

EVAR Planning, Stenting, and Follow-up

John R. Laird
Professor of Medicine
Medical Director of the Vascular Center
UC Davis Medical Center

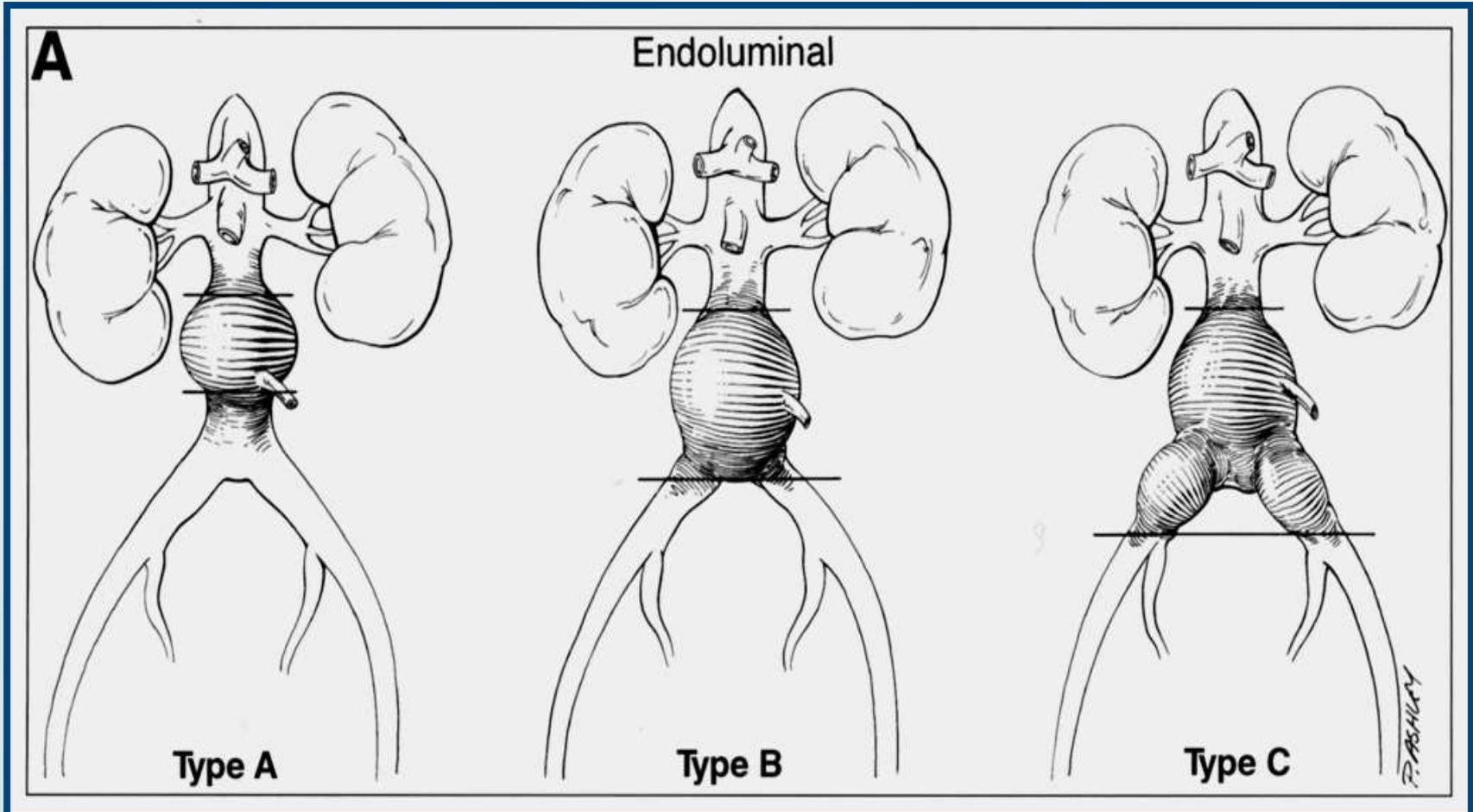
Disclosure Statement of Financial Interest

- Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- | <u>Affiliation/Financial Relationship</u> | <u>Company</u> |
|---|---|
| ■ Consulting Fees/Honoraria | Boston Scientific, Medtronic, Abbott, Covidien, Bard Peripheral Vascular, Volcano |
| ■ Research Support | Atrium Medical, WL Gore |
| ■ Scientific Advisory board/stock options | AngioScore, Angioslide, NexGen, Reflow, Endoluminal Sciences, Syntervention |

Board Member VIVA Physicians

Aneurysm Morphology



Endovascular Stent-Grafting *Technique*

Critical Dimensions:

- Diameter and length of proximal neck (proximal attachment site)
- Diameter and length of the common iliac arteries (distal attachment site)
- Diameter of external iliac and common femoral arteries (for device passage)
- Length from lowest renal artery to aortic bifurcation and right and left iliac bifurcation (device selection)

Endovascular Stent-Grafting

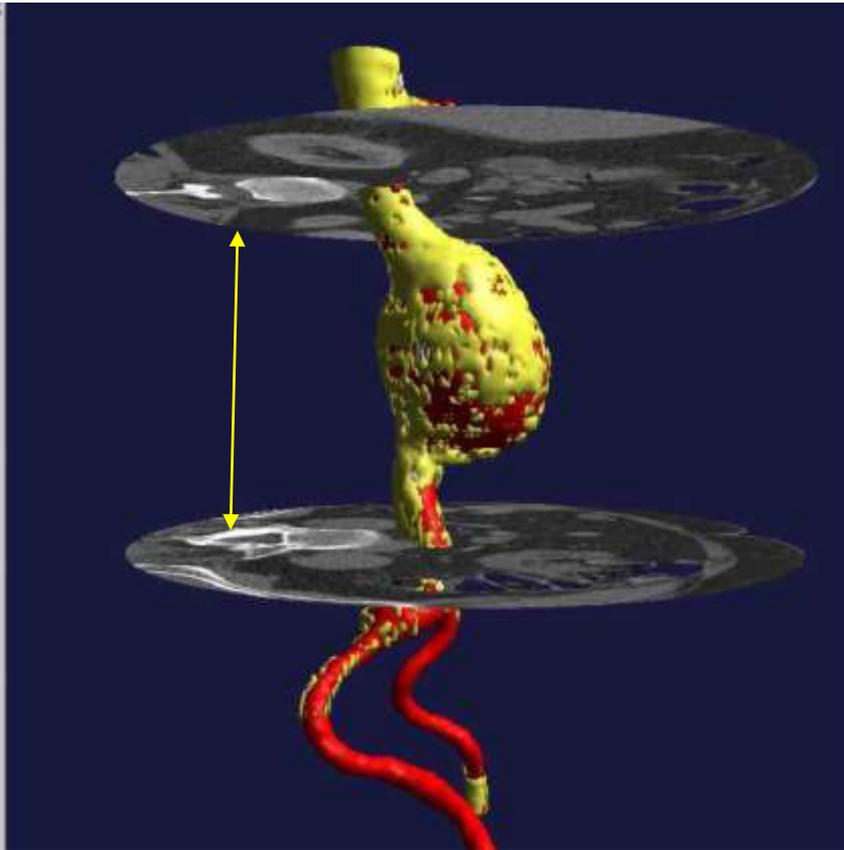
Other Important Factors

- Quality of the infrarenal neck
 - Reverse taper
 - Presence of thrombus or calcification
 - Angulation
- Tortuosity and calcification of the iliac arteries (device delivery)
- Size and amount of disease in common femoral arteries (suitability for percutaneous access)

