Iliac Vein Obstruction: What Have We Learned About Stent Failure

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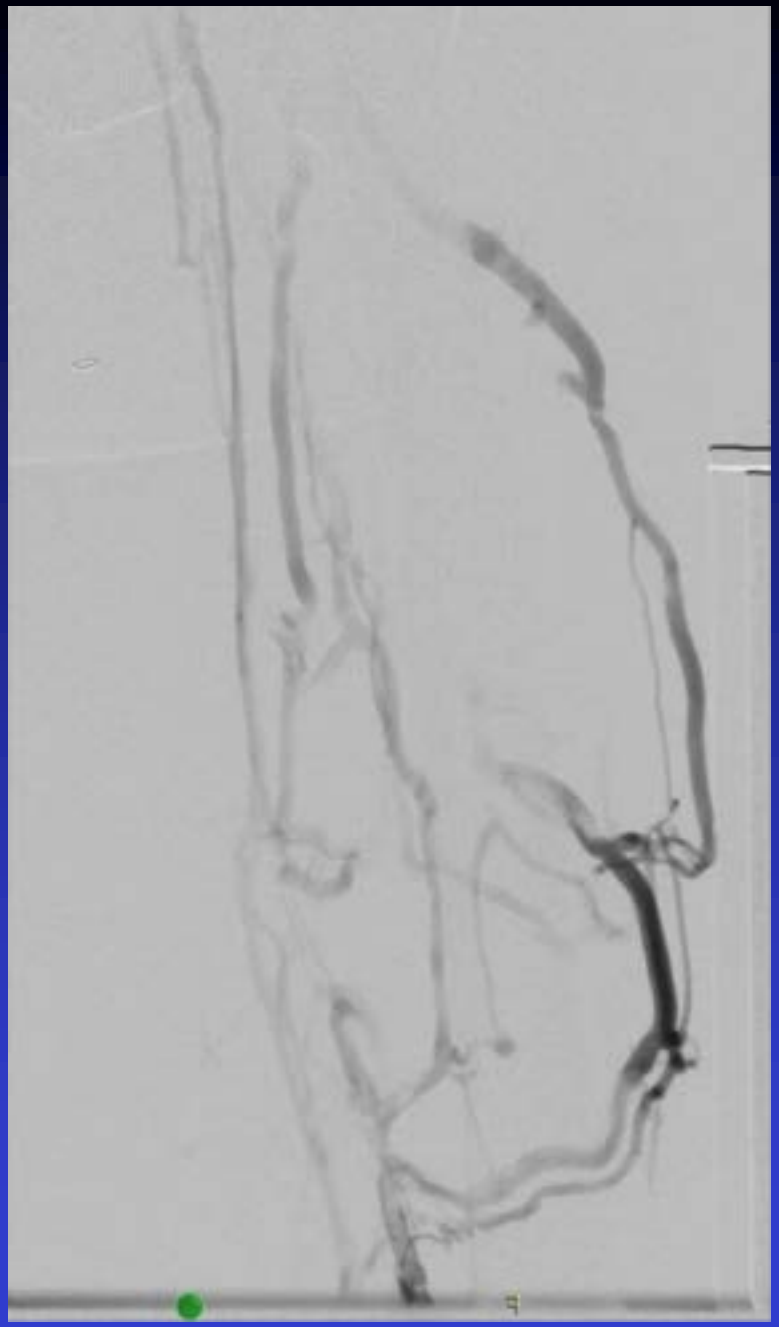
DISCLOSURE

William Marston, MD

- **Consultant / Advisory Board:** Veniti Inc, Factor Therapeutics, Tactile Medical

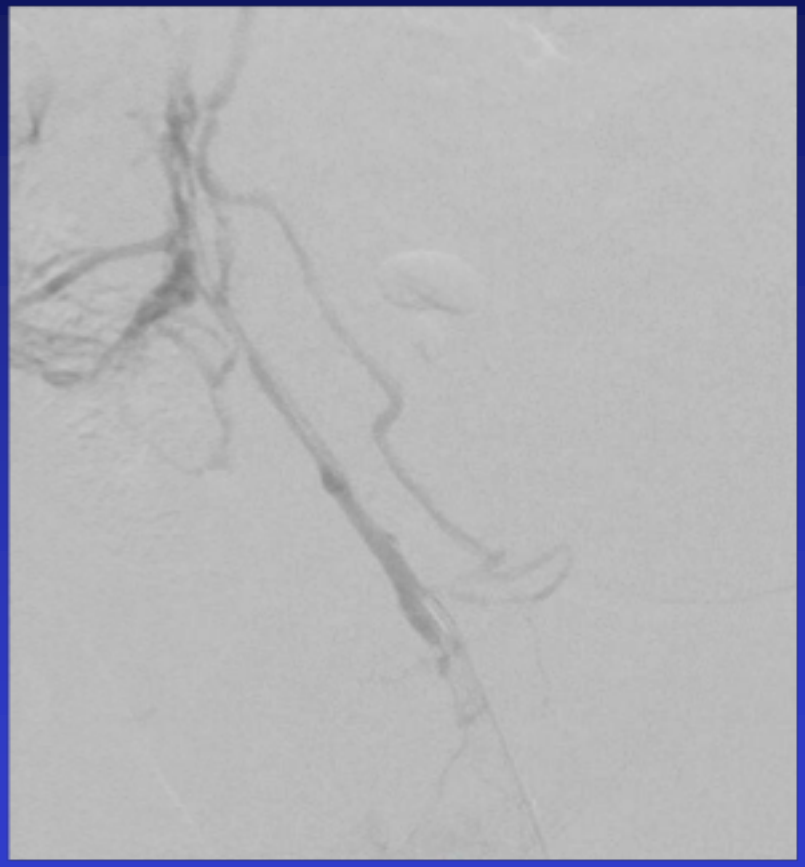
36 yo female presents with severe left leg edema, pain

