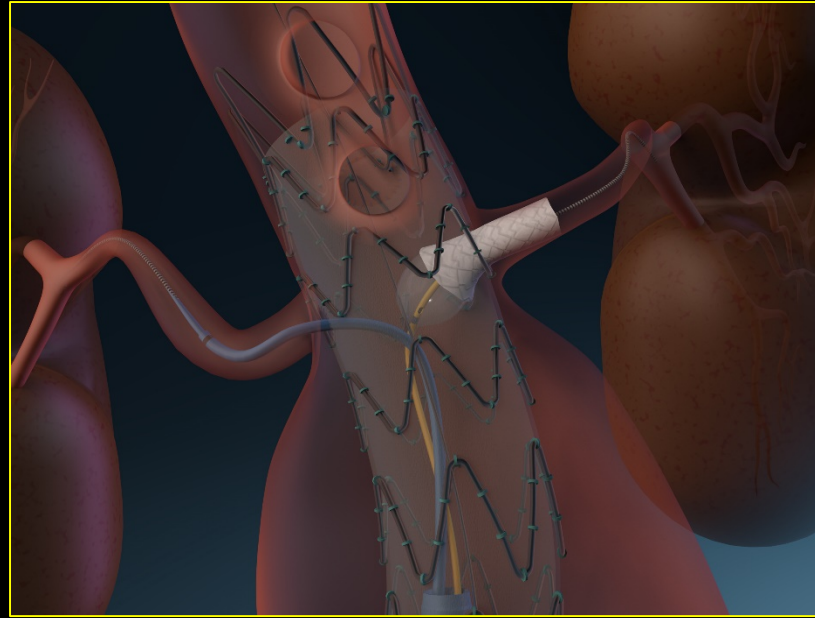




Clinical Perspective: It's The Patient's Fault!



Benjamin W. Starnes MD

Alexander Whitehill Clowes MD Endowed Chair of Vascular Surgery

Professor of Surgery

Chief, Division of Vascular Surgery

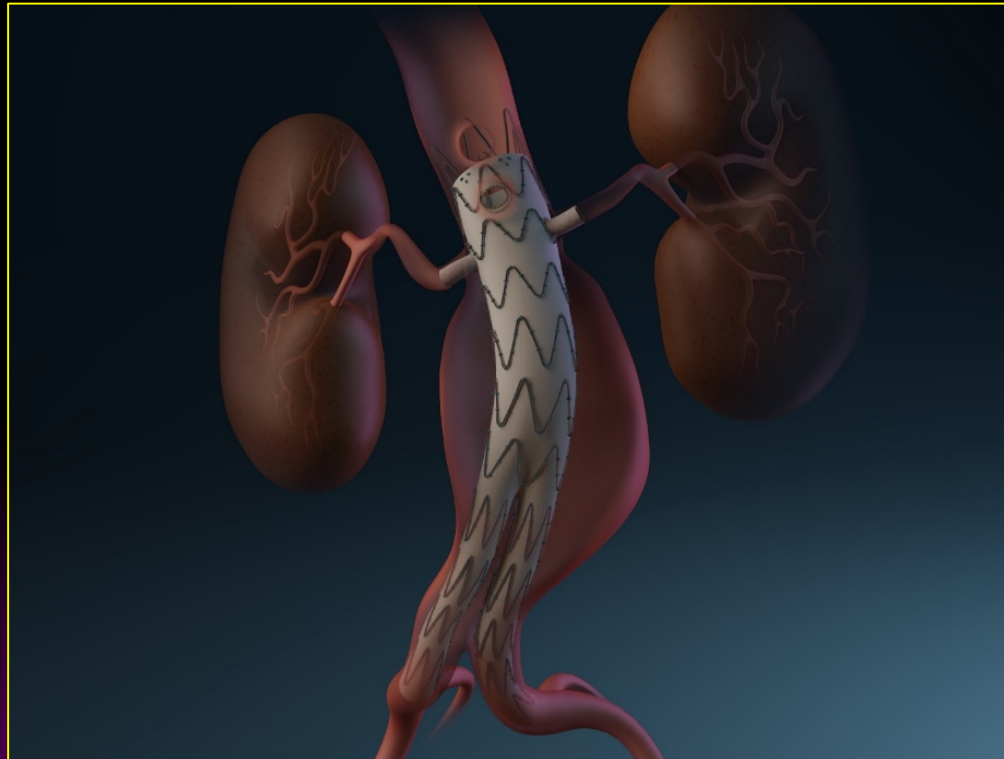
University of Washington

Seattle, WA



Disclosures

- AORTICA CORPORATION: Co-Founder





What to Talk About in 7 minutes



- Migration of Aortic Devices
- Component Separation
- When?
- Why?
- How Should They be Managed?
- What Are Risks and Benefits of 2nd Intervention?



Matt's Guidance...



- Role of Disease Progression or Morphology Changes in The Patient's Anatomy



Migration



- What do we do to prevent migration?
 - Oversize the Device
 - Active Fixation- Barbs / Anchors
 - Maximize Seal Zone Length (eSZL)



“Effective” Seal Zone Length



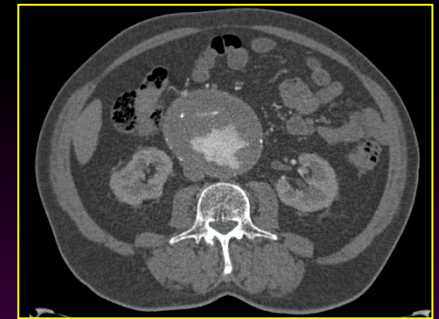
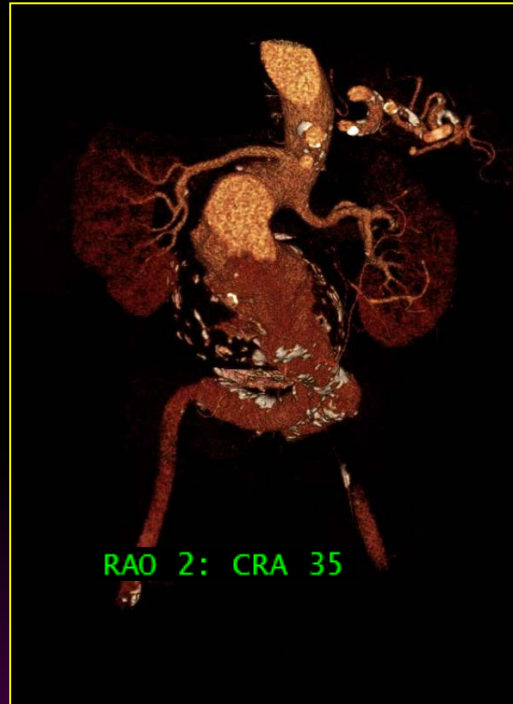
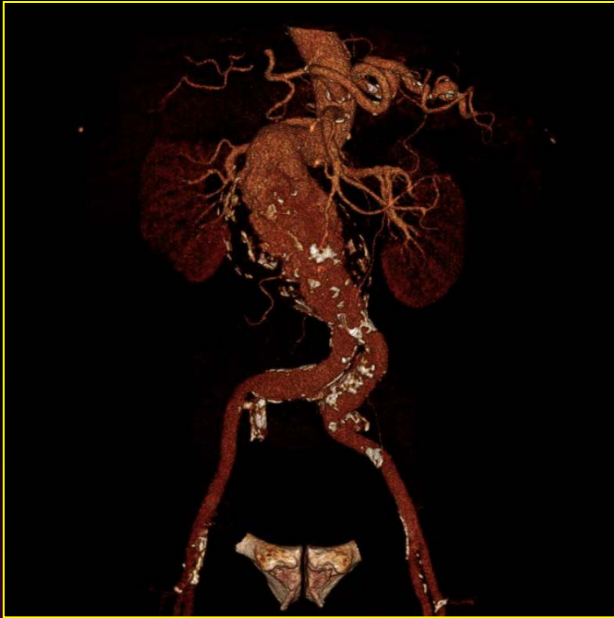
$$eSZL = cgSZL + irNL$$

- $eSZL$ = Effective Seal Zone Length
- $cgSZL$ = Circumferential Graft Seal Zone Length
- $irNL$ = Healthy Infra-Renal Neck Length



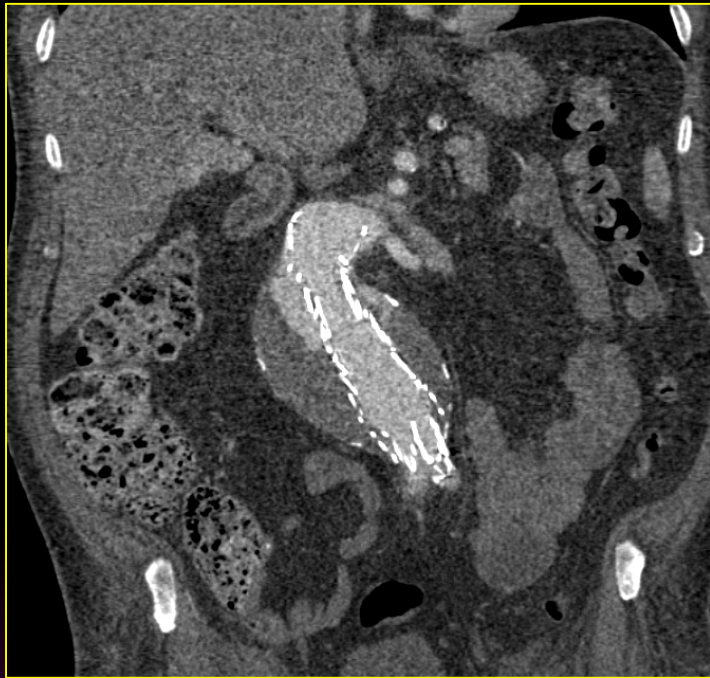
Examples of Migrated Devices

- 73 M with a 10 cm AAA





- 36x113 Zenith bifurcated main body
- 37x10 Gore TAG proximal extension
- 36x127 Zenith proximal extension
- 24x39 ipsilateral (right) limb
- 24x56 contralateral (left) limb