Pre-Procedure Planning

- Good quality CTA of abdomen and pelvis with thin cuts
- 3-D reconstruction for precise, center-line measurements of diameter and length:
 - M2S Program
 - TeraRecon, etc
- Device specific measurements and device sizing (Virtual Graft simulation)

Length Measurements



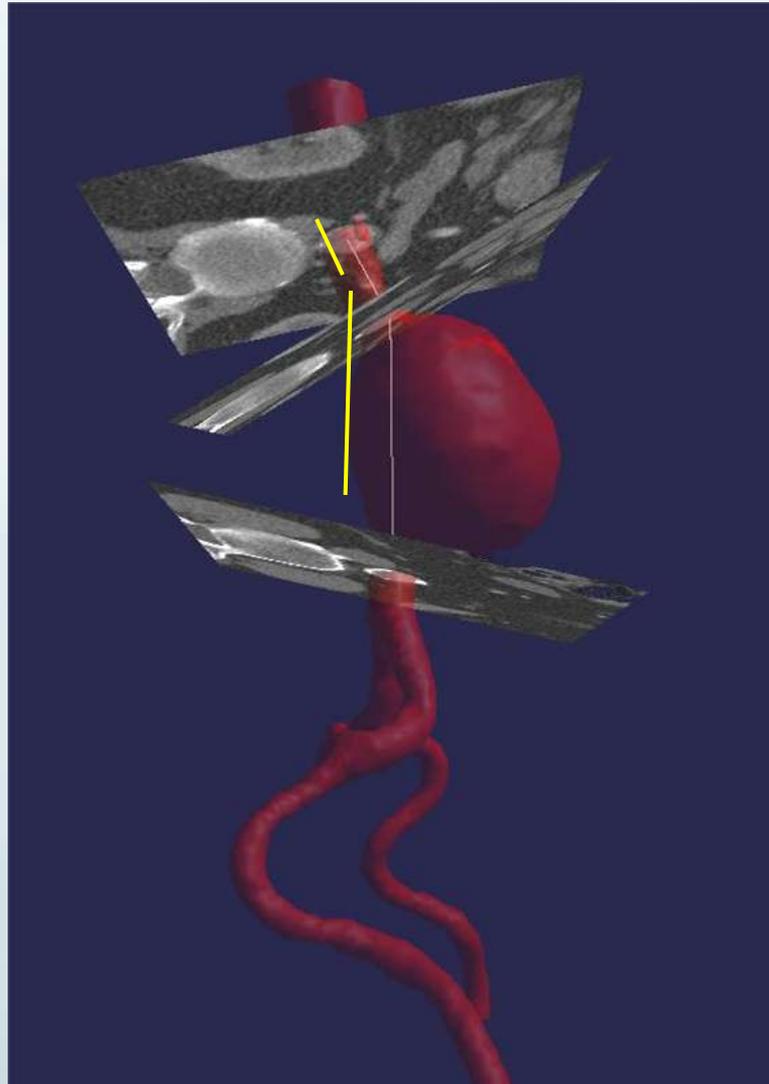
Standard length measurements from 2D axial slices do not account for vessel tortuosity



"Centerline" length measurements accurately define the vessel length

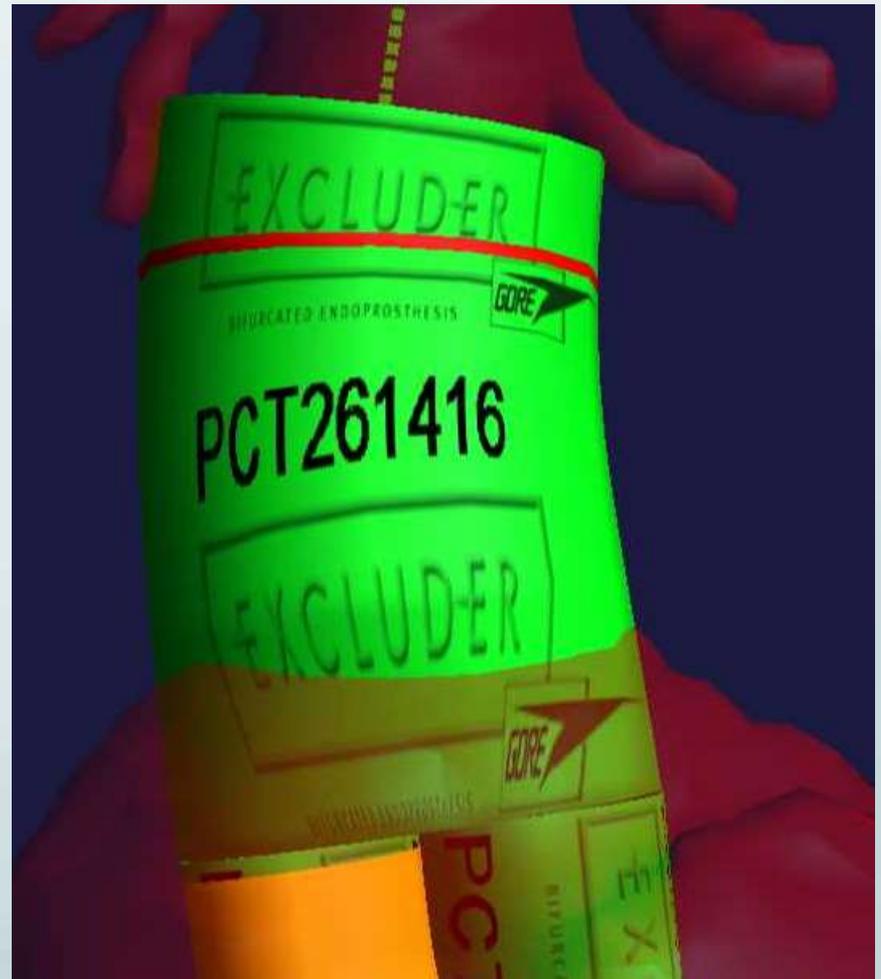
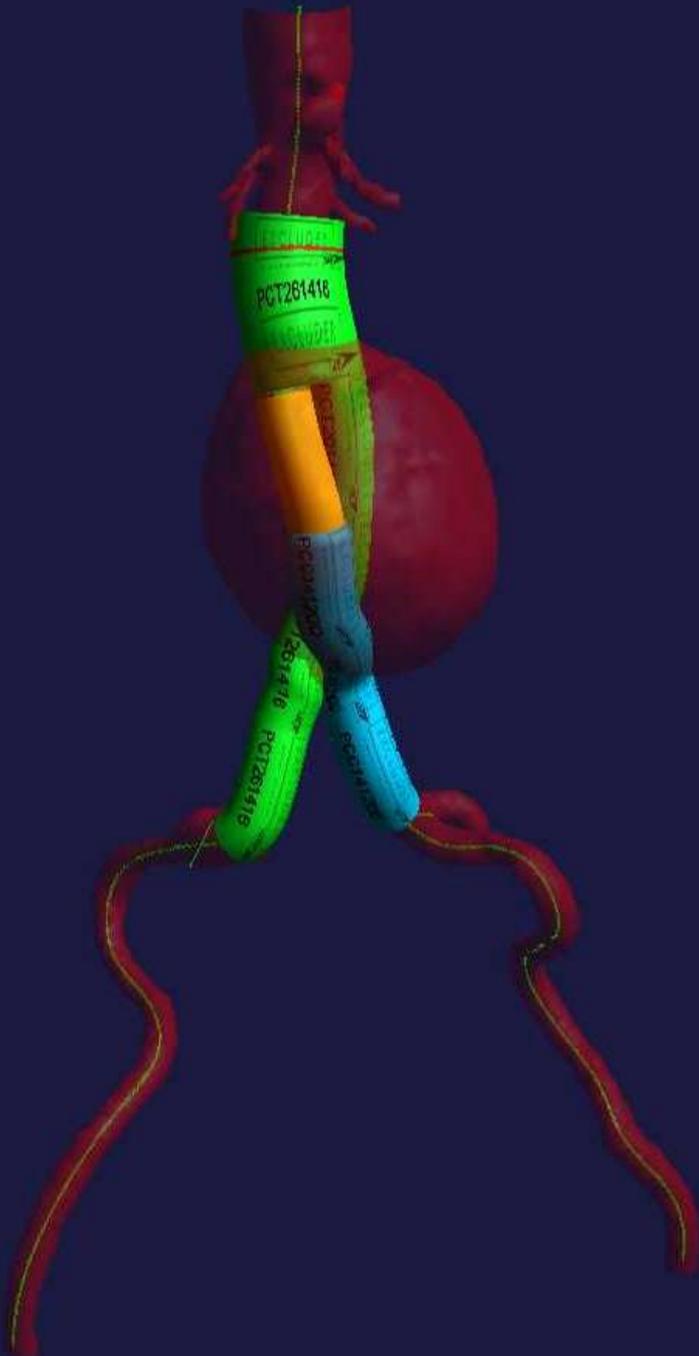
Angle Measurements