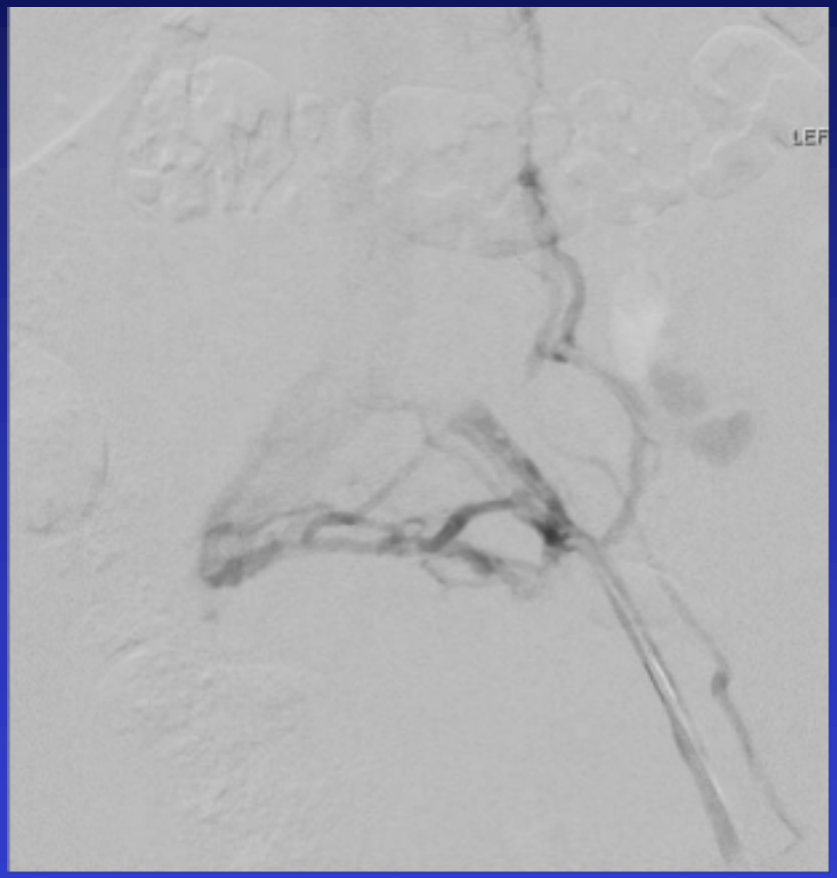
- **H/o left leg DVT 9 months ago**
- **Treated with anticoagulation despite severe edema and pain**
- **Never improved much**
- **Duplex c/w iliac vein occlusion**



Venogram

Crossing with Tri-force

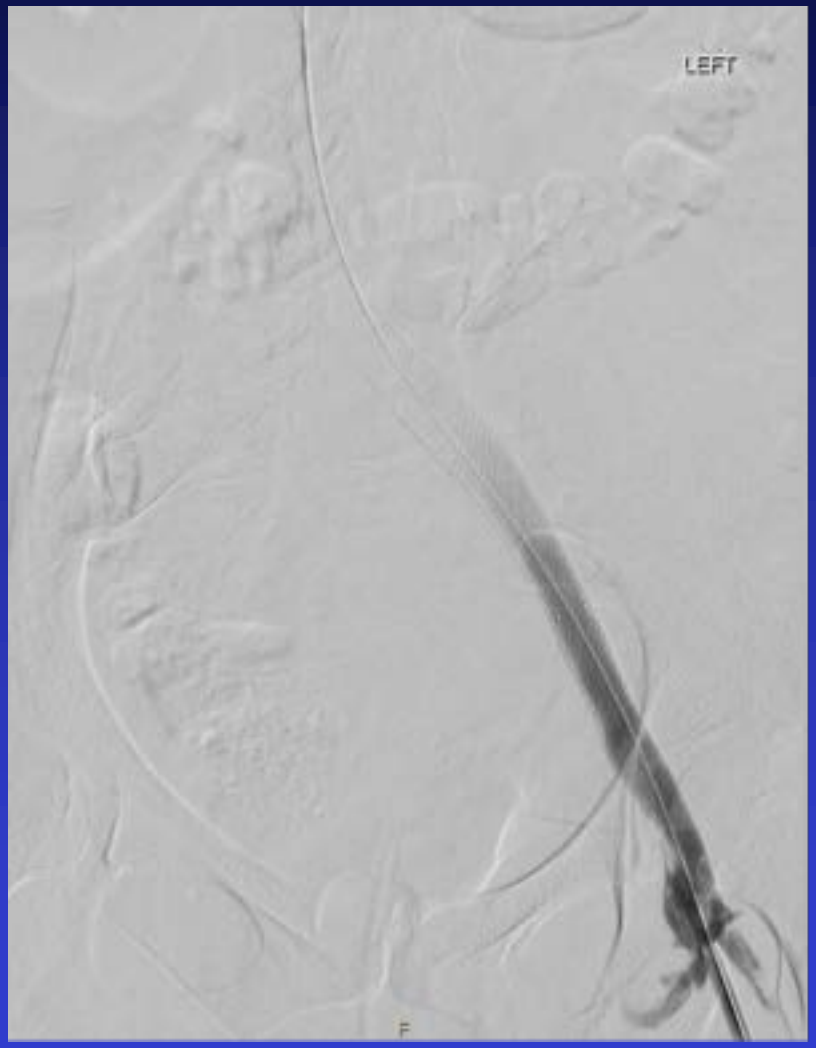




- Inserted 2 Wallstents
- 18 x 90 and 14 x 90

- Dilated femoral vein with 10 mm balloons

Completion venogram



Post procedure course

- Did well for 15 months
- Then began to notice edema after hiking or other vigorous activity
- Over 4-6 months symptoms slowly worsened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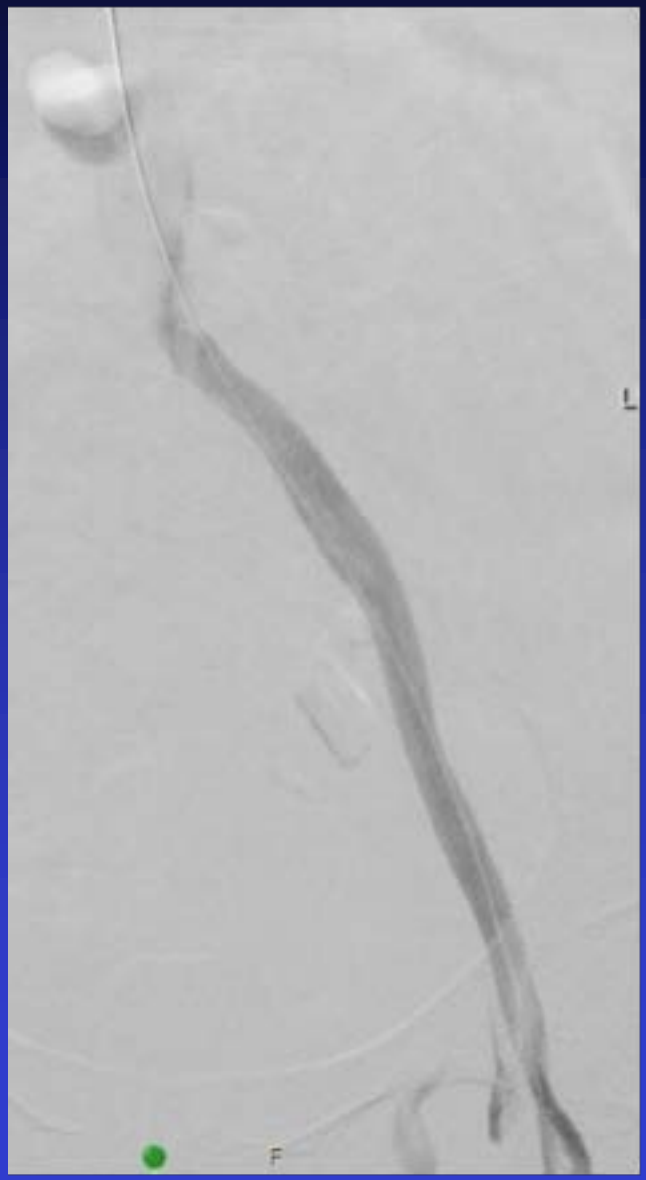
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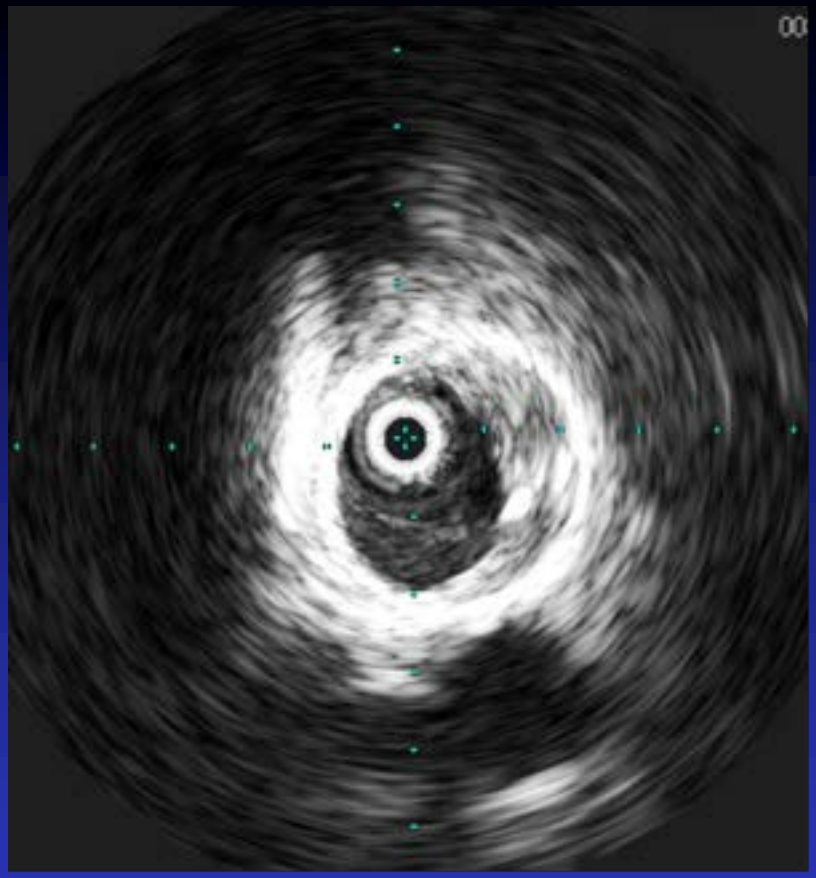