My Experience FEVAR

- Migration doesn't occur when eSZL is maximized and seal zone is healthy
- In our IDE we have seen no device migrations (>5mm?) in 114 pts.
- I *have* seen device migrations in ZFEN patients treated OIFU



PS-IDE Midterm Results: Cohort 1



- FDA approved study of physician modification of endovascular grafts to treat patients with juxtarenal AAA
 - High anatomical complexity >> not candidates for standard EVAR
 - High surgical risk >> not candidates for elective open repair (ASA ≥ 3)
 - Typical configuration: 2 Renal and 1 SMA fenestration
 - First 60 patients attempted in Cohort 1: manual planning

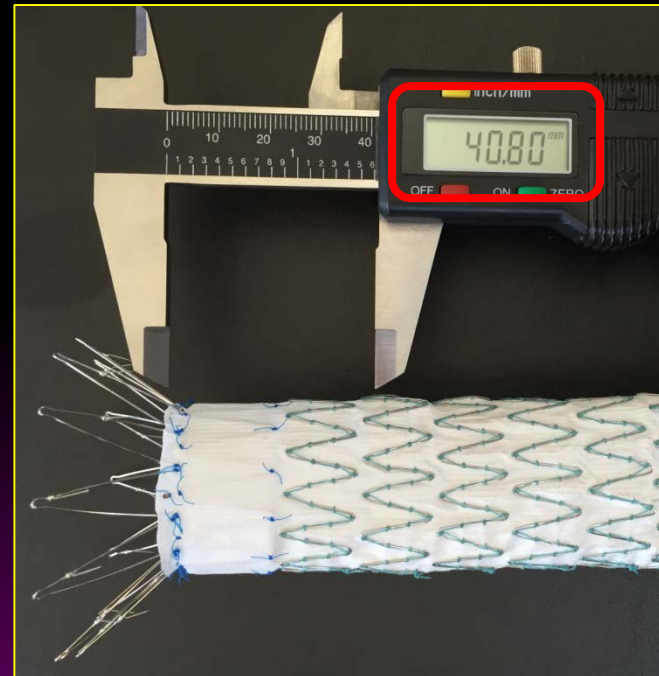
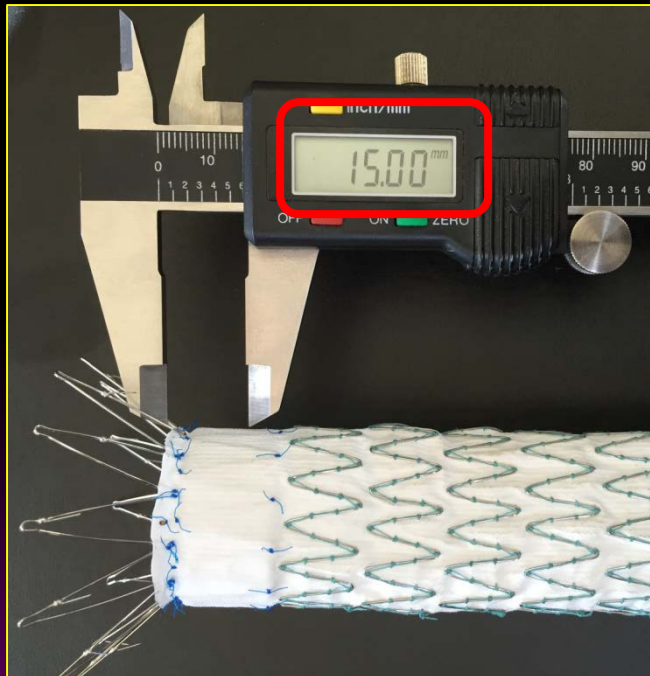
MAEs (30d)	N (%)	Criteria	N (%)
Death	3 / (5.1)	Technical Success	57/60 (95)
Myocardial Infarction	3 / (5.1)	Freedom from Migration at 12 mo	44/44 (100)
Stroke	1 / (1.7)	Freedom from Rupture or Conversion at 12 mo	44/44 (100)
Renal Failure	1 / (1.7)	Freedom from Type 1 or 3 Endoleak at 12 mo	42/44 (95.5)
Respiratory Failure	4 / (6.8)	Freedom from Sac Enlargement at 12 mo	43/44 (97.7)
Paralysis	1 / (1.7)		
Bowel Ischemia	1 / (1.7)		
Blood Loss ≥ 1000 ml	1 / (1.7)		

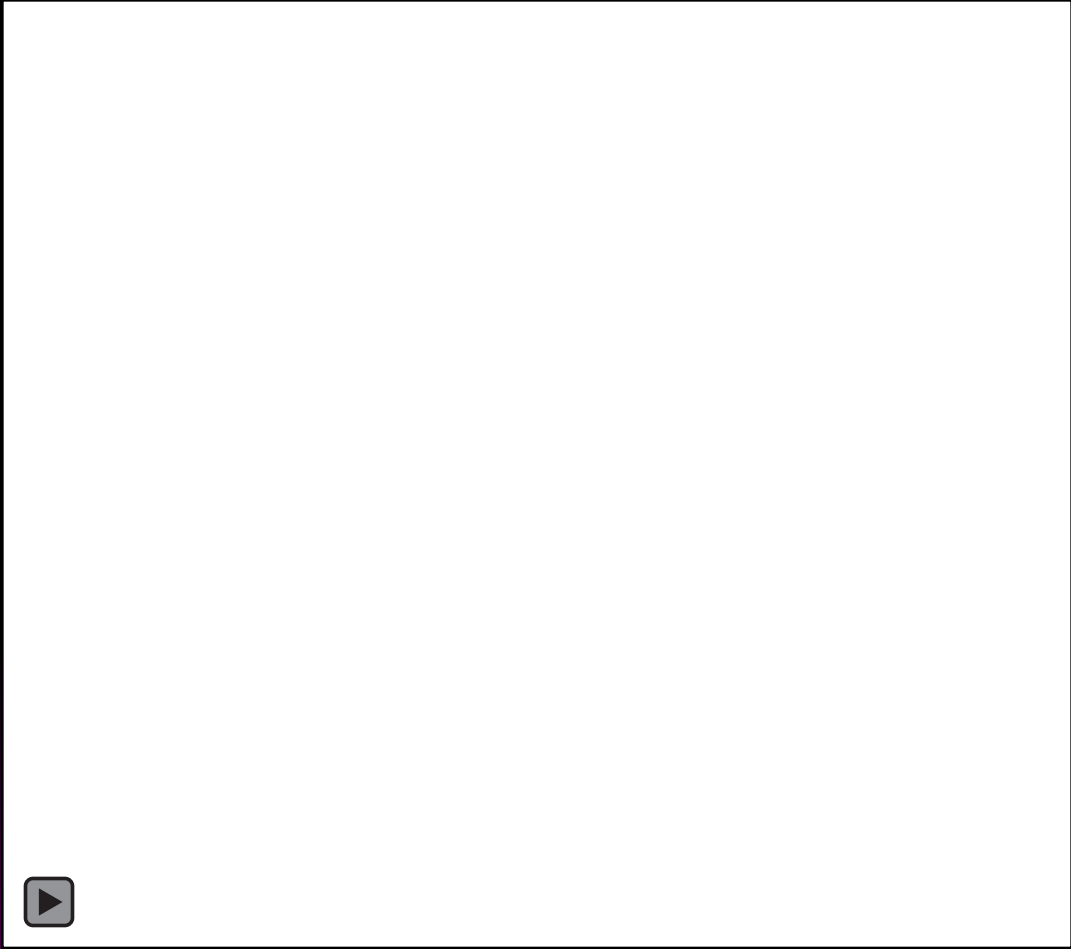
*94.1% of patients met the primary endpoint at 12 months