Vessel angulation is easily calculated

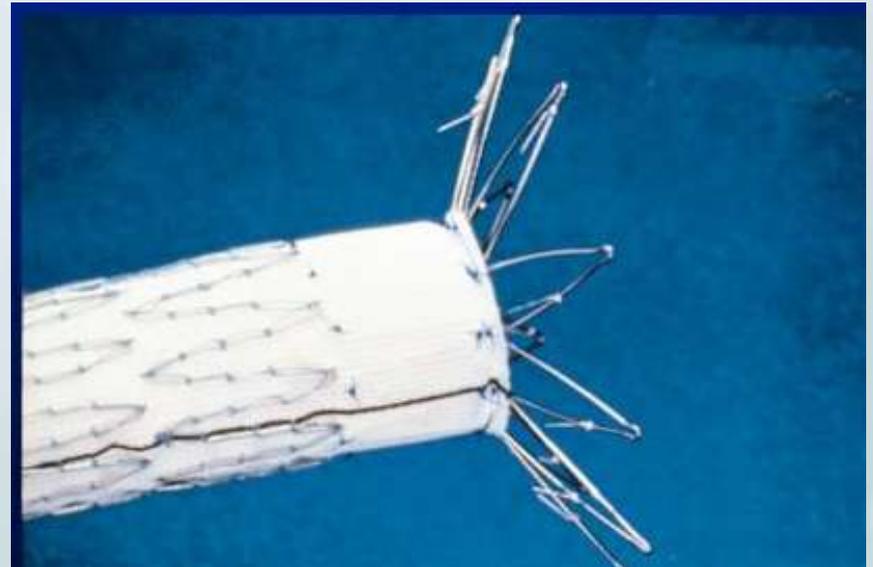
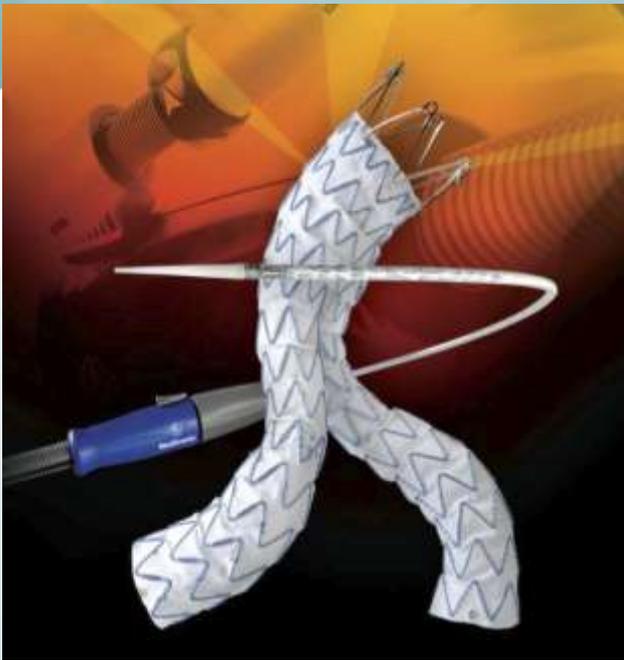


Manufacturer Specific Virtual Graft™

Computer Simulation of Graft Fit

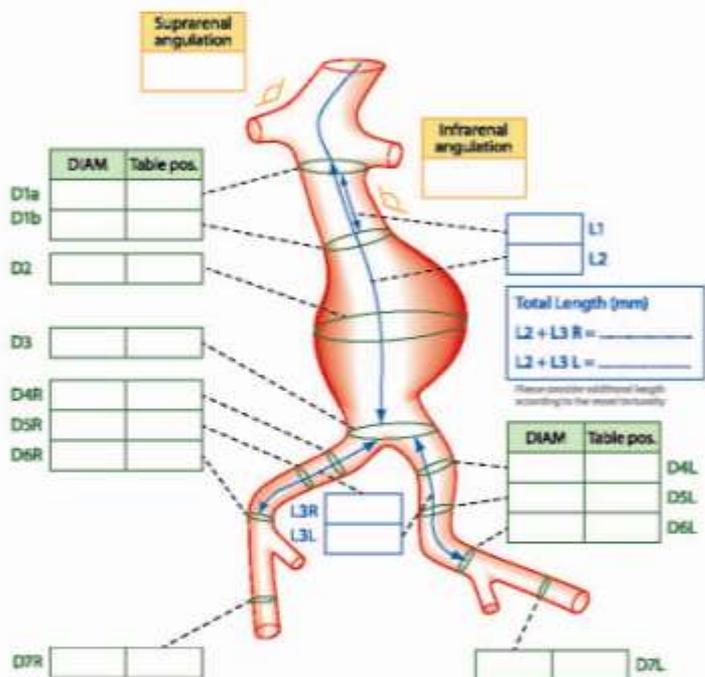


EVAR Devices



FOR USE BY PHYSICIAN ONLY

Date of CT Study: _____ Patient ID: _____ Patient DOB: ____/____/____
 CT Slice Thickness: _____ Implanting Physician: _____ Hospital Name: _____
 Evaluation Date: _____ Procedure Date: _____



SIA patent
 Yes No

Lowest renal artery
 Right Left

Proximal neck angulation
 Nil Mild
 Moderate Severe

Proximal neck thrombus
 Nil Mild
 Moderate Severe

Proximal neck calcification
 Nil Mild
 Moderate Severe

IIA patent
 Yes No

Right iliac calcification
 Nil Mild
 Moderate Severe

Left iliac calcification
 Nil Mild
 Moderate Severe

Coil hypo
 Right Left
 No

Proposed bifur side
 Right Left

Drawing

Please reference appropriate product instructions for use for a more detailed list of indications, warnings, precautions and potential adverse events.