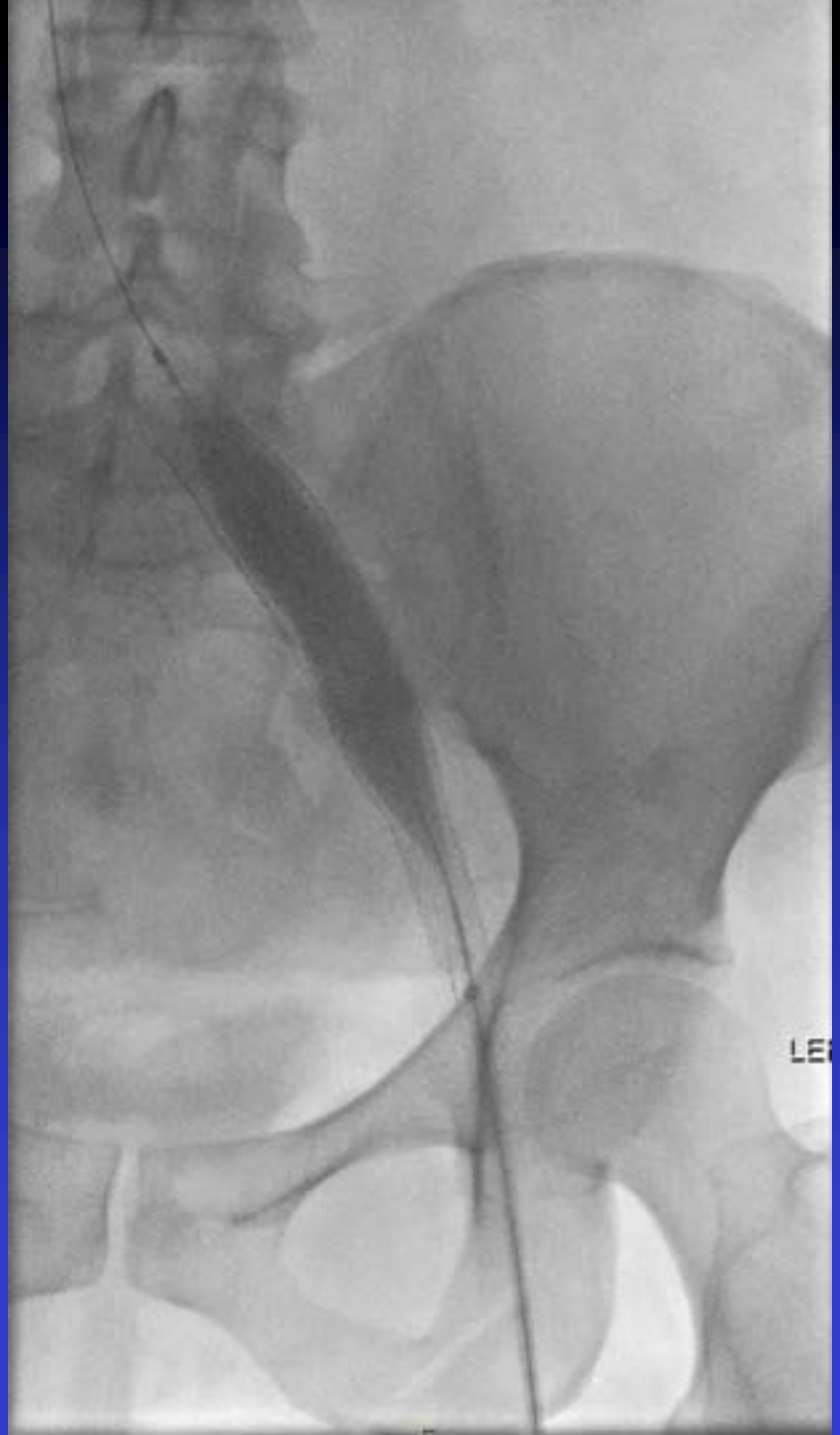


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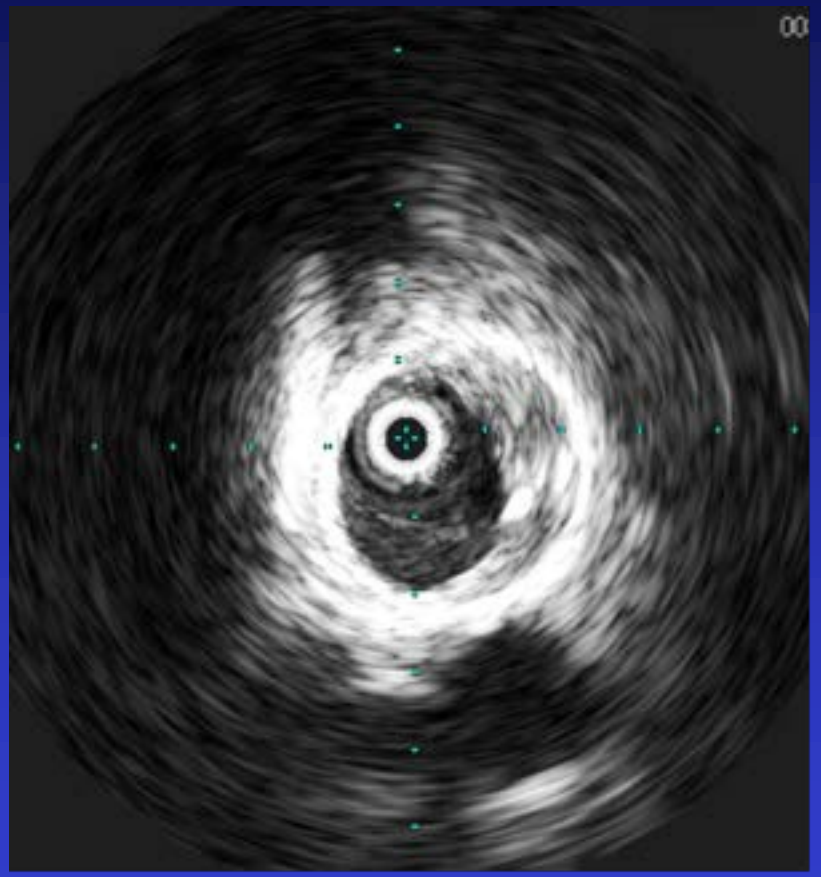
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From the American Venous Forum

Stenting of the venous outflow in chronic venous disease: Long-term stent-related outcome, clinical, and hemodynamic result

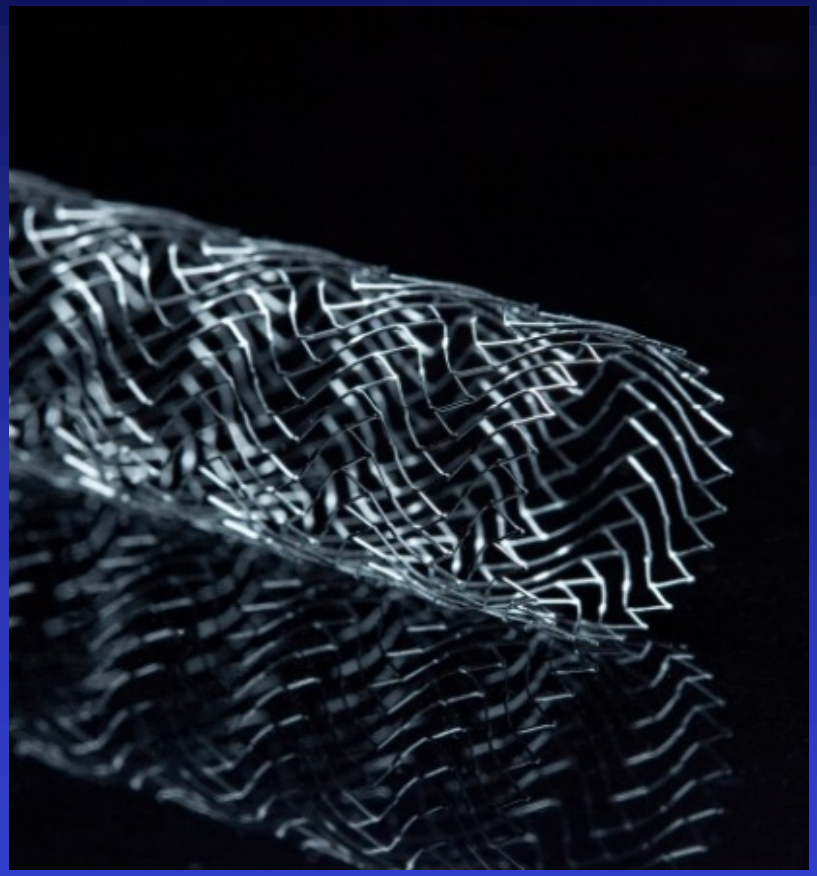
Peter Neglén, MD, PhD,[a] Kathryn C. Hollis, BA,[a] Jake Olivier, PhD,[b] and Seshadri Raju, MD,[b]
Jackson, Miss

