VIRTUS Trial: Pivotal Cohort 12-Month Primary Safety and Efficacy Results of the VICI Venous Stent System

Mahmood K. Razavi, MD

St. Joseph Cardiac and Vascular Center

Orange, CA, USA

Disclosure

Speaker name:

Mahmood K. Razavi

I have the following potential conflicts of interest to report:

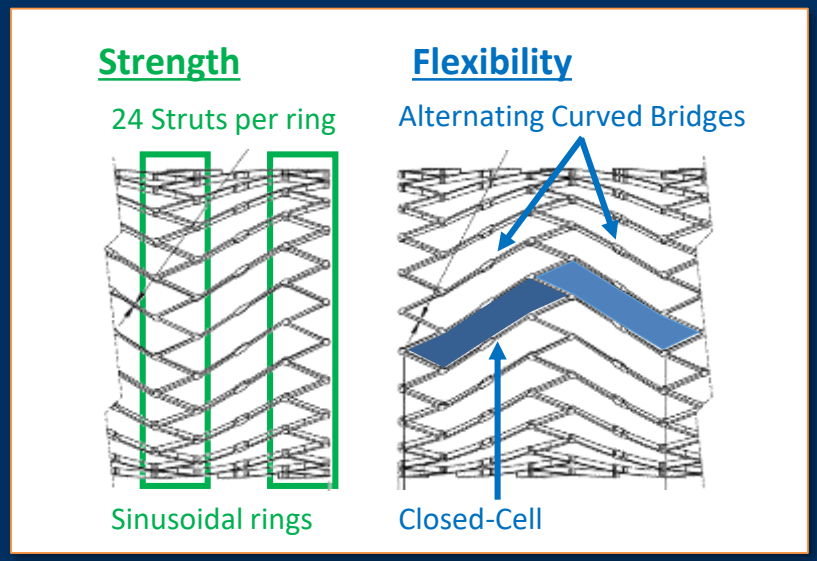
- [X] Consulting (BSC/Veniti)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

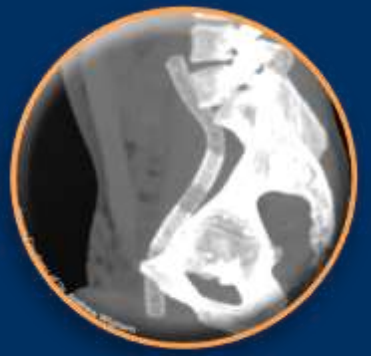
VICI Venous Stent™ System

Designed for:

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



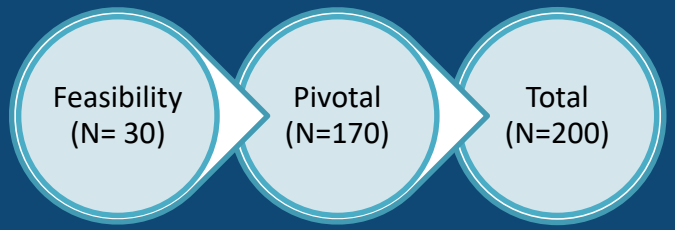
- Self-expanding Nickel-Titanium (Nitinol)
  - 12, 14, and 16 mm diameter
  - 60, 90, and 120 mm length
- Two delivery systems for controlled stent placement centrally or peripherally



VICI Venous Stent is an investigational device limited by U.S. law to investigational use only. Not available for sale in the U.S.

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 Endpoints

Primary Effectiveness Endpoint	**Primary patency rate at 12 months post-intervention** • Freedom from occlusion by thrombosis and • Freedom from surgical or endovascular intervention on target vessel which are found to have re-stenosis or stent occlusion to maintain patency and • Freedom from in-stent stenosis more than **50% by venogram**
Primary Safety Endpoint	Composite endpoint of **freedom from any Major Adverse Event** within 30 days of index procedure (adjudicated by a Clinical Events Committee) • Device or procedure-related death • Device or procedure-related bleeding at the target vessel and/or the target lesion or at the access site • Device or procedure-related arterial or venous injury occurring in the target vessel segment and/or target lesion location or at the access site • Device or procedure related acute DVT outside of the target vein segment • Clinically significant pulmonary embolism • Embolization of stent