Endurant Stent Graft
 AneuRx AAAAdvantage
 Not an endovascular candidate

| QTY | PRODUCT CODE | QTY | PRODUCT CODE |
|-----|--------------|-----|--------------|
| | | | |
| | | | |
| | | | |
| | | | |

Comments

Physician Signature: _____

| | | | |
|-------------|----------------------|------------------------------|-------------|
| Patient ID | TV1003590-20JUN41-ZS | Date Reviewed (dd/mm/yyyy) | 14-Jun-2013 |
| Institution | UCDMC | Date of CT Scan (dd/mm/yyyy) | 31-May-2013 |
| Physician | Dr. Laird | Slice Thickness (mm) | 1.50 |

| | | | | |
|--|-------|-------------------------------------|------|--------------------------|
| Lowest Renal Artery | Right | <input checked="" type="checkbox"/> | Left | <input type="checkbox"/> |
| Angulation (degrees) | Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| Significant posterior angulation (on the lower limb) between 30-35mm and 35-32mm | | | | |
| 82.0 * | | | | |

| Aortic Diameters (mm), "IR" = Inferior Renal Artery | | | |
|--|-------------|-------------|-------------|
| All diameters should be reported as luminal diameter (LD) unless extensive thrombus is present. In that case, measurement should be taken midway between flow lumen and the vessel wall. | | | |
| From the IR location: (-) indicates towards heart and (+) indicates away from heart. | | | |
| | Min | Max | Avg |
| IR - 35mm | 25.8 | 26.6 | 26.2 |
| IR (or intended position) | 22.6 | 24.0 | 23.3 |
| IR + 7mm | 19.8 | 22.1 | 21.0 |
| IR + 13mm | 17.9 | 19.0 | 18.5 |
| IR + 16mm | 17.9 | 19.2 | 18.6 |
| IR + 20mm | 20.6 | 40.0 | 30.3 |
| IR + 45mm (Flow Lumen) | 22.6 | 26.4 | 24.5 |
| IR + 80 mm (Flow Lumen) | 30.7 | 34.7 | 32.7 |
| Native Bifurcation (on the slice -30mm proximal to the point of clear stenosis) | 17.8 | 28.3 | |

| Lengths (mm) | | |
|--|-----|----------------|
| IR to Native Aortic Bifurcation | 130 | |
| IR to Right Internal Iliac Artery Origin | 215 | (RCIA = 85 mm) |
| IR to Left Internal Iliac Artery Origin | 215 | (LCIA = 85 mm) |

| Iliac Artery Diameters (mm) | | | | | |
|---|--|-----|------|------|------|
| All diameters should be reported as inner wall diameter (LD) unless extensive thrombus is present. In that case, measurement should be taken midway between flow lumen and the vessel wall. | | | | | |
| | Pos. # | Min | Max | Avg | |
| Right | Mid (largest diameter within 3-Slice above iliaciac distal edge) | 225 | 10.1 | 11.2 | 10.7 |
| | Distal (- Slice proximal to intended device landing position) | 236 | 9.6 | 9.8 | 9.7 |
| | External (mm) | | 9.3 | 9.6 | 9.5 |
| Left | Mid (largest diameter within 3-Slice above iliaciac distal edge) | 150 | 13.7 | 14.9 | 14.3 |
| | Distal (- Slice proximal to intended device landing position) | 190 | 14.2 | 14.7 | 14.5 |
| | External (mm) | | 7.9 | 8.0 | 8.0 |

| | | | | | | |
|--------------------------------------|-------|-------------------------------------|--------|-------------------------------------|----|--------------------------|
| Patient Recommended | Yes | <input type="checkbox"/> | UNSURE | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> |
| Aortic Body Introduction Side | Right | <input checked="" type="checkbox"/> | Left | <input type="checkbox"/> | | |

| Recommended Devices | | | |
|-----------------------------|-------------|----------------------|---|
| Aortic Body | 23 mm | Qty. | |
| Patient Right Iliac Limb(s) | 12 x 140 mm | 1 | |
| Patient Left Iliac Limb(s) | 16 x 140 mm | 1 | |
| Additional Components | | | |
| 12x120 (R Alternate) | 1 | 16x120 (L Alternate) | 1 |
| 12x100 (R Alternate) | 1 | 16x100 (L Alternate) | 1 |
| 12x45 (R Extension) | 1 | 16x45 (L Extension) | 1 |

Case planning notes

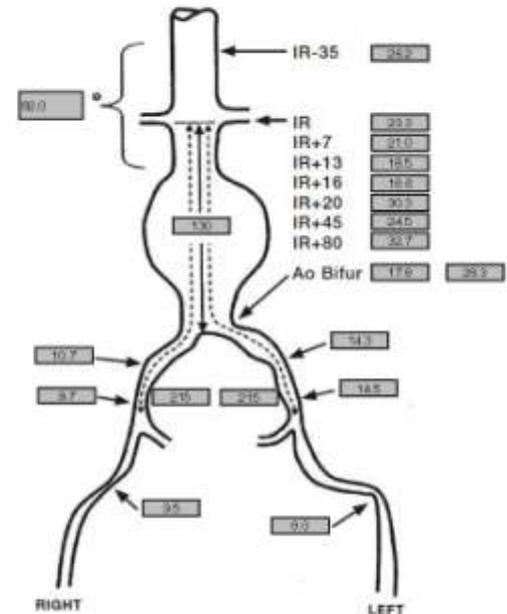
Access:
- Good bilateral access

Aortic Body:
- Long aortic sealing area noted
- Significant Juxtarenal angle present - 82 Degrees
- Angle begins at IR1
- Important to land proximal edge of the Aortic Body directly at the Inferior Renal (Right)
- During polymer injection, pull stiff wire back into delivery catheter
- Check aortic seal at 20 minutes post polymer injection. Balloon if necessary
- Have palmaz stent available if needed
- Patent IMA and lumbar noted

Iliac Limbs:
- RCIA and Right Internal aneurysm noted. Coil embolize and extend to REIA
- Recommend 12mm REIA Limb
- Recommend 16mm for LCIA

| | |
|----------------------|---------------------|
| Right Common: | Left Common: |
| RCIA- Aneurysmal | LCIA150- 13.7x14.9 |
| REIA225- 10.1x11.2 | LCIA170- 12.8x13.3 |
| REIA235- 9.6x9.8 | LCIA190- 14.2x14.7 |
| REIA245- 9.2x9.7 | LCIA200- 13.7x14.4 |
| | LCIA215- 13x13 |
| R. Ext- 9.3x9.6 | L. Ext- 7.9x8 |

| | |
|---------------------|---|
| Patient ID | TV1003590-20JUN41-ZS |
| Patient Recommended | Yes <input type="checkbox"/> UNSURE <input checked="" type="checkbox"/> No <input type="checkbox"/> |



| Recommended Devices | | | | Case Planning Note | |
|-----------------------------|-------------|----------------------|---|---|--|
| Aortic Body | 23 mm | Qty. | | Access: | |
| Patient Right Iliac Limb(s) | 12 x 140 mm | 1 | | - Good bilateral access | |
| Patient Left Iliac Limb(s) | 16 x 140 mm | 1 | | Aortic Body: | |
| Additional Components | | | | - Long aortic sealing area noted | |
| 12x120 (R Alternate) | 1 | 16x120 (L Alternate) | 1 | - Significant Juxtarenal angle present - 82 Degrees | |
| 12x100 (R Alternate) | 1 | 16x100 (L Alternate) | 1 | - Angle begins at IR1 | |
| 12x45 (R Extension) | 1 | 16x45 (L Extension) | 1 | - Important to land proximal edge of the Aortic Body directly at the Inferior Renal (Right) | |
| | | | | - During polymer injection, pull stiff wire back into delivery catheter | |
| | | | | - Check aortic seal at 20 minutes post polymer injection. Balloon if necessary | |
| | | | | - Have palmaz stent available if needed | |
| | | | | - Patent IMA and lumbar noted | |
| | | | | Iliac Limbs: | |
| | | | | - RCIA and Right Internal aneurysm noted. Coil embolize and extend to REIA | |
| | | | | - Recommend 12mm REIA limb | |
| | | | | - Recommend 16mm for LCIA | |