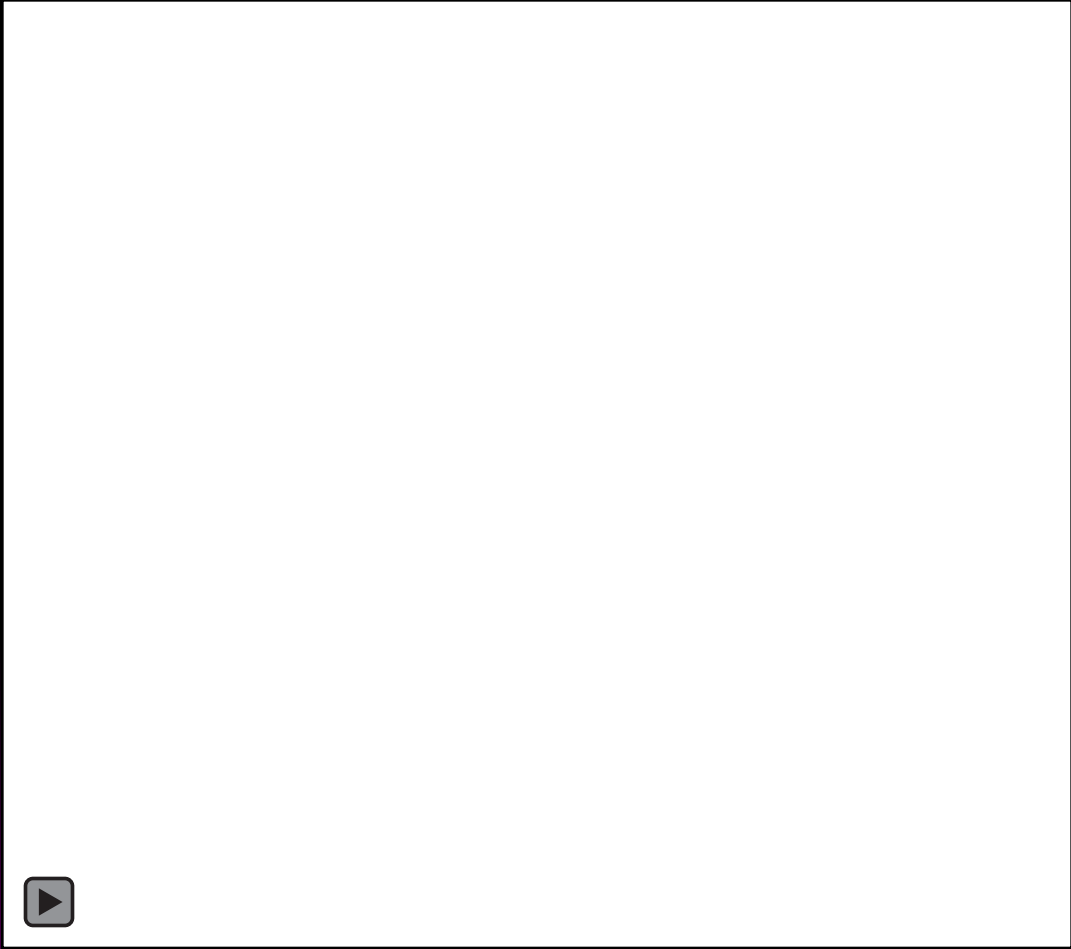
*11.9% of patients experienced MAE within 30 days

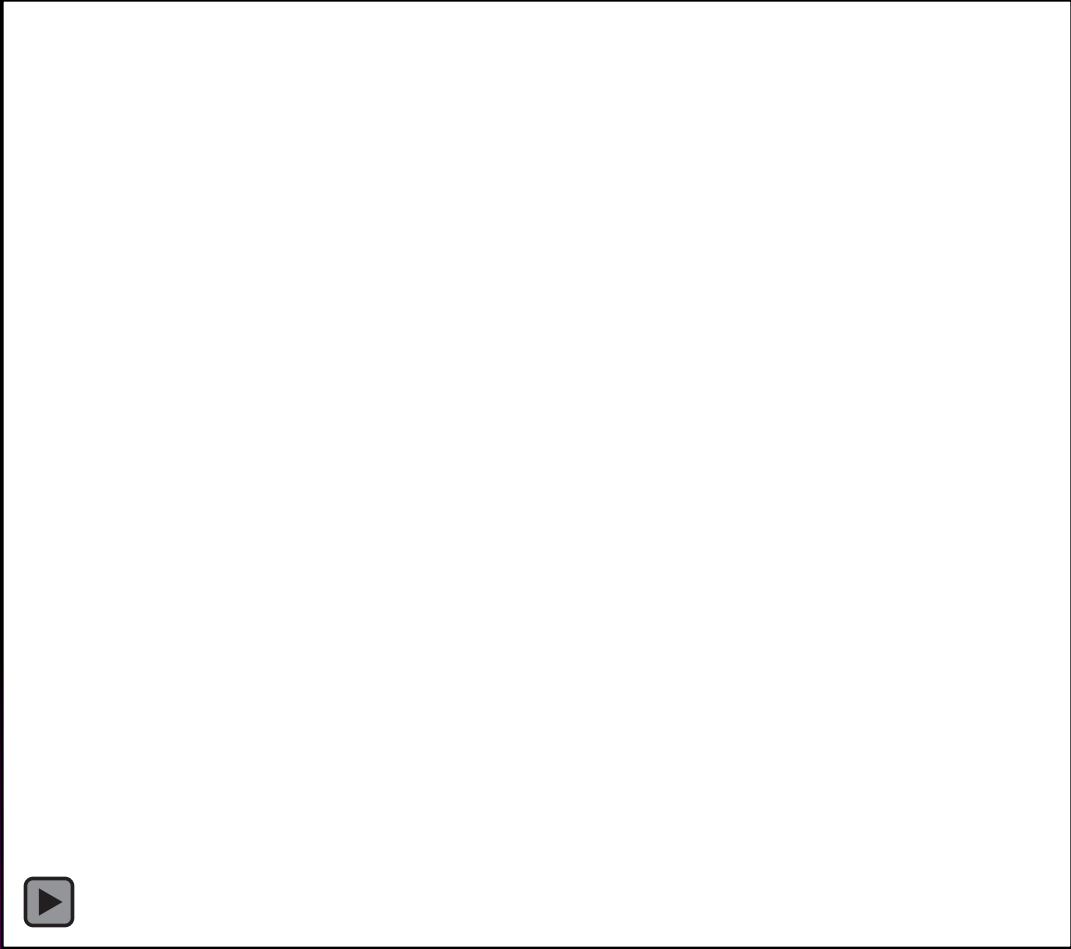
Seal Zone Length

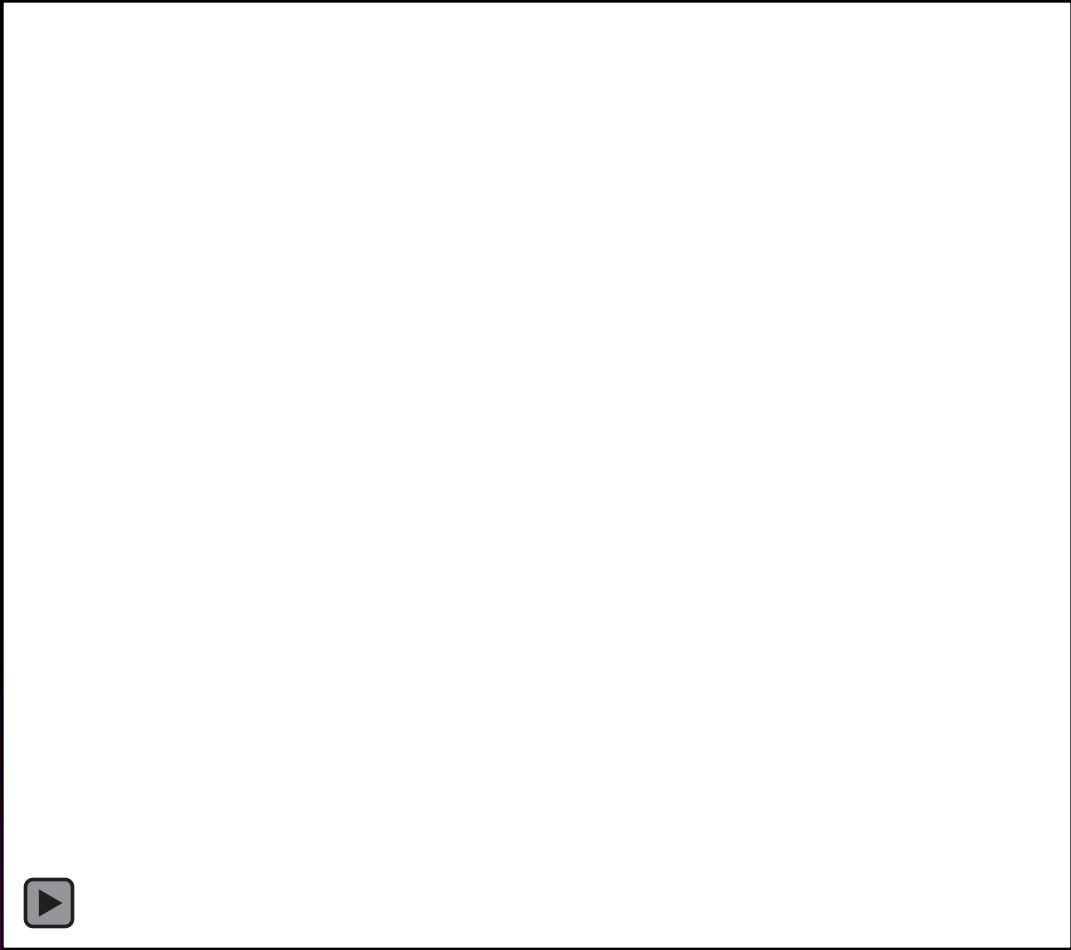
Measurement	Mean / (Range)
Maximum Aneurysm Diameter	65.9 mm +/- 12.2 / (49 - 104mm)
Proximal Aortic Neck Length	5.4 mm +/- 3.2 / (2 - 13mm)
Proximal Seal Zone Length	40.8 mm +/- 6.7 (18.9-72mm)