- Iliac vein patency at 72 months
  - 67% primary
  - 89% assisted primary
  - 93% secondary
- 15-25% of post-thrombotic cases had restenosis or re-occlusion in first year

J Vasc Surg 2007;46:979

Novel venous stents: Design characteristics Veniti stent

- Nitinol self expanding
- Closed cell design
  - Increased density
  - No gaps between struts
- 9F delivery system
- lengths to 120 mm
- Diameters 12 to 16 mm



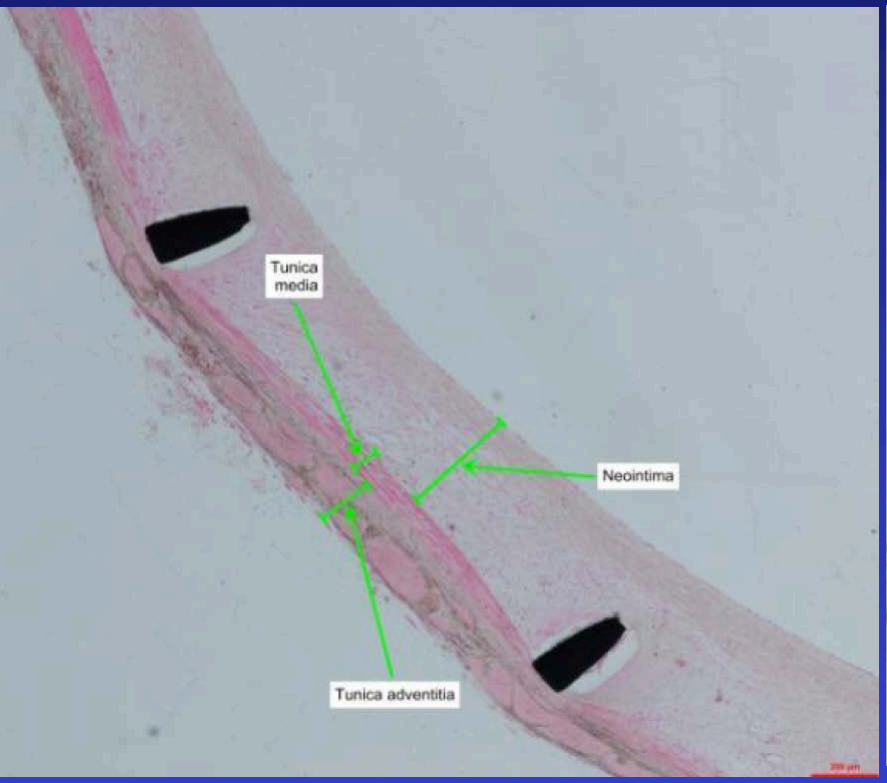
Veniti Vici animal validation study: Methods