*Anonymized patient data has been submitted to TVTmed for consideration for a randomized trial with the patient and with the use of the TVTmed for Disease Abolished Overload System. The data is based on the untreated patient data to be read and taken to the nearest 0.1 mm only. In addition, at all times, the responsibility of the clinician to confirm all measurements and to make the decision to proceed with the treatment remains with the clinician and is not to be used.

Case

- 71 year old male
- History of smoking (150 pack-years)
- Recent evaluation for back pain
- Further evaluation revealed 5.5 cm infra-renal abdominal aortic aneurysm



CT Angiography



5.5 cm fusiform infrarenal aneurysm

CT Angiogram



Dilated common iliac arteries



- Short common iliac arteries (bilateral)
 - ~30 mm in length
 - > 20 mm diameter
- Iliac arteries tortuous

Endograft Procedure Planning

The screenshot displays the Aquarius iNtuition software interface for endograft procedure planning. The main window is divided into three panels:

- Top Left (3D View):** Shows a 3D reconstruction of the aorta and iliac arteries. Measurements include:
 - D1a: 27.5 mm
 - D1b: 25.8 mm
 - 77 deg
 - 100 deg
- Top Right (2D Axial View):** Shows a cross-sectional view of the aorta with a yellow centerline. Measurements include:
 - D1a: 27.5 mm
 - D1b: 25.8 mm
 - B2a: 54.9 mm
 - D3: 38.2 mm
 - D4r: 20.1 mm
 - D6r: 17.6 mm
 - Renal: 19.6 mm
 - L2: 127 mm
 - 173 mm
- Bottom Left (2D Axial View):** Shows a cross-sectional view of the aorta with a blue circle indicating the diameter. Measurements include:
 - Avg. Diameter: 11.6 mm
 - Min. Diameter: 11.2 mm
 - Max. Diameter: 12.0 mm
 - Area: 106 mm²

The right-hand panel contains the software's control interface, including a Patient List, Viewer, and Output sections. The EVAR (Endovascular Aortic Repair) workflow is selected, showing Overview, CPR, and EVAR views. The Measurement Protocols section is expanded to show the Medtronic Endurant AAA Stent Graft protocol, with the following checked items:

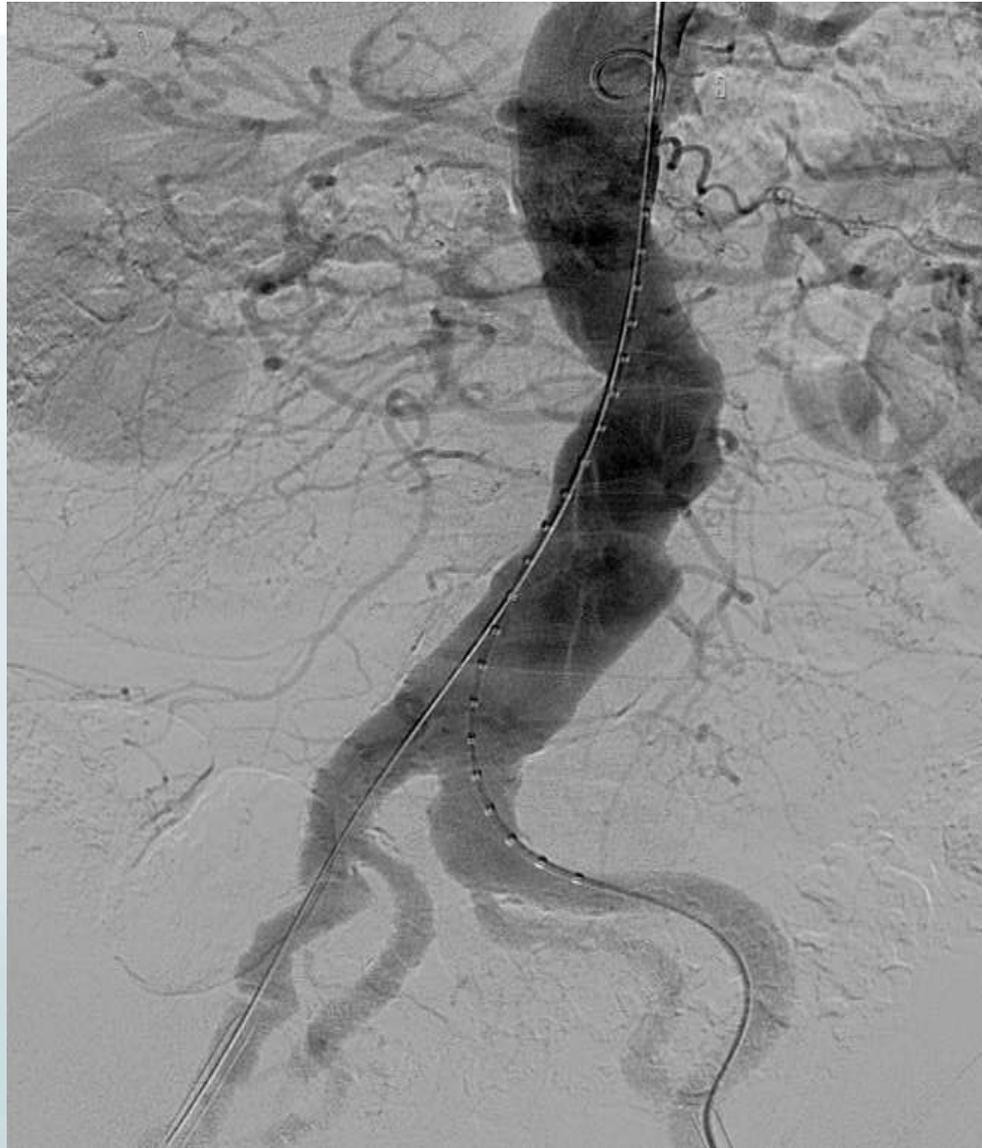
- Extract Centerline
- Select aorta-riht external iliac centerline
- Renal: Lowest Renal Artery
- D1a: Proximal Aortic Neck Diameter
- D1b: Distal Aortic Neck Diameter
- L1: Aortic Neck Length
- D2a: Aneurysm Lumen Diameter
- D2a: Aneurysm Sac Diameter
- D3: Diameter at Aortic Bifurcation