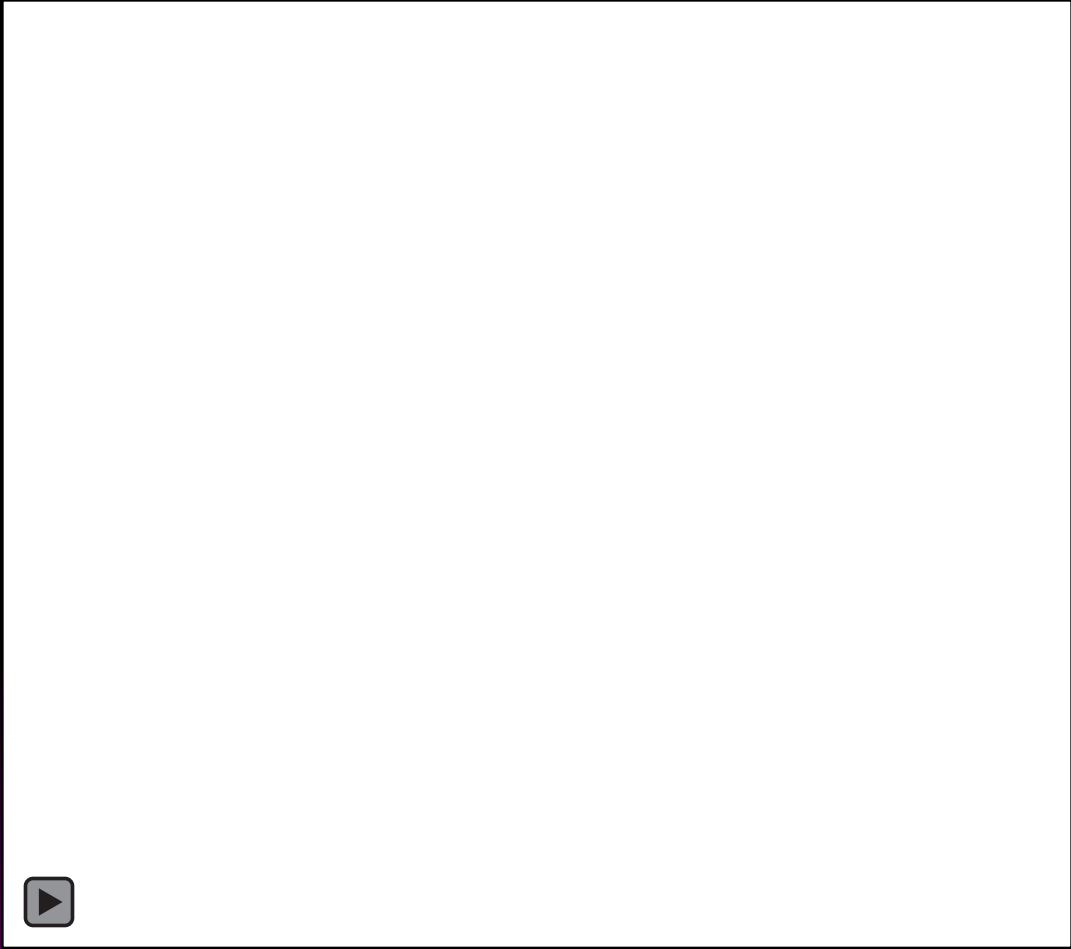
















Secondary Intervention?





Results

- 92 subjects treated with FEVAR between April, 2011 and December, 2016
- 21 Secondary Interventions in 16 subjects (17.4%)
 - 8 Access related 8.7%
 - 7 Branch related 7.6%
 - 6 Endoleak related 6.5%
 - 1 Both Branch and Endoleak related 1.1%



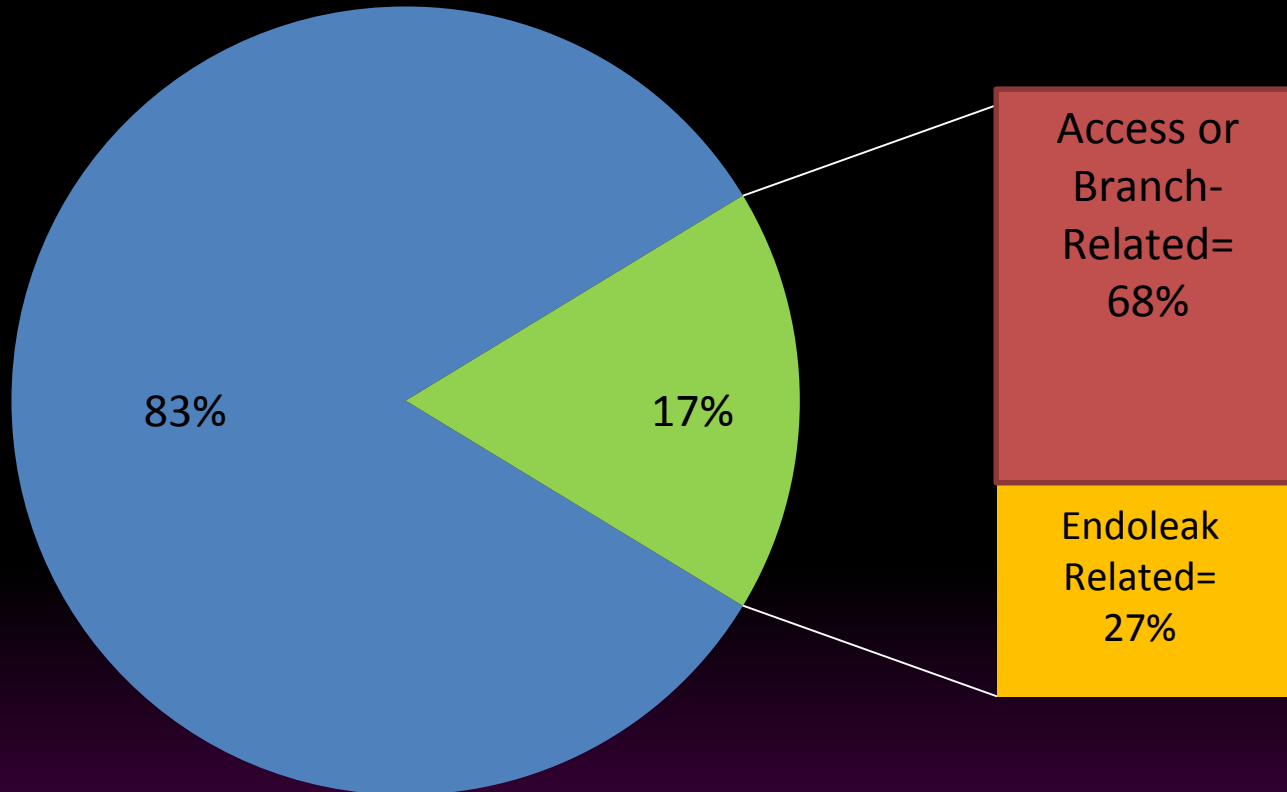
Access



- 8 Access Related Interventions
 - 6 CFA Pseudoaneurysms
 - Days (4,39,43,88,1407,1866)
 - 1 CFA, SFA Thrombosis
 - Day 90
 - I Common Iliac Artery Stenosis
 - Day 259



FEVAR- Secondary Interventions

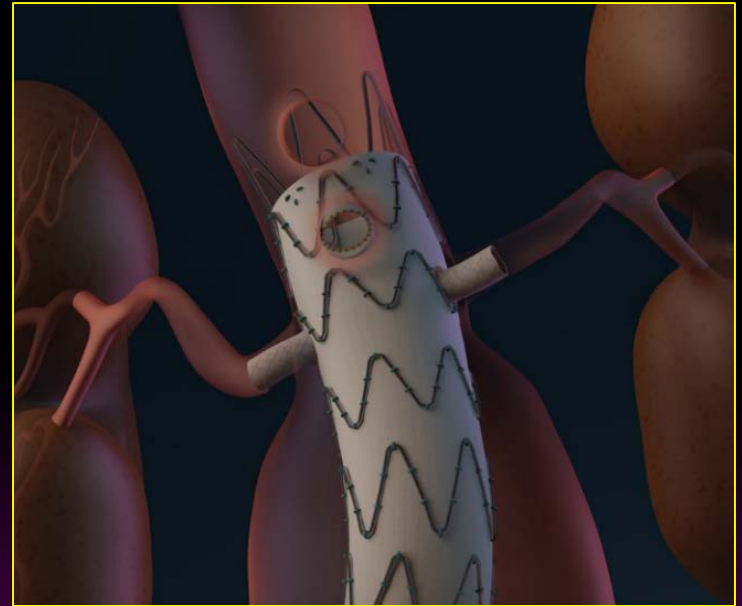


Starnes et al, JVS In Press- Presented at VAM 2017



Branch Vessels

- 242 Fenestrations
 - 7 Branch Vessel Interventions (2.9%)
 - 1 Celiac Stenosis (d-1323)
 - 1 SMA Stenosis (d-376)
 - 2 RA Stenoses (ds-329 / 409)
 - 1 Untreated RA (d-7)
 - 2 Renal Stent Separations (ds-225 / 397)



