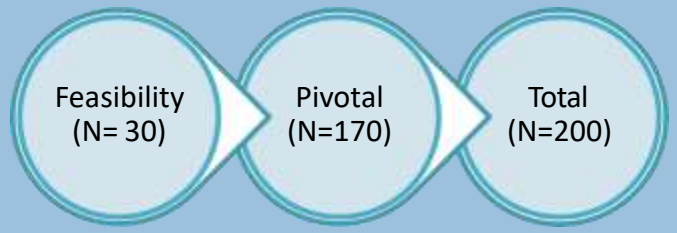


Clinical outcome: CEAP anaylsis



VIRTUS Trial Design

Objective	**Assess safety & effectiveness in achieving patency of target venous lesion through 12 months post stent placement, in patients with obstruction of the iliofemoral venous outflow tract**
Study Design	Prospective, multicenter, single arm non-randomized
Patients	Feasibility: N=30 (9 sites) Pivotal: N=170 (22 sites) USA and Europe
Endpoints	Safety: MAEs @ 30 days Effectiveness: Primary Patency @ 12 Months



- **Results for the pivotal cohort (N=170) are presented here**

VIRTUS

12 Month Patency

Endpoint	Rate
Primary Patency (primary endpoint[a])	**84.0%**

- Primary endpoint was met: Primary patency rate exceeded the performance goal of 72.1% ($p<0.0001$)[a,b]
- Primary patency based on venography only[c]
  - 79.8% Post-thrombotic
  - 96.2% Non-thrombotic

Primary patency defined as stenosis of target lesion ≤50% (based on venogram) without surgical or endovascular intervention on target vessel to restore patency.

[a]For the primary endpoint, patients who did not have venography performed at 12 months had their result imputed by random selection from subjects with a venogram result who had the same etiology and the same DUS outcome (if available).

[b]Primary effectiveness analysis based on the combined result from 15 imputations; t-statistic 4.0; $p<0.0001$.

[c]12-month venograms were available for 125 patients.

VIRTUS

VIRTUS 24-Month Results

Pivotal Cohort (N=170)

- **79.4%** primary patency at 24 months (DUS)
- 74% of evaluable DUS from post-thrombotic etiology, consistent with overall enrollment

2-Year Primary Patency

Total (N=170)	PT (N=127)	NT (N=43)
79.4% (85/107)	**73.4%** (58/79)	**96.4%** (27/28)

Core lab confirmed DUS patency at 24 months. DUS evaluable for 107 patients (79 PT and 28 NT).

CEC-adjudicated Death & Major Adverse Events

	24 Months (N=150)
Death	**0.7%** (1/150)
Target vessel revascularization (TLR and non-TLR)	**11.3%** (17/150)
Deep venous thrombosis	**0.7%** (1/150)
Suspected or confirmed pulmonary embolism	**0.7%** (1/150)
Stent movement	**0.0%** (0/150)

Note: The death was not procedure- or device-related. Target vessel revascularization (TVR) includes both TLR and non-TLR revascularizations (CEC classification pending).

BSC Data on File. CEC, Clinical Events Committee; DUS, duplex ultrasound; PT, post-thrombotic; NT, non-thrombotic.