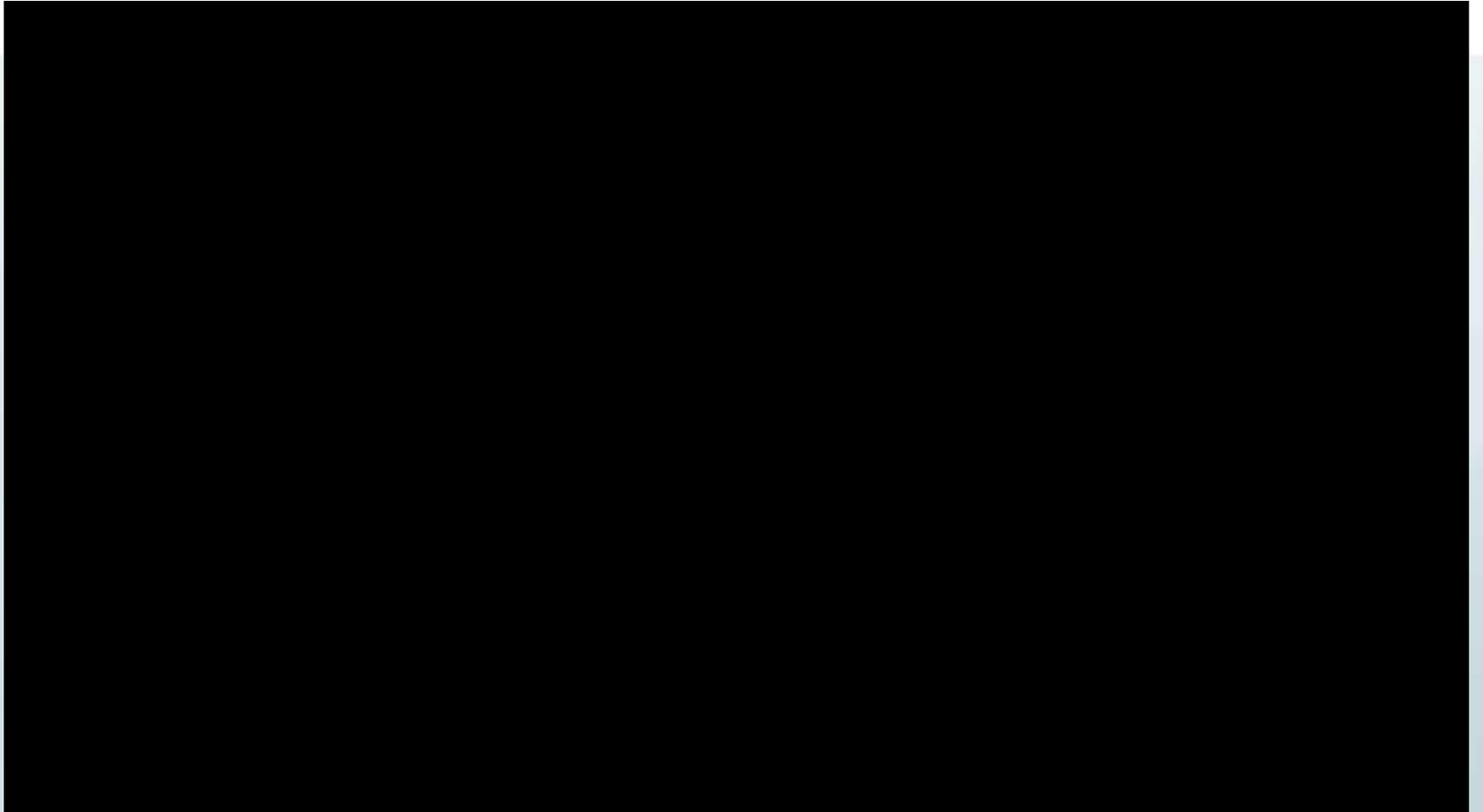
The software also includes an Observation field and a Generate Report button.

Plan

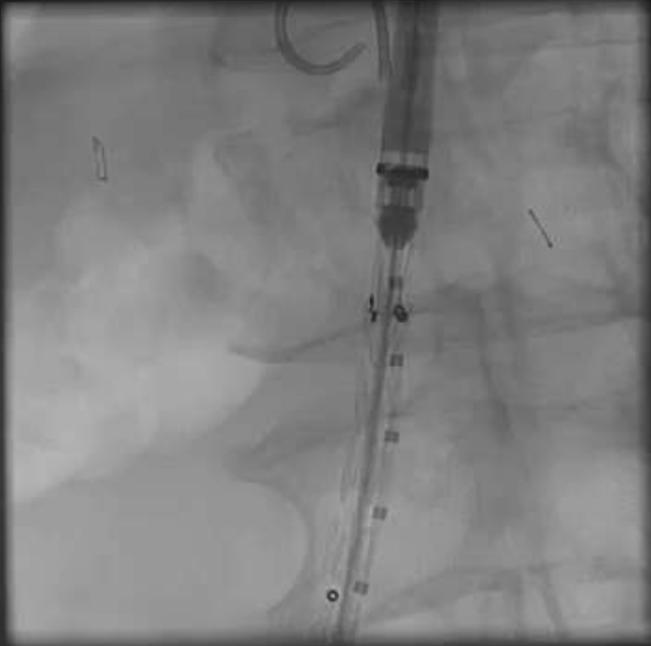
- Percutaneous technique
 - Ultrasound guided access
 - “Pre-close”
- Angiography to confirm measurements
- Device ?
- Delivery techniques – primary access from right or left femoral artery

