Update on the VIRTUS trial

Early experience of the VICI VENOUS STENT® in patients with chronic nonmalignant obstruction of the iliofemoral venous segment

LINC 2016

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Disclosure

Speaker name: Mr. Stephen Black

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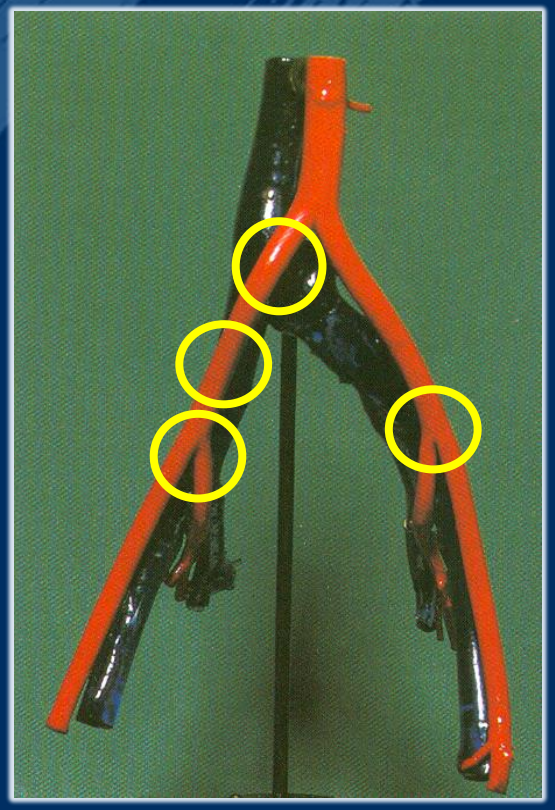
I have the following potential conflicts of interest to report:

- [x] Consulting: Medtronic, Cook, Veniti, Volcano, Optimed
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

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

Etiology of Venous Outflow Obstruction

- Classic Non-thrombotic iliac vein lesion (NIVL)