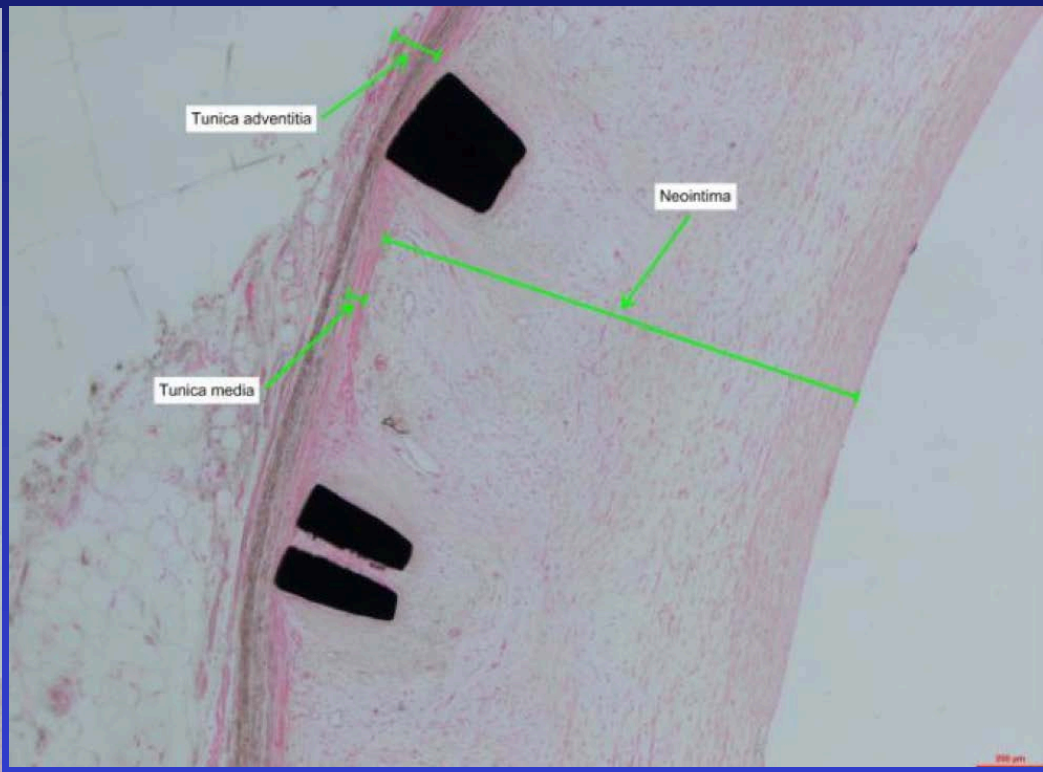
- Eight adult sheep

- Bilateral iliac vein stent insertion
  - One side received new venous stent (NVS)
  - Other side received Wallstent (WS)
  - Fluoroscopy and IVUS used for guidance
    - Before and after stent insertion
  - 4 animals studied at 8 weeks after stent insertion
  - 4 animals studied at 6 months

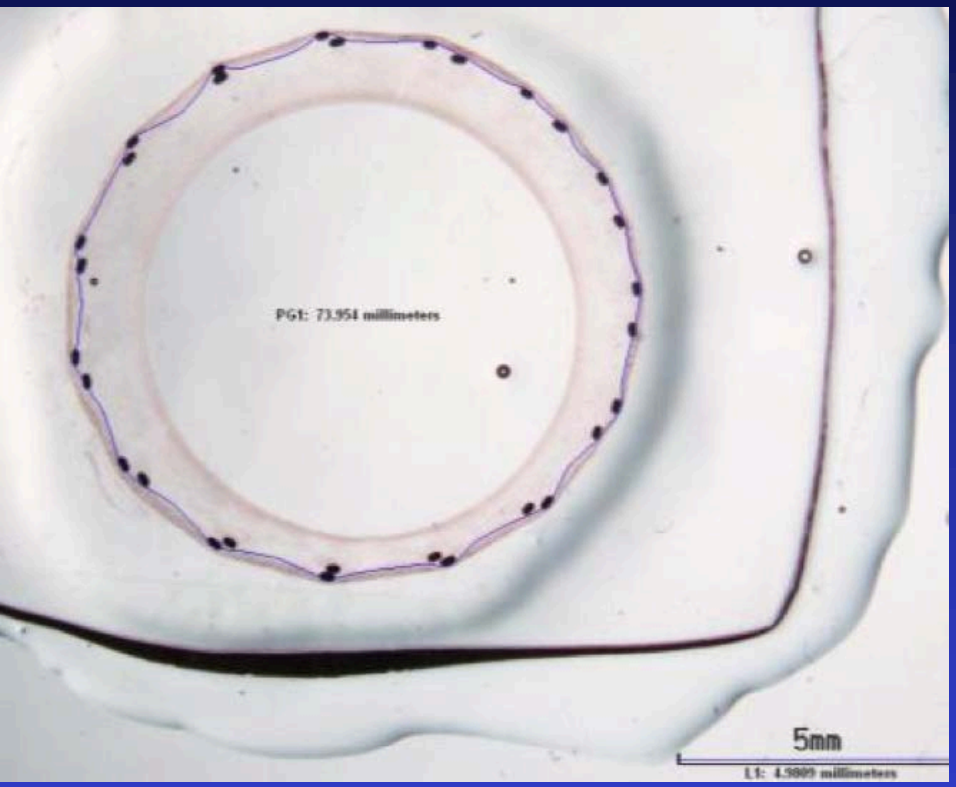
Neointimal thickness:

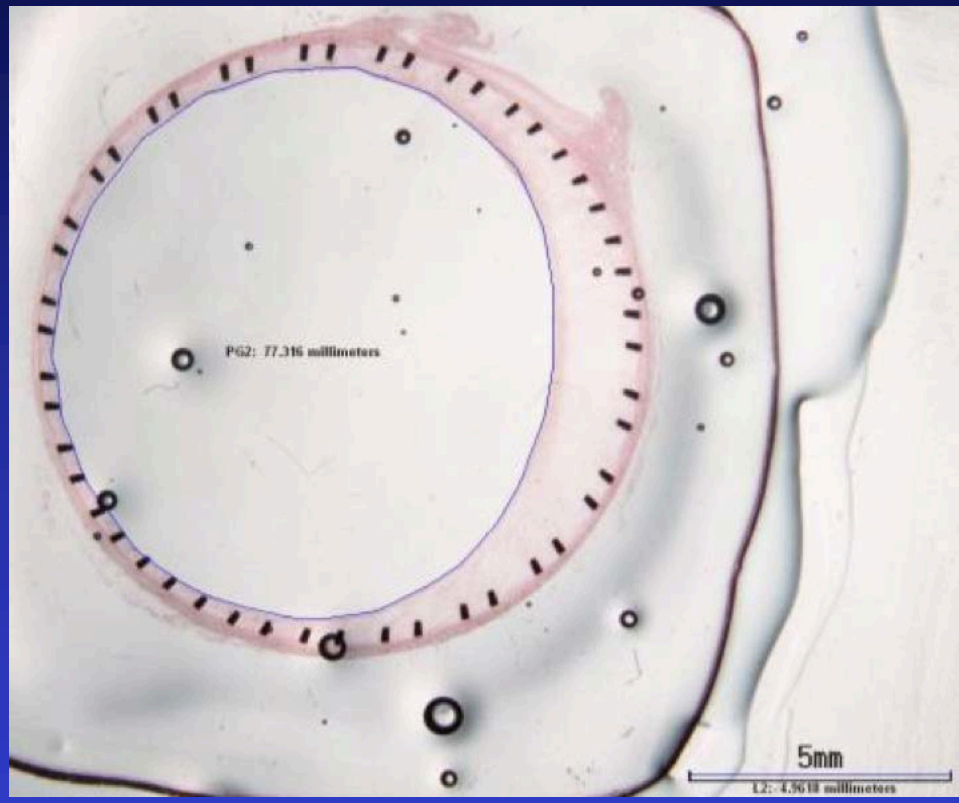
No statistical difference between WS and NVS