VIRTUS Trial Design

Key Inclusion Criteria

- Unilateral, clinically significant, chronic non-malignant obstruction of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof
  - ≥50% reduction in target vessel lumen diameter (venogram)
- Clinically significant venous obstruction defined as:

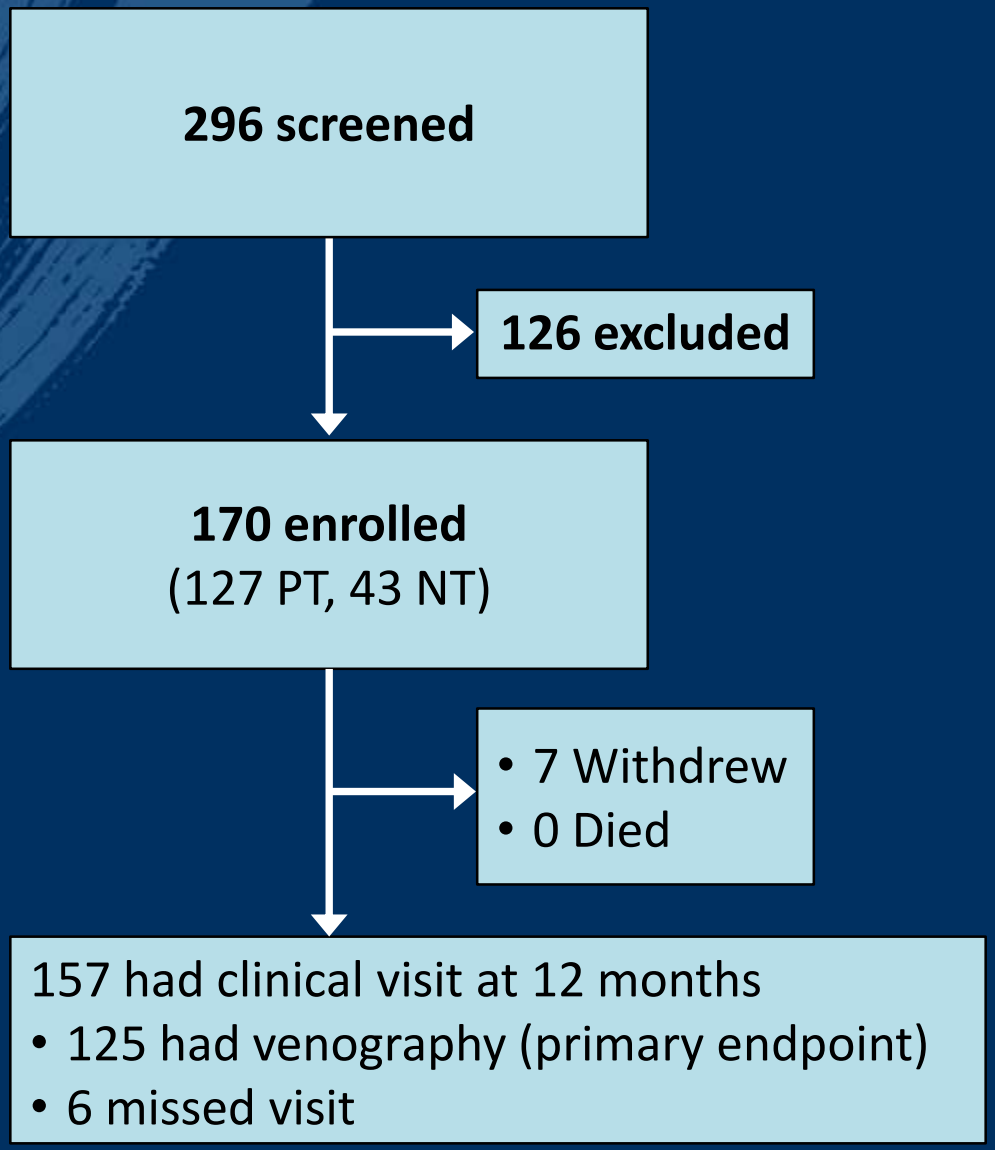
CEAP "C" ≥3 OR VCSS Pain ≥2

Imaging Schedule

	Pre-stent	Post-stent	12 Months
Venography	✓	✓	✓ Patency endpoint
DUS		✓ Discharge or 3d post-procedure	✓
IVUS	✓	✓	✓