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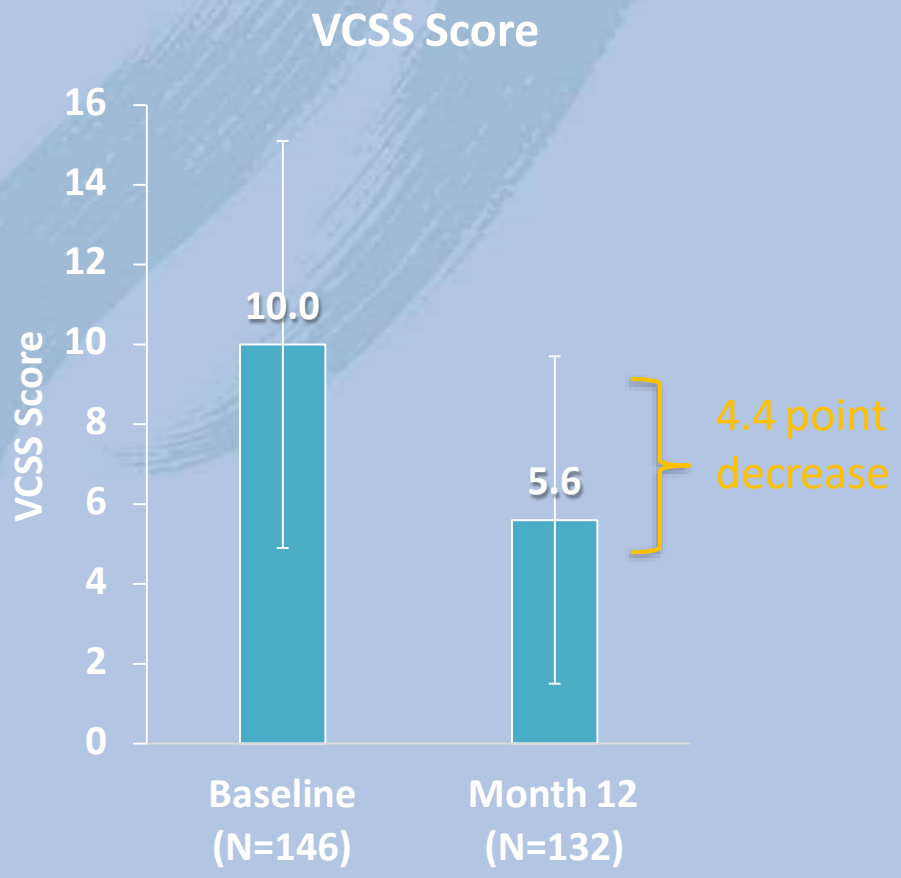
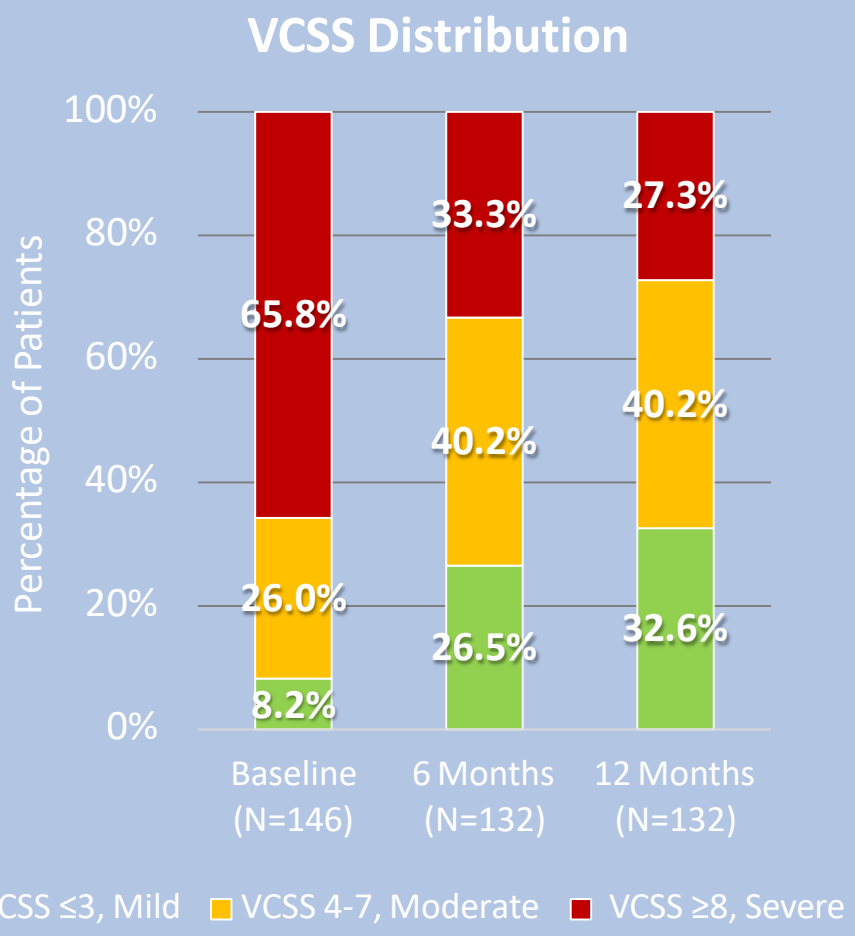
Clinical Severity