Abdominal Aortography



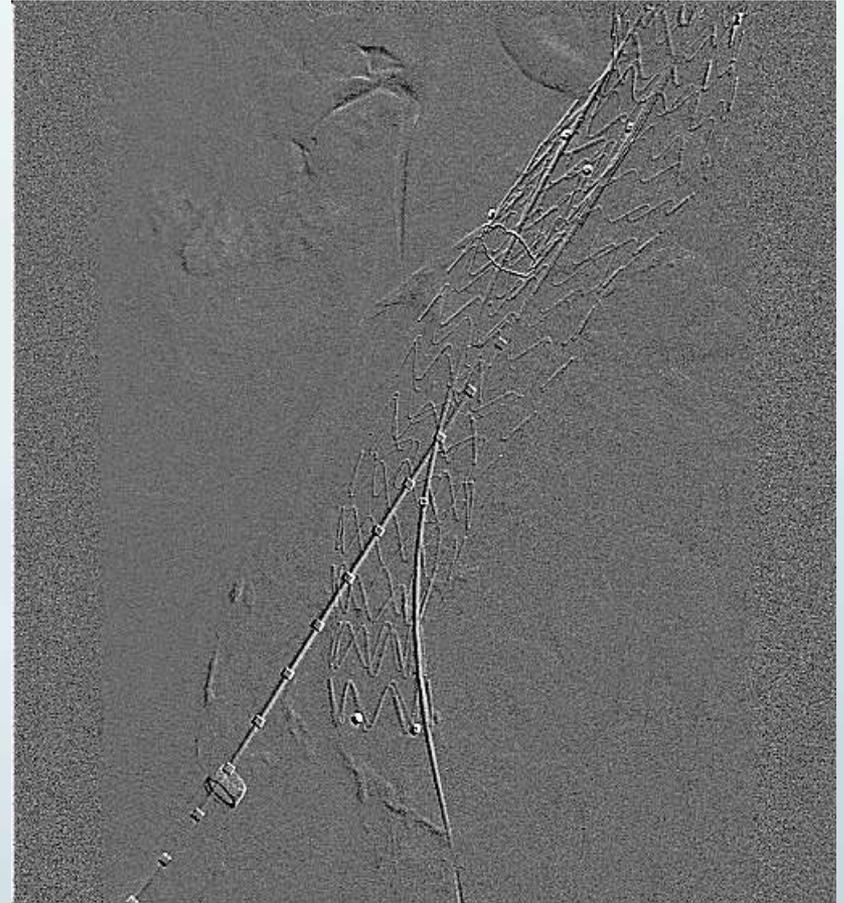


Proximal Body Deployment



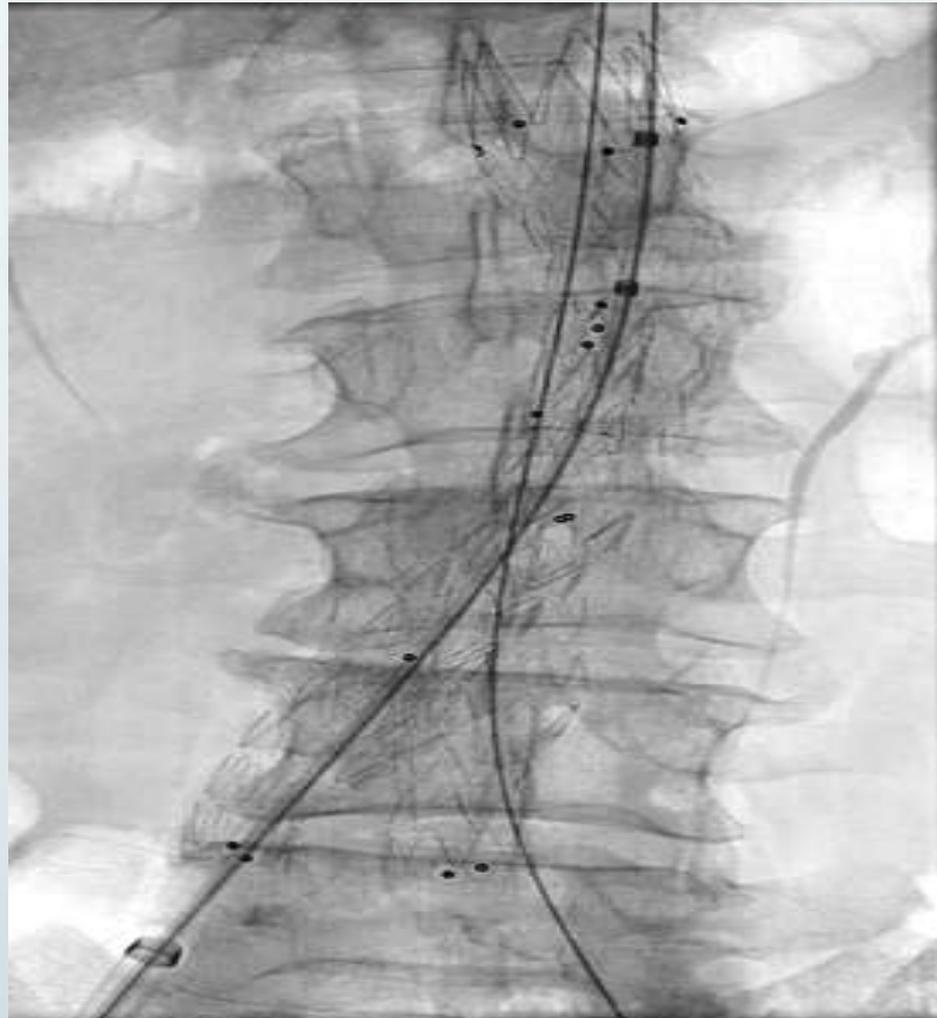
Endurant Stent Graft

Contralateral Limb Deployment



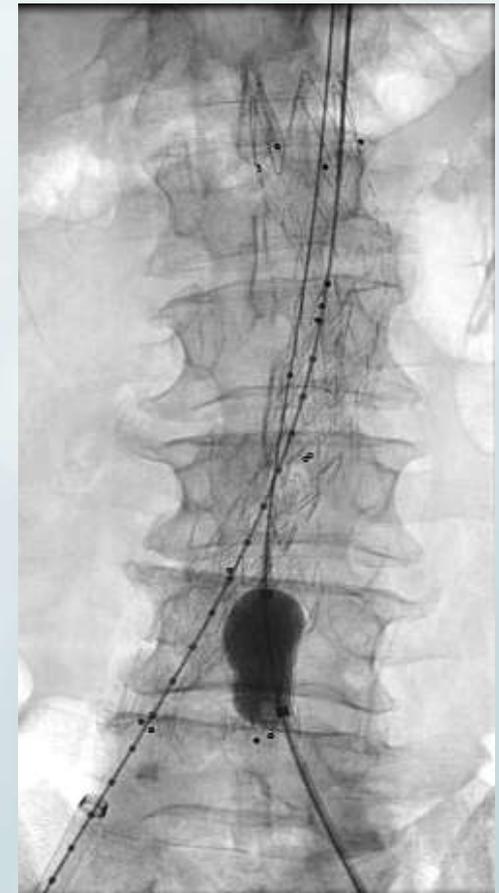
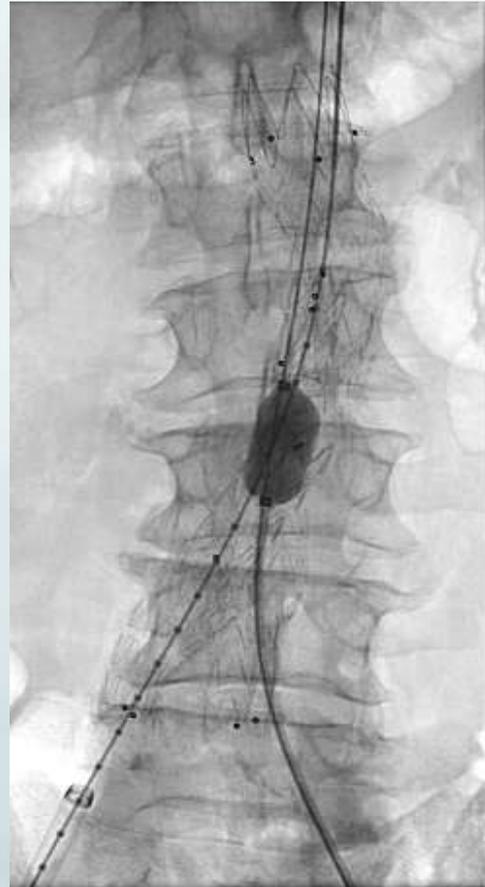
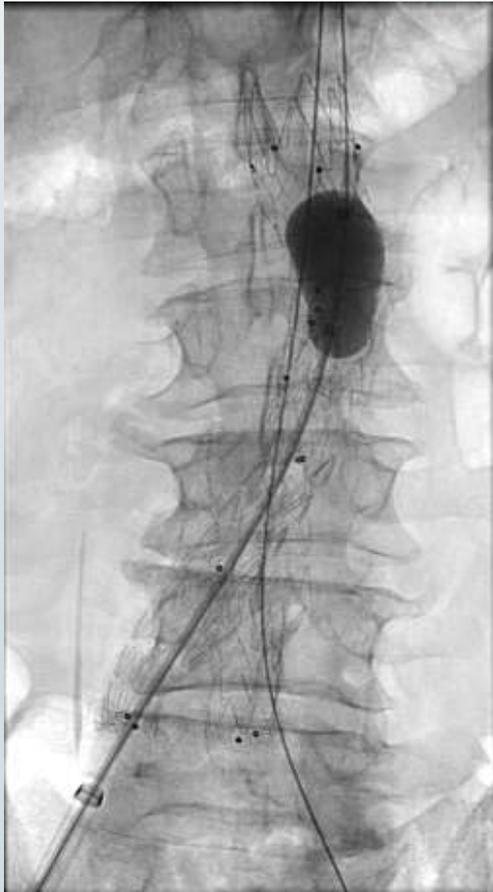
24 x 16 x 124 mm Limb