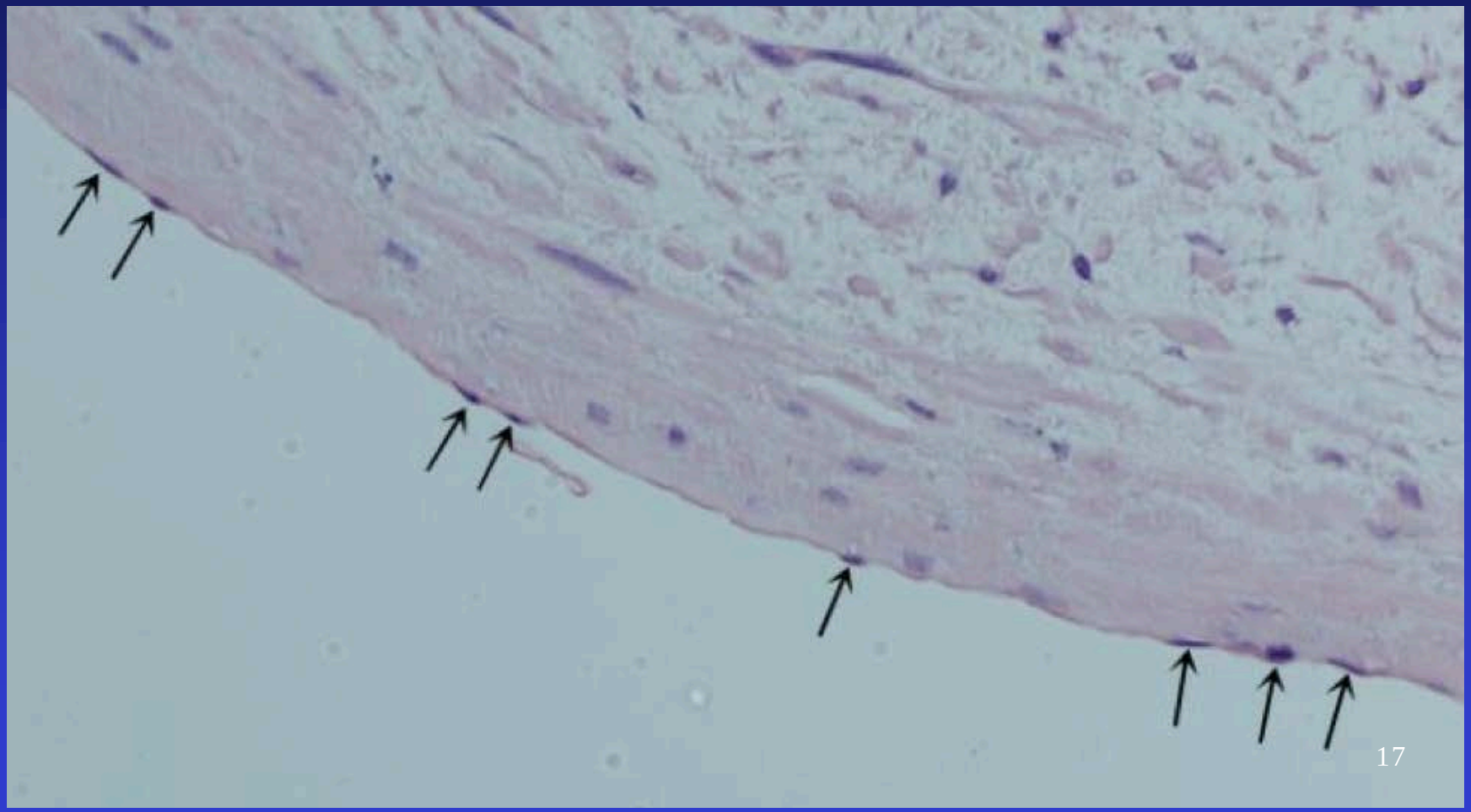
Luminal cross sections at 56 and 180 days similar:





Appeared that majority of thickening occurred early after stent placement

What is the tissue comprising endothelial thickening?