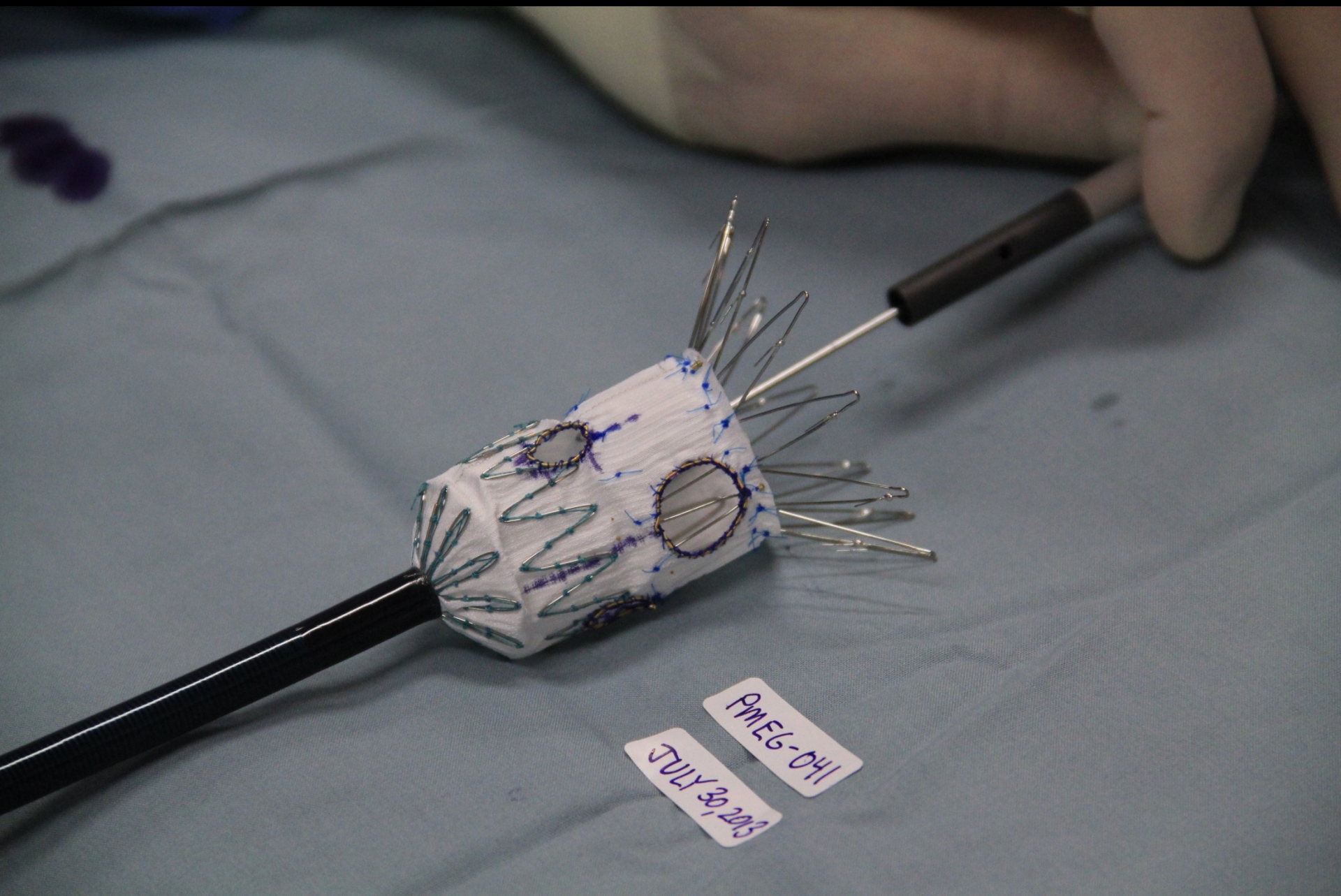
Starnes et al, JVS In Press- Presented at VAM 2017



My First Renal Stent Fracture



- August 10th 2017



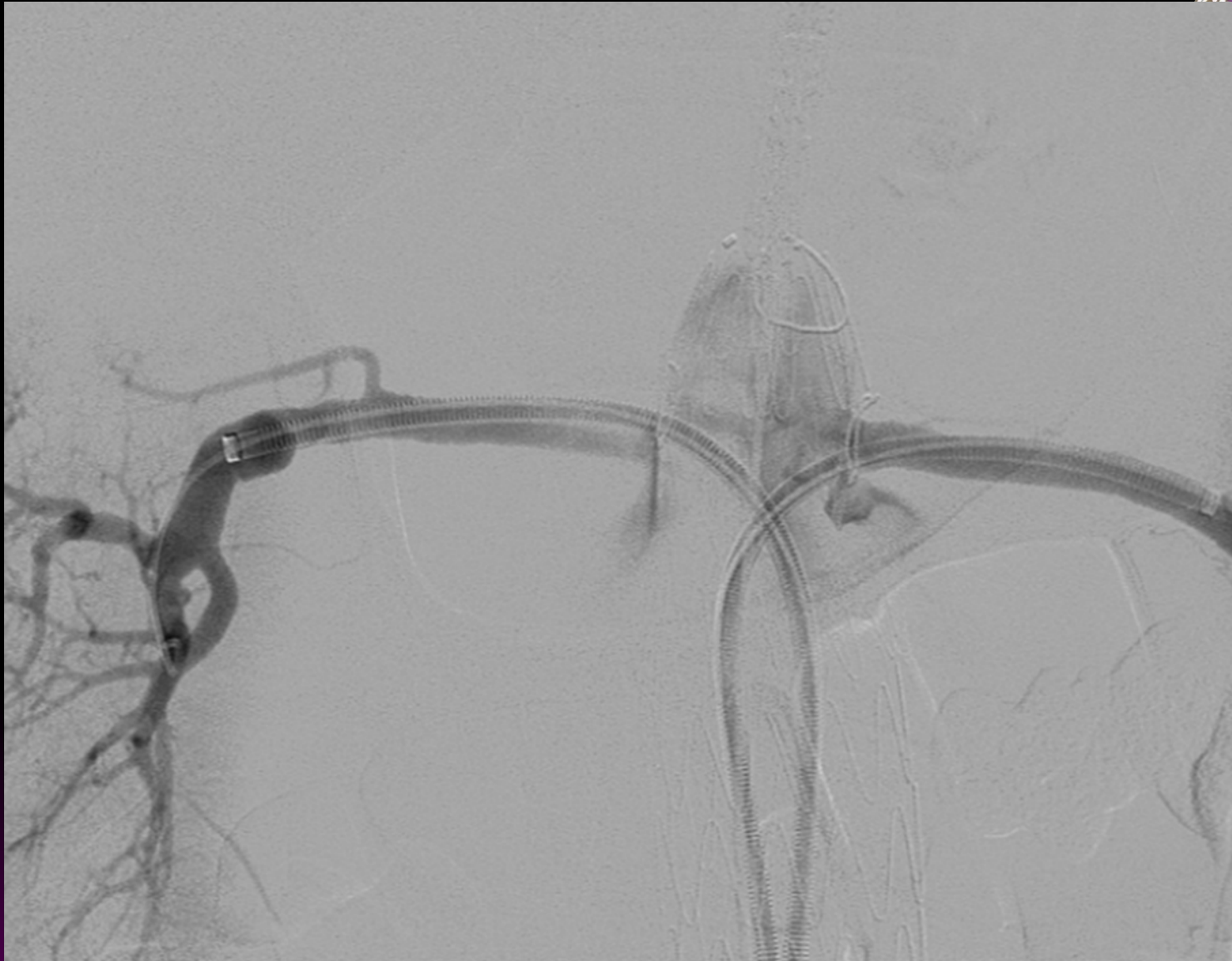
PMEG-041
JULY 30, 2013



Device Specs

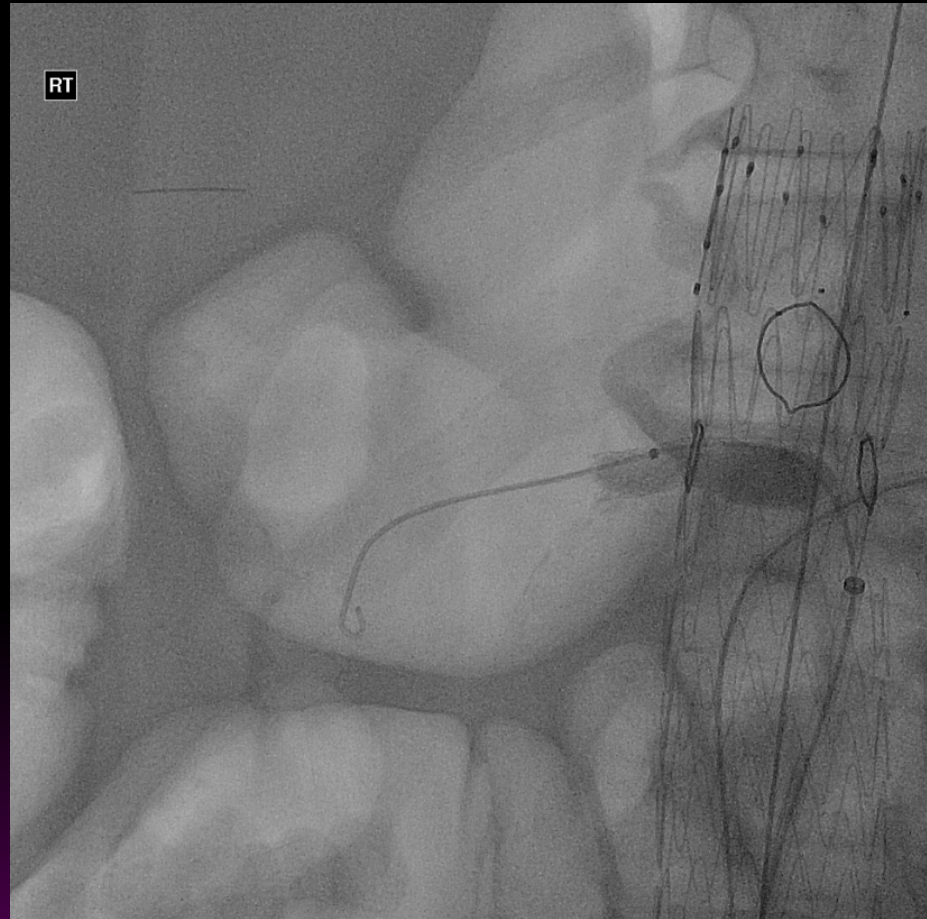
- Celiac: 12:30
- SMA: 12:15 (15°) 3.6 – 15.8 mm
- RRA: 09:30 (-75°) 21.8– 28.8 mm
- LRA: 02:30 (75°) 22.7 – 30.5 mm