- Fibrotic webs and spurs of PTS

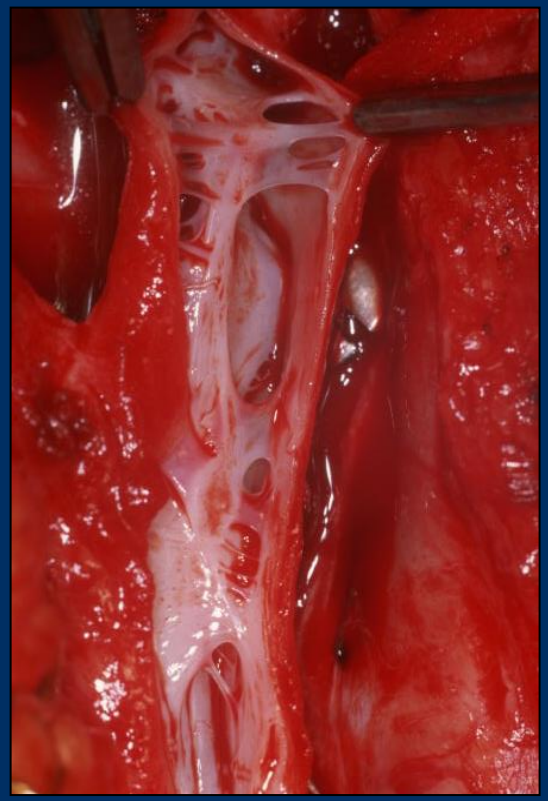


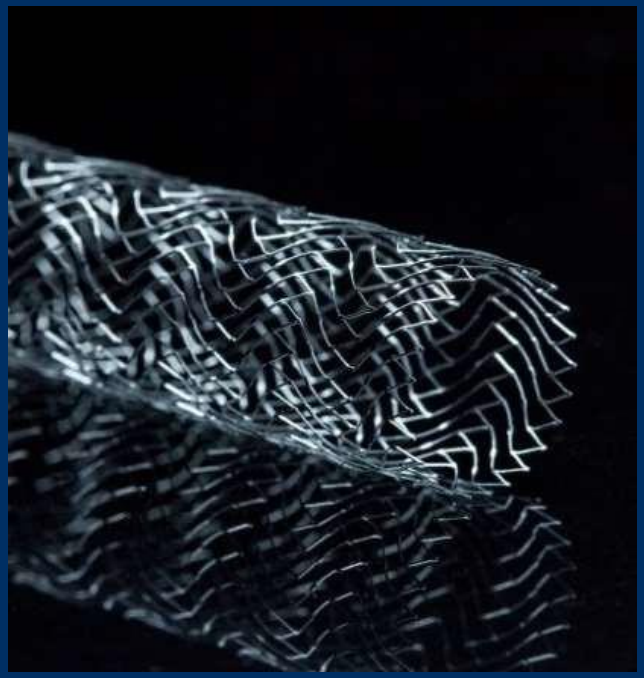
Image courtesy 0f Prof. Anthony Comerota

The “Perfect” Venous Stent

- Necessary chronic outward force
- Sufficient radial resistive force
- Self-expandable
- Adequate wall coverage
- Minimal foreshortening in-vivo
- Sufficient flexibility as to prevent kinking at physiological angles
- Allow repeated shortening, twisting, and/or bending at the groin
- Selection of diameters and lengths

VENITI® nitinol venous stent: Design characteristics

- High Crush Resistance
- Closed cell design – no gapping
- End-to-end shape and strength
- Consistent Deployment
- 9F delivery system
- lengths 60, 90, 120 mm
- Diameters 12, 14, 16 mm



VENITI VICI VENOUS STENT: VIRTUS Trial

Objective

- Assess Safety & Effectiveness in achieving patency of target venous lesion through 60-M post stent placement

Study Design

- Prospective, multicenter, single-arm non-randomized, up to 45 sites OUS and US

Subject Population

- 200 subjects with clinically significant chronic non-malignant obstruction of the ileo-femoral venous segment

VIRTUS Trial - Endpoints

- **Primary Efficacy Endpoint**
  - Primary patency at 12-M post-intervention
    - Freedom from thrombotic occlusion
    - Freedom from surgical/endovascular intervention to maintain patency
    - Freedom from in-stent stenosis > 50% by venogram
- **Primary Safety Endpoint**
  - Major Adverse Event (MAE) 30 days post-intervention
    - Procedure or device-related death
    - Procedure-related bleeding
    - Procedure-related arterial or venous injury
    - Device or procedure-related acute DVT
    - Clinically significant pulmonary embolism
    - Stent Embolization

VIRTUS Study: Feasibility Cohort

Demographics (n=30)		
Median Age (Min/Max):	44.5yrs (20-76)	
Gender:	Female: 80%	Male: 20%
Obstruction:	60% PTS	40% NIVL

CEAP Class	Percent (n=30)
0	3%
1	0%
2	0%
3	53%
4	33%
5	7%
6	3%

VIRTUS Study: Feasibility Cohort

Target Lesion Length (mm)	
Mean	118.8
St Deviation	67.8
Median	128.5
Min	30
Max	247

Stented Length (mm)	
Mean	156.5
St Deviation	56.8
Median	170.0
Min	60
Max	240

VIRTUS Study: Feasibility Cohort

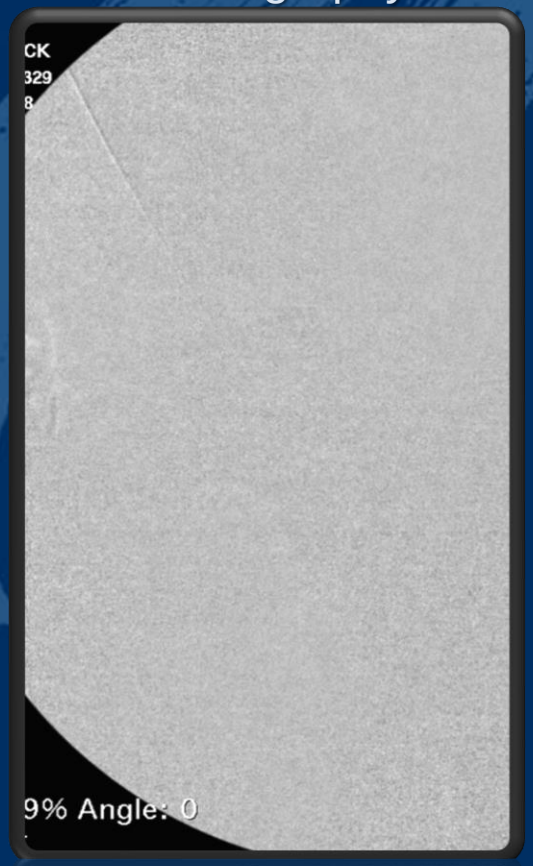
Pre-Implant Stenosis (%)	
Mean	85.2
St Deviation	17.5
Median	91.0
Min	50
Max	100