Inflammation

No inflammation or mild inflammation seen in both groups

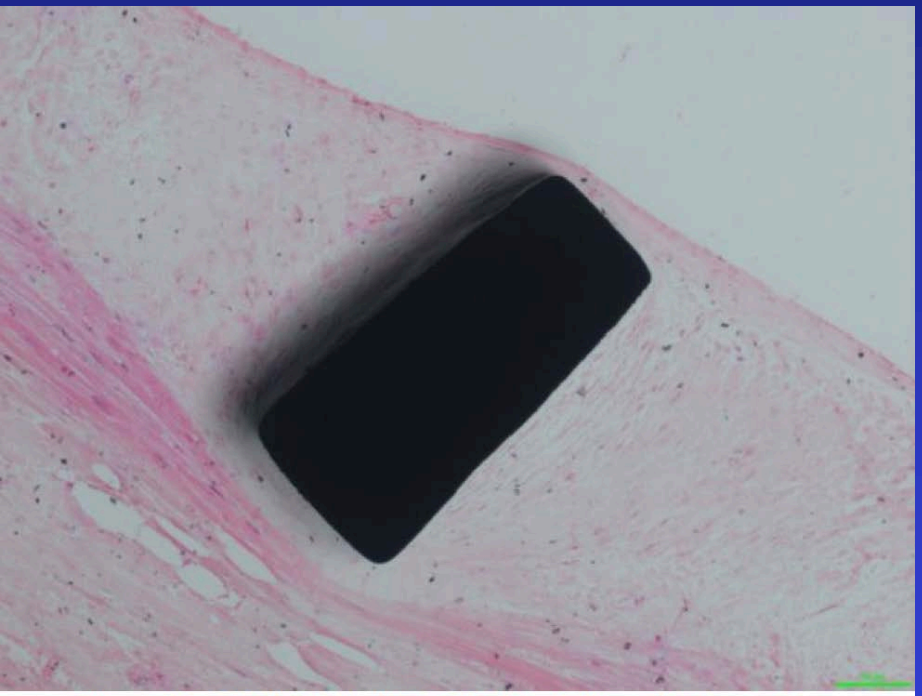
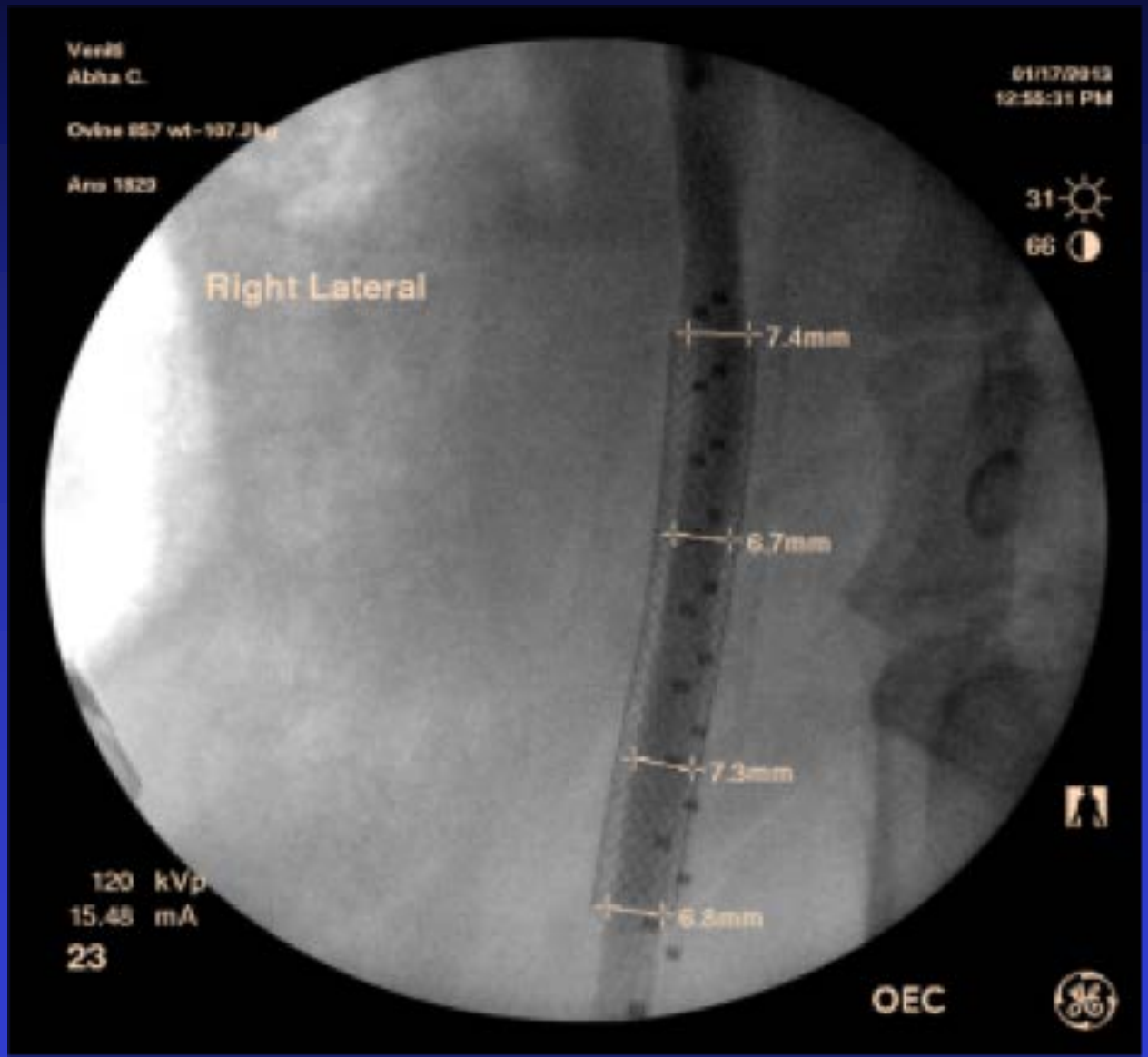


Figure 48. 859 LI-Middle H&E 20X: Strut without inflammation

Thrombus and Injury

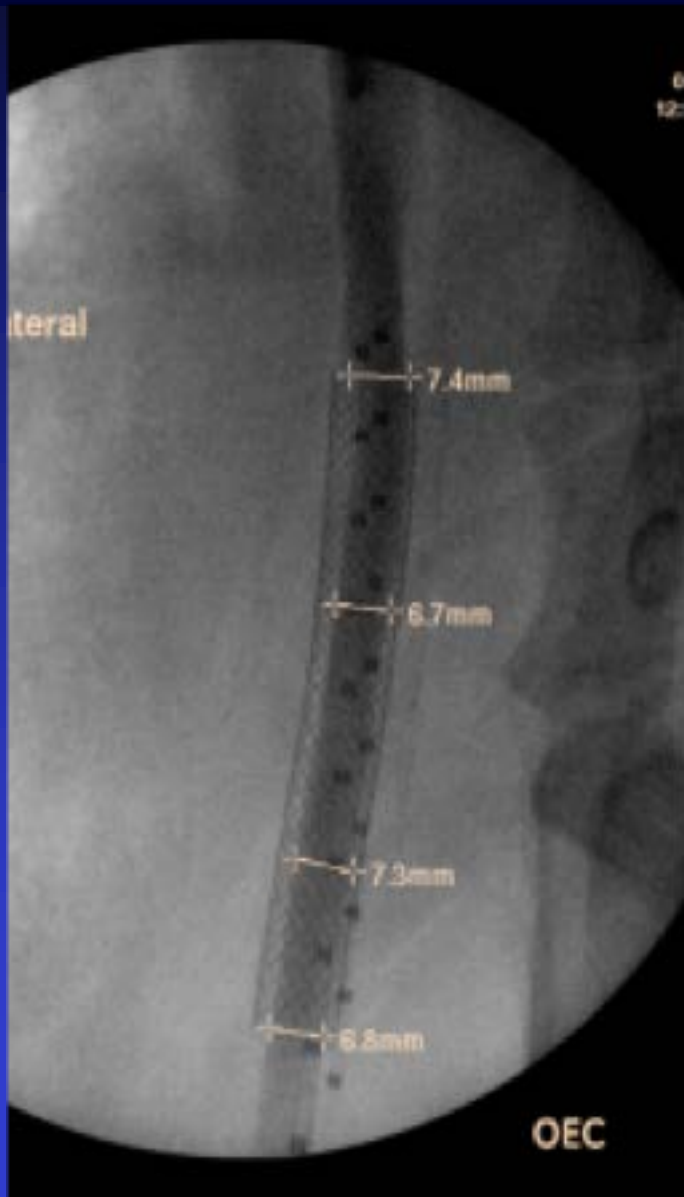
- Small areas of thrombus or fibrin in a few cases in each group
- Some disruption of inner elastic membrane but no more serious vessel injuries noted

Luminal narrowing at 180 days



End result 6 months after stent insertion

- Stent increases diameter of internal elastic lamina of vein relative to strength
- Tissue growth occurs within stent to create a lumen of uniform diameter based on the narrowest segment of the vein



What is this tissue?