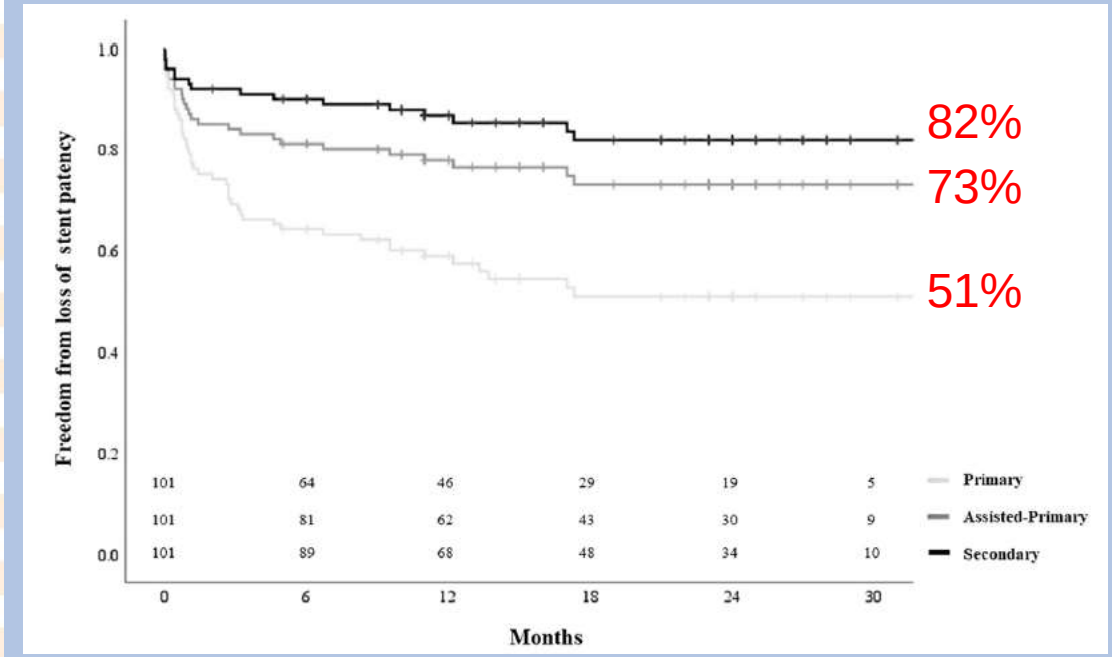
VIRTUS

Eur J Vasc Endovasc Surg (2018) 56, 710–718

Two Year Outcome After Chronic Iliac Vein Occlusion Recanalisation Using the Vici Venous Stent®

Stephen Black [a,*], Adam Gwozdz [a], Narayan Karunanithy [b], Justinas Silickas [a], Karen Breen [c], Beverley Hunt [c], Alberto Smith [a], Ander Cohen [c], Prakash Saha [a]

Patient characteristics ($n = 88$)	n (%) or median (range)
Age (y)	42 (13–83)
Male	28 (32)
Post-thrombotic syndrome	88 (100)
Thrombophilia	29 (33)
Factor V Leiden	14 (16)
APS	11 (13)
Protein S deficiency	2 (2)
Anti-thrombin III deficiency	1 (1)
HbSC	1 (1)
Bilateral treatment	13 (15)
Left leg only	69 (78)
Right leg only	6 (7)
Limb characteristics ($n = 101$)	
CEAP C class	
C3	10 (10)
C4a	64 (63)
C4b	12 (12)
C5	3 (3)
C6	12 (12)
Villalta score	14 (5–33)[a]
Vessel involvement	
IVC	31 (31)[a]
CIV	101 (100)
EIV	101 (100)
CFV	63 (62)



Many tasty apples

Dedicated venous stents are necessary

Early clinical results are promising!

Additional thinking/research necessary to understand stent performance

Broader adoption and experience will drive additional research and learning

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