Target Limb	
L Lower Extremity	83%
R Lower Extremity	17%

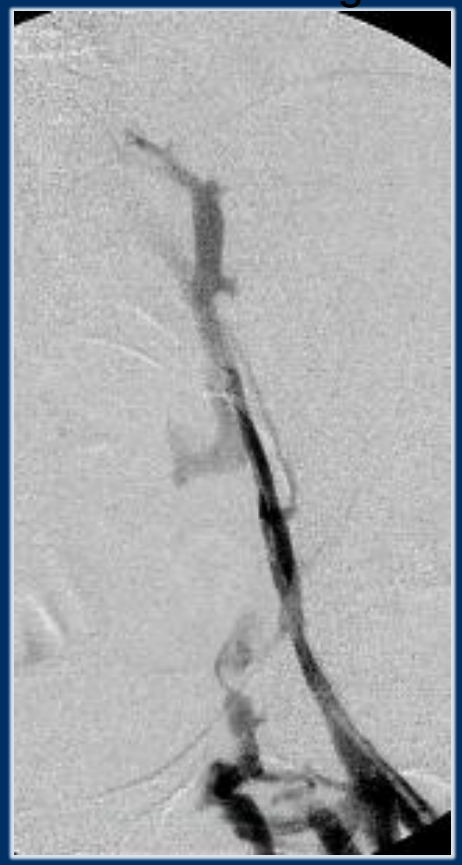
- **Post-procedure lesion stenosis is 8.1 ± 20.9%**

Case Study

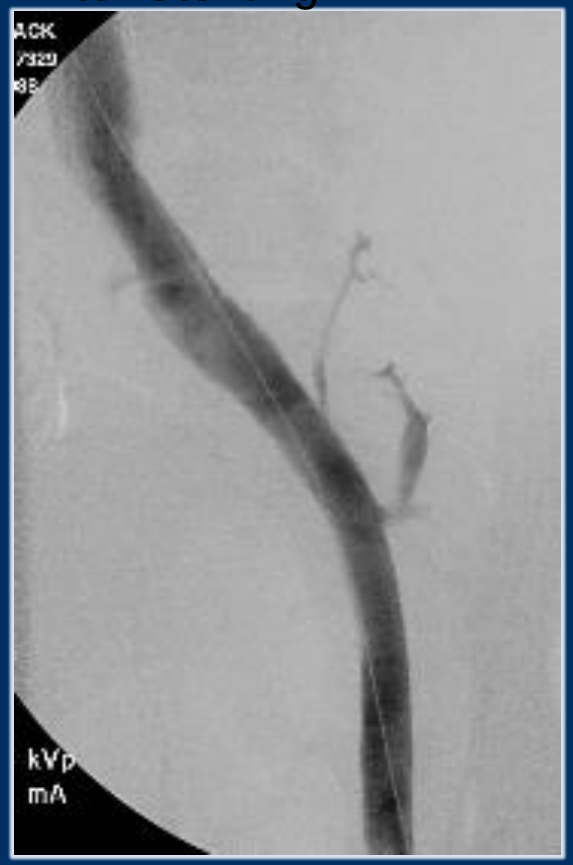
Final Venography



Before Stenting



After Stenting



Preliminary Conclusions

- Feasibility subjects are younger than population reported in literature (43 yrs vs. 60 yrs)
- Initial stenting with the VICI VENOUS STENT resulted in substantial reduction in outflow obstruction from 85% stenosis to 8%
- Need quality of life and patency outcomes at one year

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