- Staining for smooth muscle cells performed
  - Negative
  - BUT

- Overall appearance not c/w SMC hyperplasia but need additional study in new tissue to determine specific comp

Human Tissue

- Dave Williams U Mich
- Biopsies of hyperplastic intra-stent tissue
- Has tissue on over 100 patients
  - Normal D-dimers
  - Organizing thrombus
  - Currently reviewing with cardiovascular pathologist to determine exact composition of material

Stent fracture

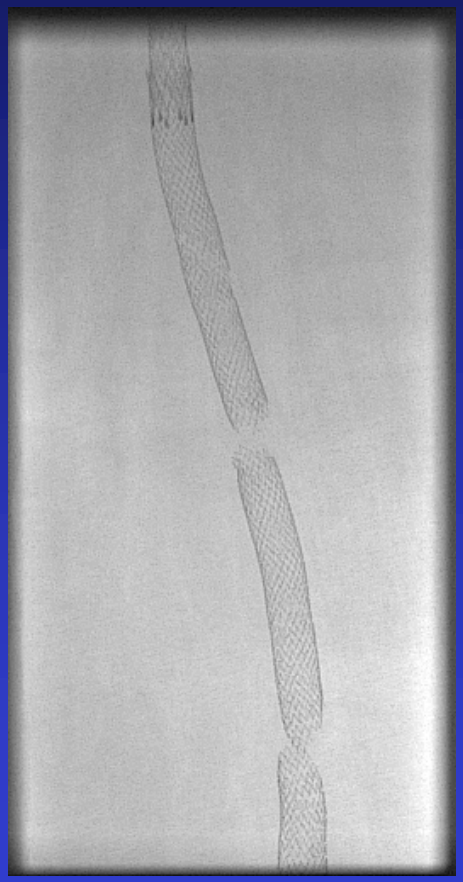
- Reports of fractures of nitinol stents in venous cases
- Highest incidence in stents taken across inguinal ligament to extend down to CFV
- Incidence appears low with SS stents but has been reported with many nitinols including stents under study for FDA approval

What is the importance of stent fracture in the venous system?

- Most have appeared benign with little clinical sequelae (limited follow-up time)
- Is there evidence of increased venous damage in cases with fractured stents?

Pre-Fractured Veniti Venous Stent in Peripheral Vessels in the Ovine Model

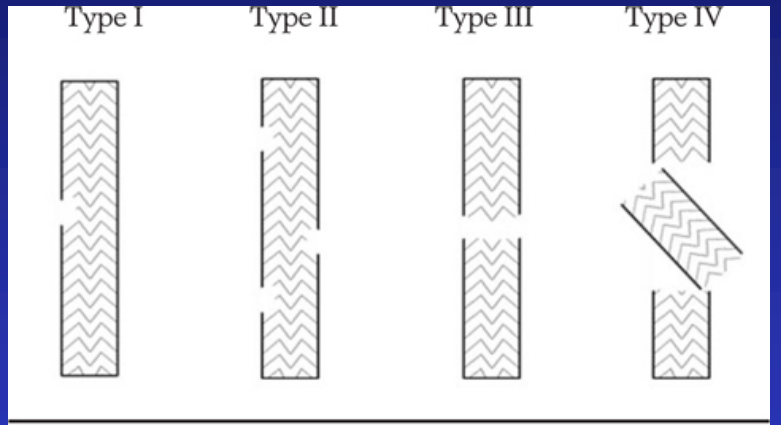
- Pre-fractured stents placed into sheep iliac veins using similar model
- Examined at 30 and 180 days to determine if fractures led to increased intimal damage, thickening or other adverse outcomes



Pre-fracture stent animal study results

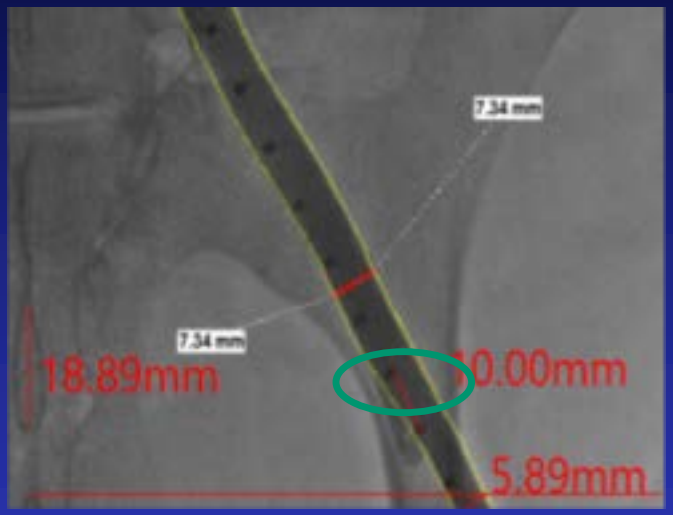
- Non-fractured stents compared to partially fractured and completely fractured stents

- Fractures appeared to have no effect on intimal thickness, inflammation or other measured parameters

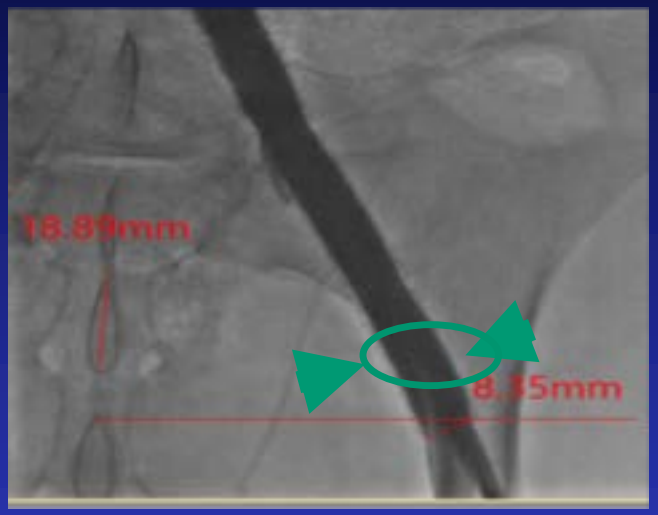


Type I	A single strut fracture only
Type II	Multiple single nitinol stent fractures that can occur at different sites
Type III	Multiple nitinol stent fractures resulting in complete transverse linear fracture, but without stent displacement
Type IV	A complete transverse linear type III fracture with stent displacement.

Relation of Inflow to vessel remodeling (Venogram)



Inflow diameter approximated at Profunda



Narrowest vein diameter at 30/180 days

- The vein diameter appears to reduce over time to be equal to the inflow diameter.
- This effect is more pronounced at 180 days post implant.

Summary

- Stents may develop a thick layer of neo-intima covering
  - Particularly in PTS cases where stents extended down to CFV
  - Exact contents of layer unclear – organizing thrombus?
- Appears to relate to inflow vessel size and maybe flow
- Relevance of stent fracture unclear at this time

So what does this all mean?

- Maximize inflow into stented segments to minimize risk of failure over time
- Patients with femoral obstruction and iliac at highest risk for failure