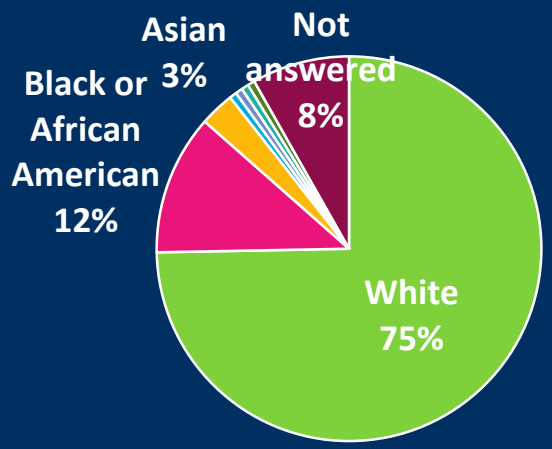
VIRTUS

Patient Flow



Baseline Patient Characteristics

Demographics and Medical History	N=170
Age, y	54.4±16.2
Male/Female	43.5%/56.5%
Diabetes	17.1%
Smoking History	
Current	12.4%
Former	24.1%
Thromboembolic disease	76.5%
Pulmonary embolism	21.5%
Deep vein thrombosis	91.5%
Coagulation disorder	13.5%
Hypertension	40.0%
Peripheral vascular disease	17.1%
Cancer	10.6%
Coronary artery disease	8.2%
Cerebrovascular accident	5.9%
Renal disease	4.7%
Hepatic disease	2.9%
PTA/stent	2.4%
CABG	2.4%
CHF	2.4%

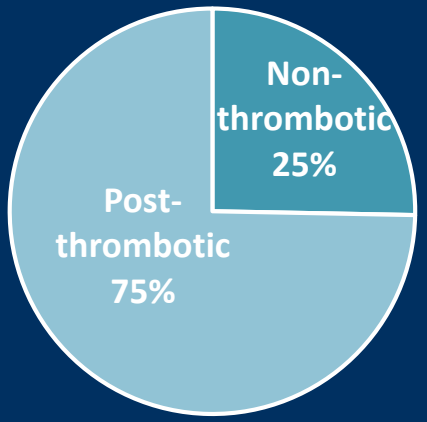


VIRTUS

Baseline Patient Characteristics

Clinical Assessment	N=170
Obstruction present in:	
Left leg	85.3%
Right leg	14.1%
Both legs	0.6%
% Stenosis	77.5%
Total Occlusion	31.2%
Lesion Length, mm	111.3 ±65.8
CEAP "C" Assessment	
0	1.2%
1	0%
2	1.2%
3	26.5%
4	45.9%
5	12.9%
6	12.4%
Target Limb VCSS Severity	
VCSS ≤3 (Mild)	8.2%
VCSS 4-7 (Moderate)	26.0%
VCSS ≥8 (Severe)	65.8%

Etiology



Lesion Location

CIV only 21.2%

CIV and EIV 34.7%

CIV, EIV, and CFV 31.8%

EIV only 6.5%

EIV and CFV 4.1%

CFV only 1.8%

CFV, common femoral vein; CIV, common iliac vein; EIV, external iliac vein.

VIRTUS

Procedures

N=170	
Stented length, mm	Median 120 (range 60-300) Mean 149.8 ± 55.7
Procedural technical success	98.8%
Post-procedure stenosis	
Venogram	4.6% ± 7.8%
IVUS	4.2% ± 7.6%

Procedural technical success defined as final residual target vessel diameter stenosis of ≤50% as measured by venogram.