- **R** Arc Length: 17.8mm
- **L** Arc Length: 14.8mm
- D1= 26mm (30 x 140 implant)





Original Stenting with Flare





Bench Top Flaring iCAST



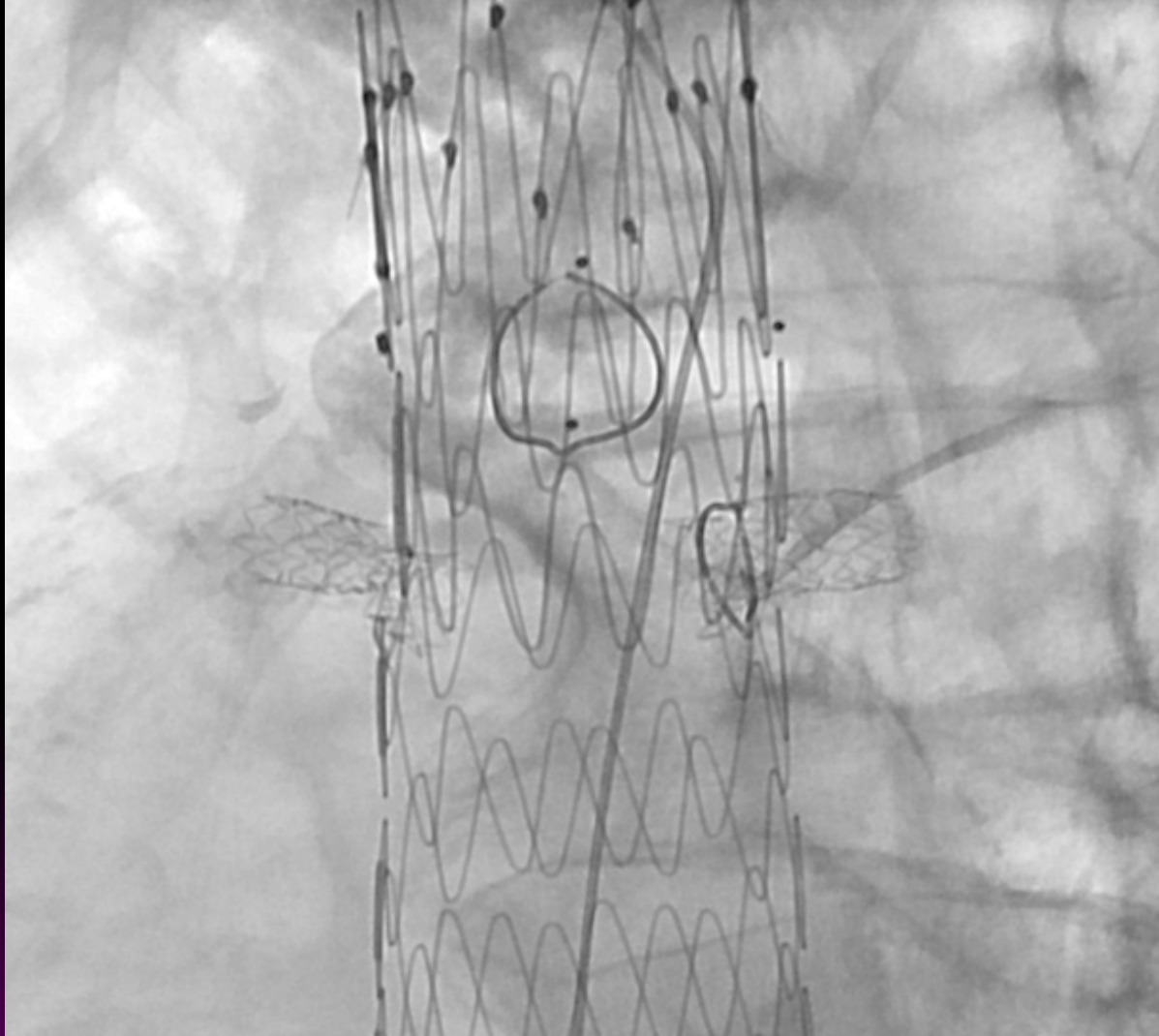


One month-D=28mm



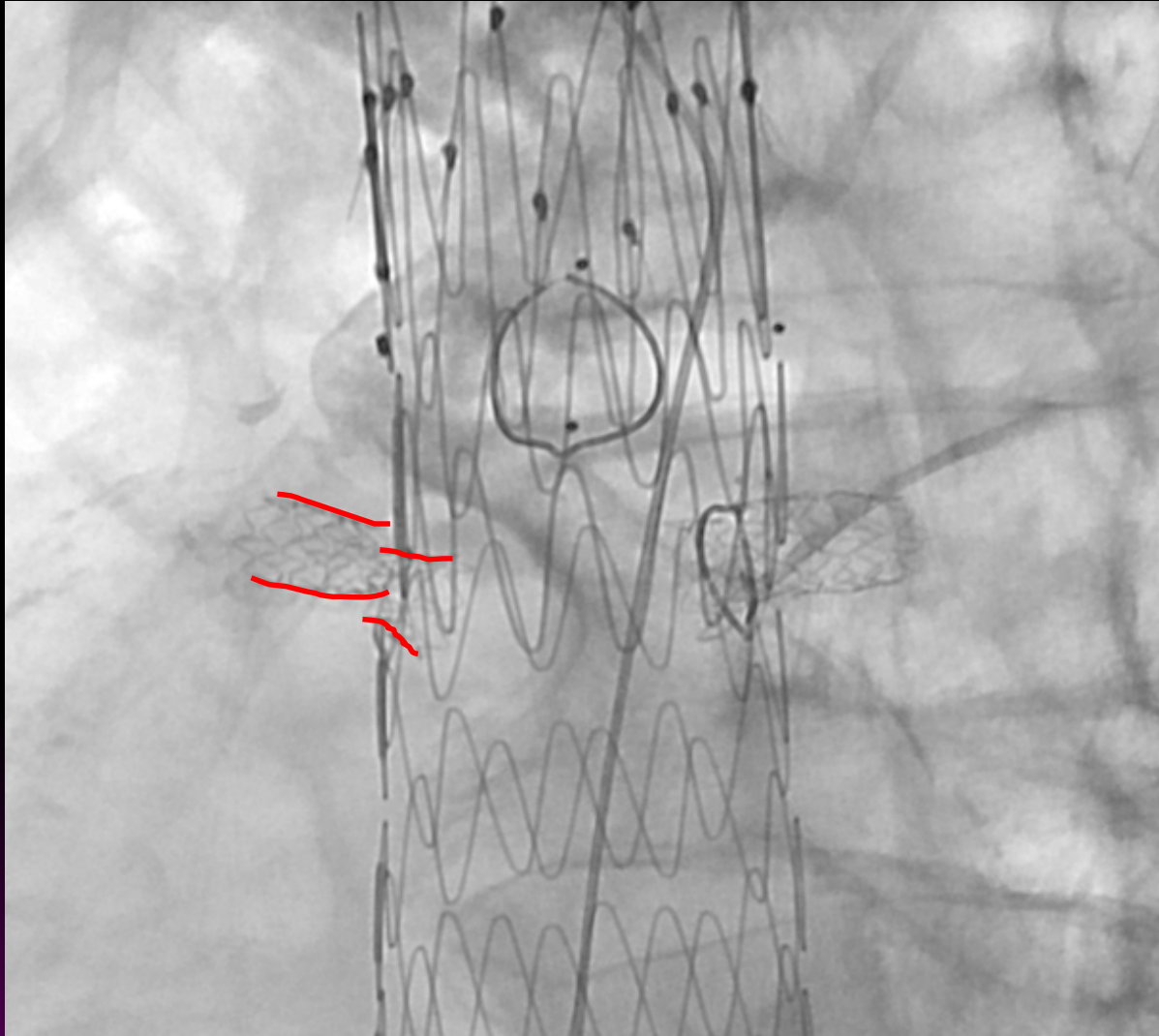


Stent Fracture at 4 years



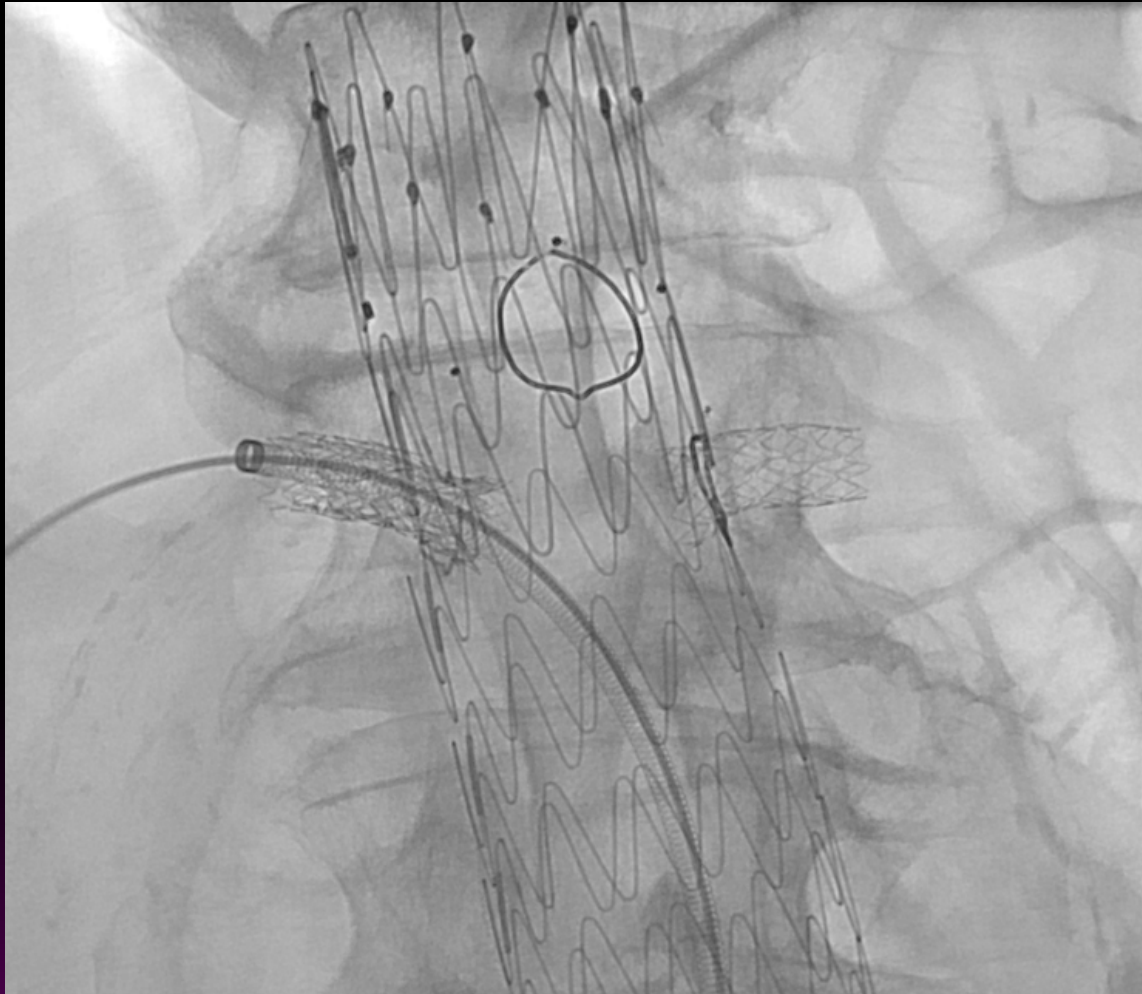


Stent Fracture



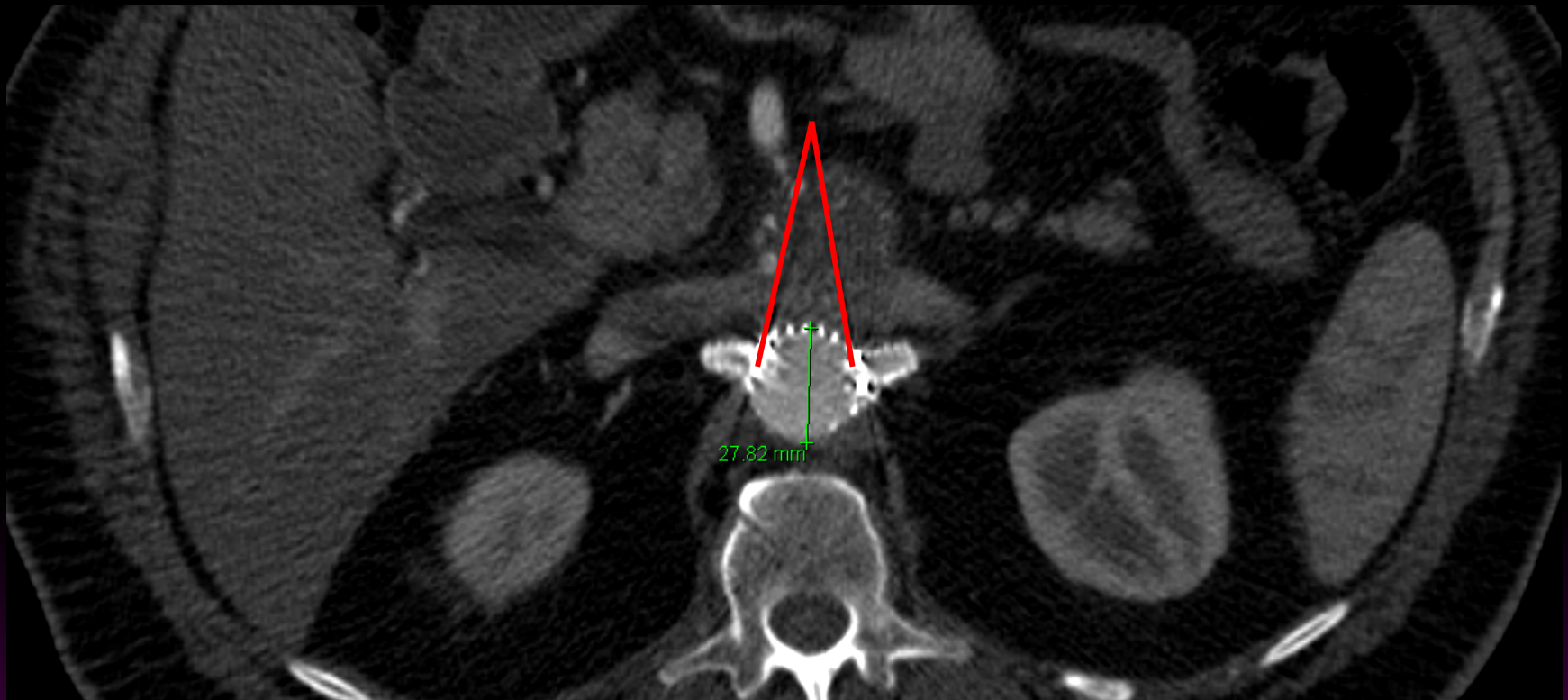


Reintervention





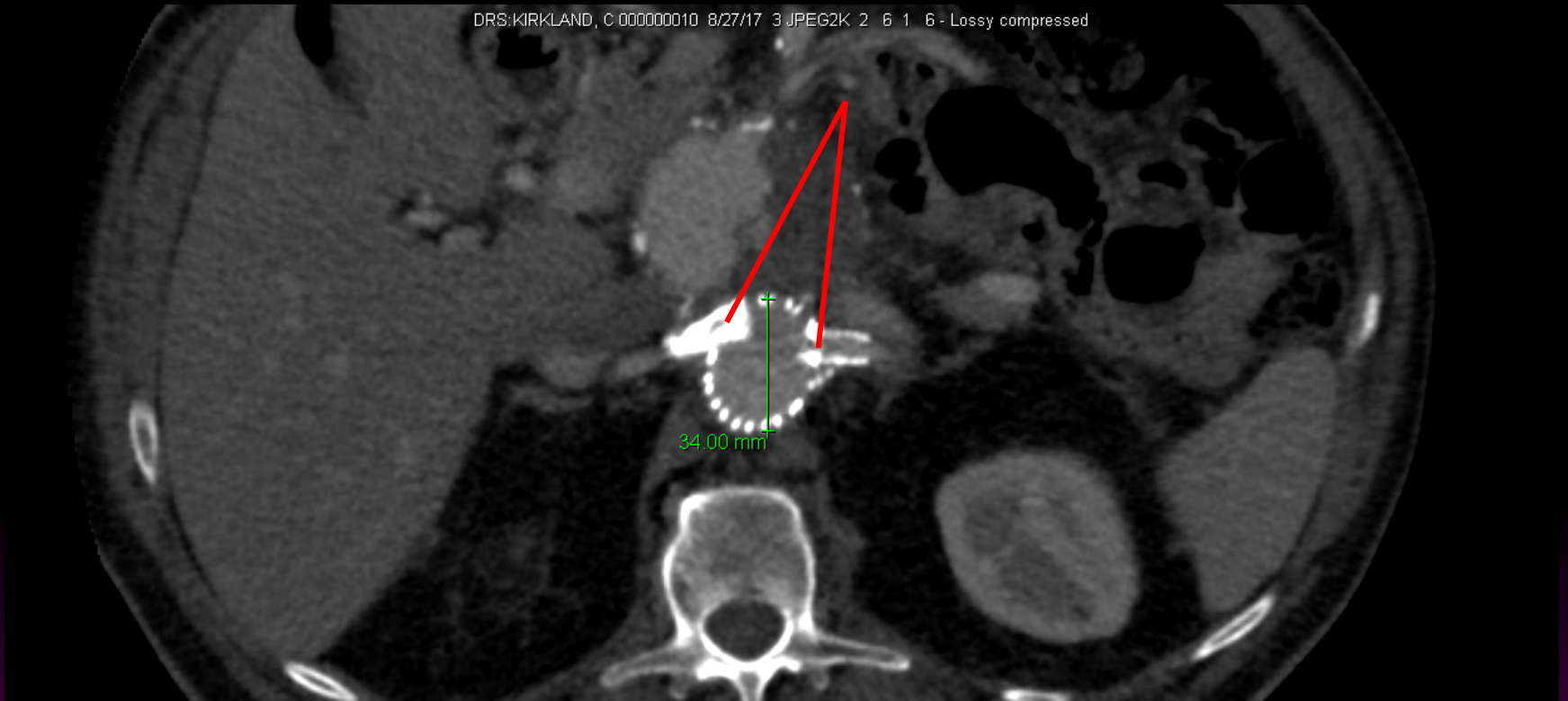