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

Safety

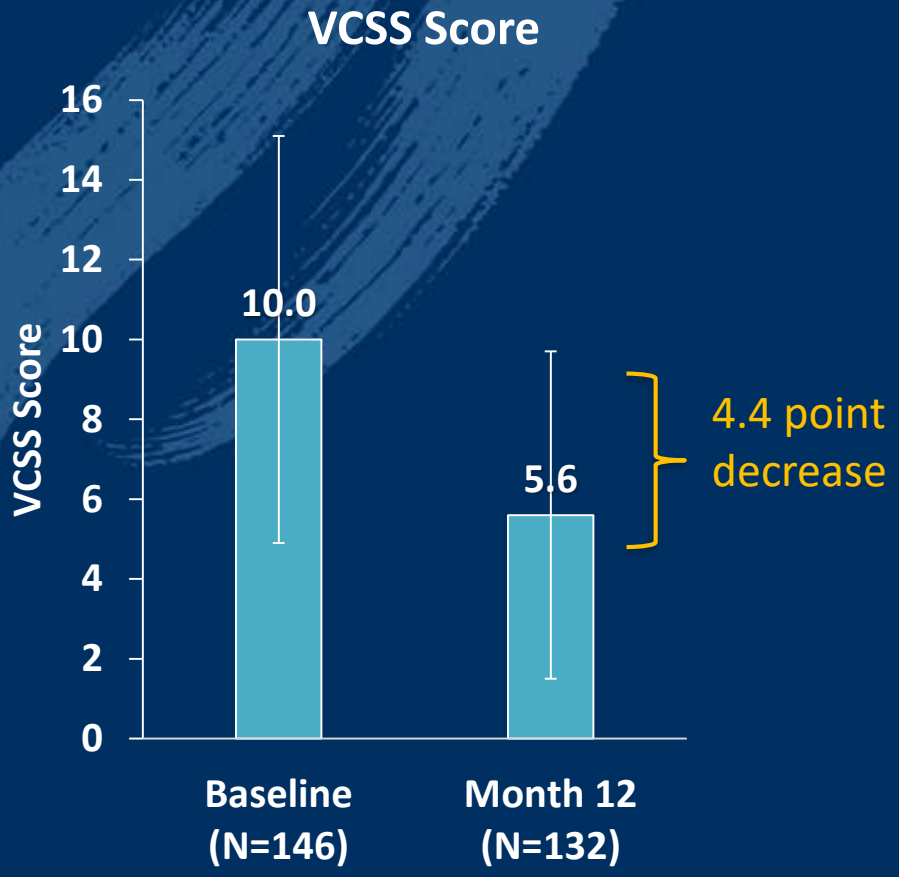
- 98.8% freedom from MAEs through 30 days
  - Lower confidence limit of 95.8% exceeded the performance goal of 94%

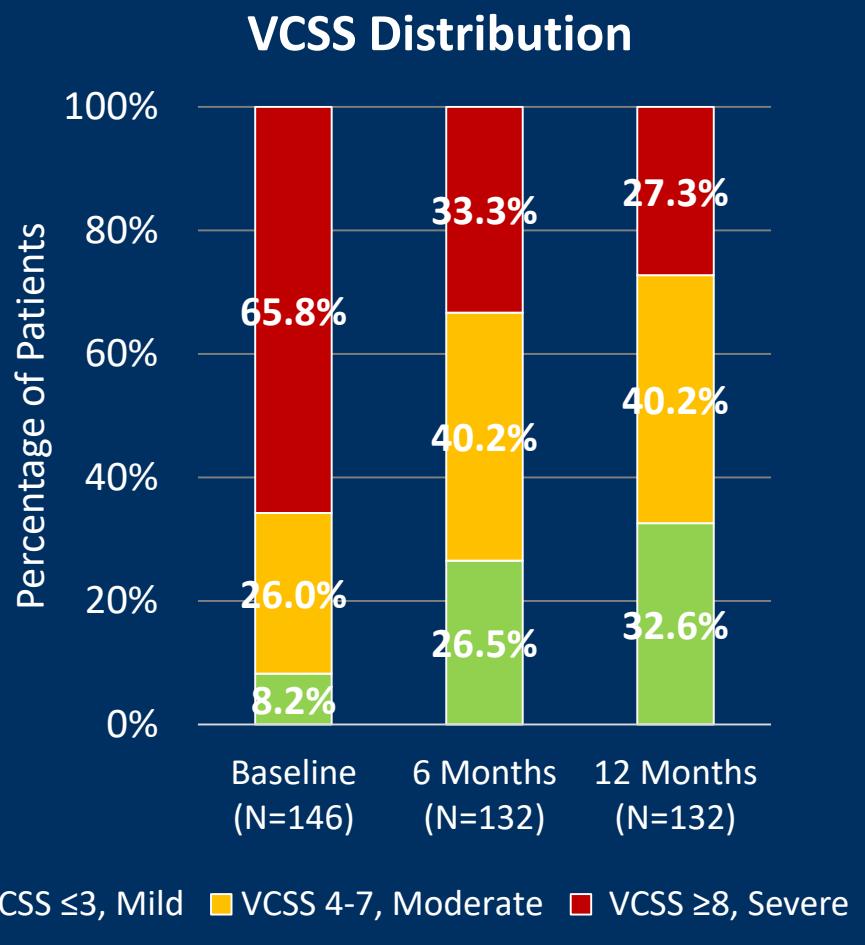
Major Adverse Events (through 30 days)	n/N
Arterial or venous injury at the target vessel segment and/or target lesion location or at the access site requiring surgical or endovascular intervention	2/169 (1.2%)
Device or procedure-related death	0/169
Bleeding at the target vessel and/or target lesion or at the access site requiring surgical or endovascular intervention or blood transfusion	0/169
Acute DVT outside the target vein segment	0/169
Clinically significant pulmonary embolism	0/169
Embolization of the stent	0/169