One month-D=28mm

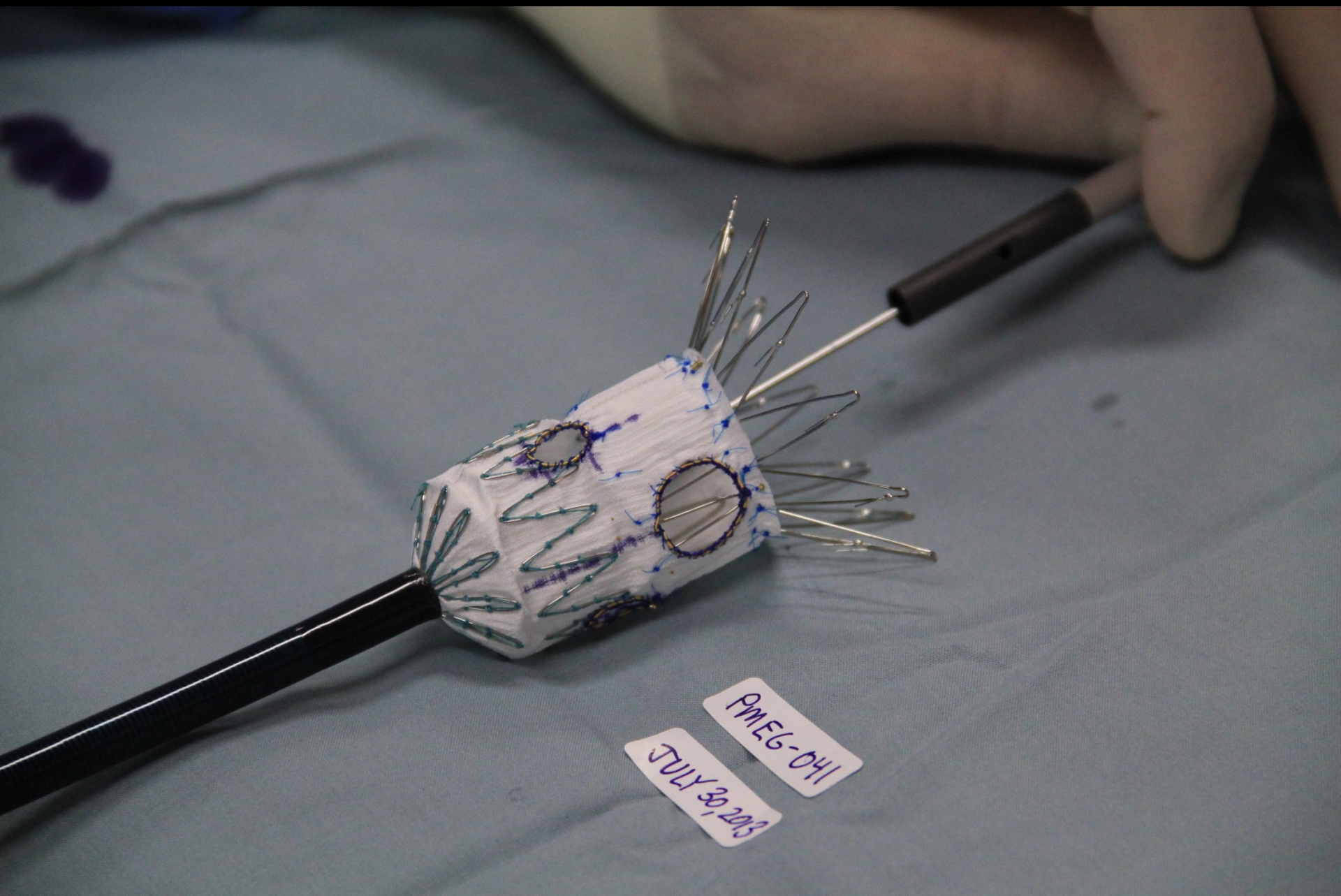




4 yrs-D=34mm

DRS:KIRKLAND, C 000000010 8/27/17 3 JPEG2K 2 6 1 6 - Lossy compressed



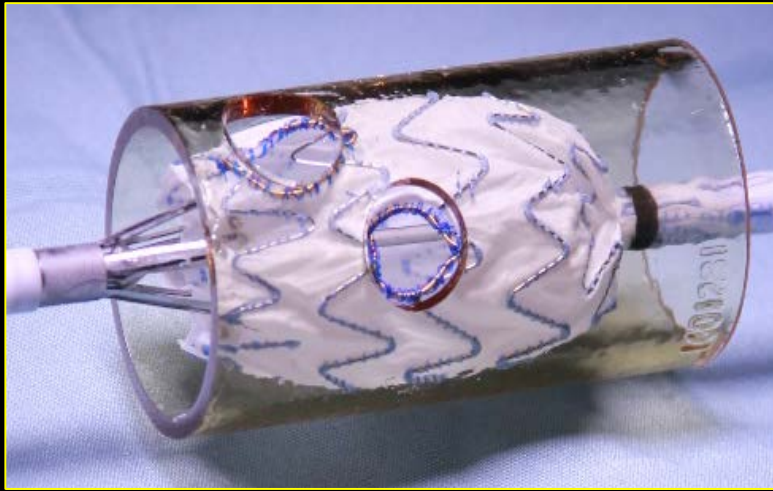


PMEG-041
JULY 30, 2013



Methods

- Confirm location of fenestrations



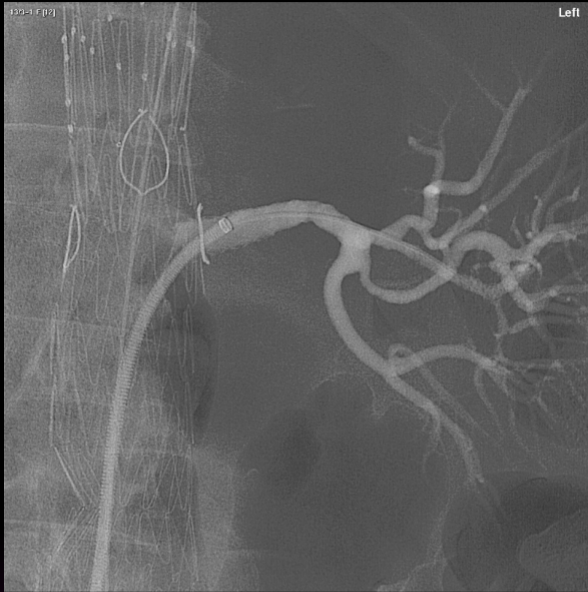


Component Separation

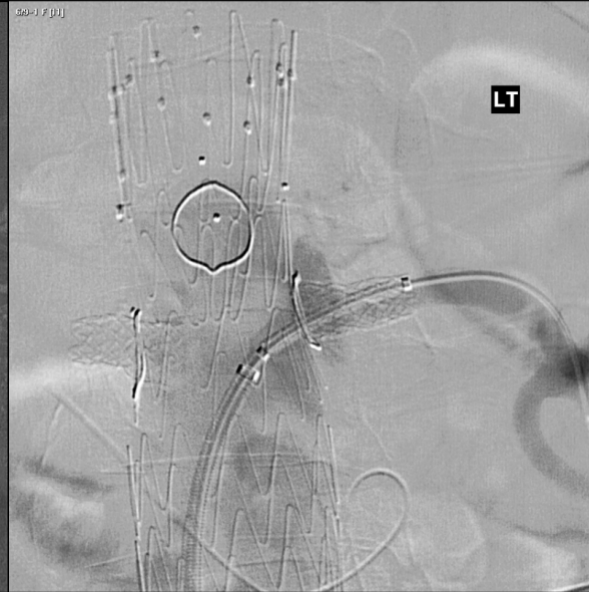




Subject 003



Index Procedure



6 Months



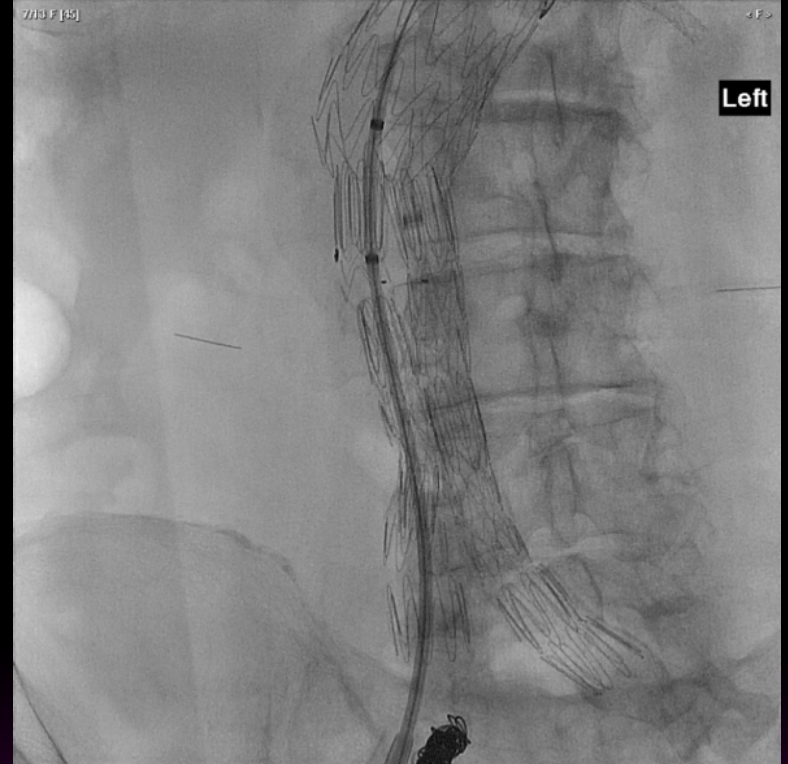
Secondary Intervention



Subject 013



3 Years



Secondary Intervention



Conclusions

- FEVAR is a Durable Alternative with Low Rates of Device Migration
- Branch vessel patency after FEVAR is Excellent. (>97%)
- Access-related complications are *Infrequent* but still the most common after FEVAR.
- We can't blame the patient- In my opinion it is almost always the physician's fault with regard to patient selection and planning.