MAEs were adjudicated by a Clinical Events Committee.

VIRTUS

Clinical Severity





Conclusions

- VIRTUS primary safety and effectiveness endpoints successfully met
- Patient sample with challenging characteristics:
  - 75% PTS
  - ~25% “C” 5-6
  - 31% with occlusion
  - 32% had involvement of the entire iliofemoral segment
- 84% 12-month primary patency for patients treated with the VICI stent
- The VICI Venous stent demonstrated excellent safety outcomes with 98.8% freedom from MAE through 30 days

VIRTUS Investigators

Co-Principal Investigators: Mahmood Razavi, MD & William Marston, MD

Principal Investigator	Site Name	Country
Carl Fastabend, MD	Imperial Health, LLP	United States
Robert Lookstein, MD	Icahn School of Medicine at Mount Sinai	United States
Mark Meissner, MD	University of Washington Medical Center	United States
Mahmood Razavi, MD	St. Joseph Hospital	United States
Mikel Sadek, MD	NYU School of Medicine	United States
Jason Crowner, MD	University of North Carolina at Chapel Hill	United States
Peter Stratil, MD	Radiology Imaging Associates	United States
Ronald Winokur, MD	NY Presbyterian Hospital/Cornell University	United States
Paul Gagne, MD	Vascular Breakthroughs	United States
Ediberto Soto-Cora, MD	Ediberto Soto-Cora, MD (previously El Paso Cardiac and Endovascular Center)	United States
David Dexter, MD	Sentara Vascular Specialists	United States
Vasili Lendel, MD	Arkansas Site Management Services, LLC	United States
Nicolas Shammas, MD	Midwest Cardiovascular Foundation	United States
Christopher Goltz, MD	Michigan Vascular Center	United States
Rahul Malhotra, MD	Healthfinity, PLLC	United States
Gerry O Sullivan, MD	University Hospital Galway	Ireland
Luis Miguel Izquierdo Lamoca, MD	Hospital Monteprincipe	Spain
Mr. Stephen Black, MD	Guy's and St. Thomas' NHS Foundation Trust	United Kingdom
Mr. Toby Richards, MD	University College London	United Kingdom
Phillipe Nicolini, MD	Infirmerie Protestante de Lyon	France
Olivier Hartung , MD	Hôpital Nord de Marseille	France
Michael Lichtenberg, MD	Klinikum Hochsauerland GmbH	Germany

VIRTUS Trial: Pivotal Cohort 12-Month Primary Safety and Efficacy Results of the VICI Venous Stent System

Mahmood K. Razavi, MD

St. Joseph Cardiac and Vascular Center

Orange, CA, USA