Ipsilateral Limb Deployment

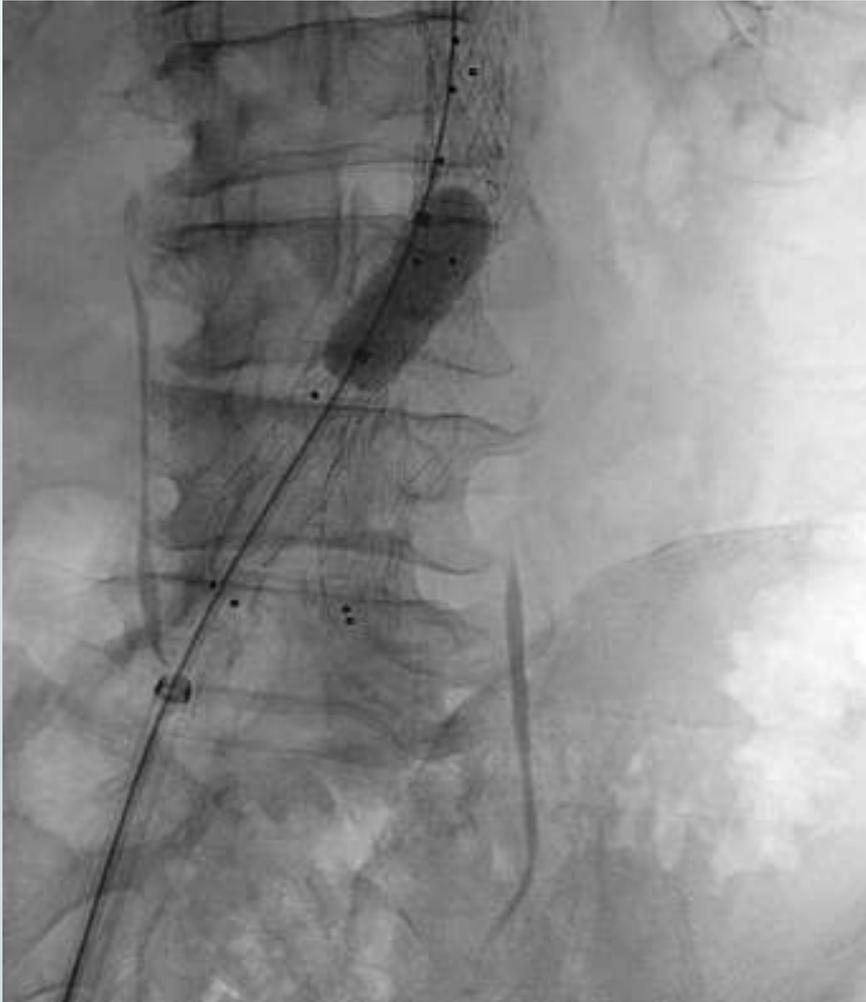


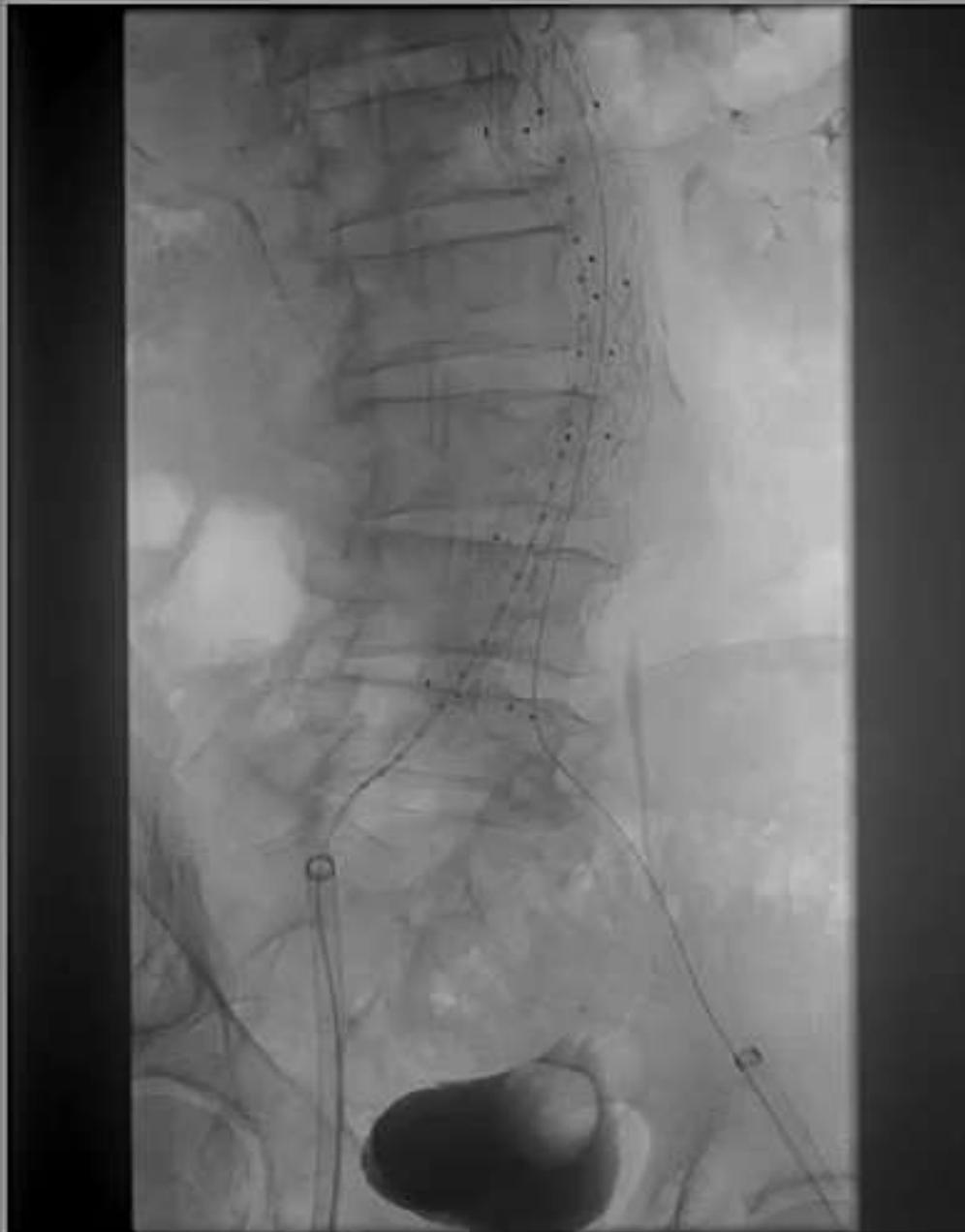
24 x 16 x 93 mm Endurant

Post Dilatation w/ Compliant Balloon



Completion Angiography



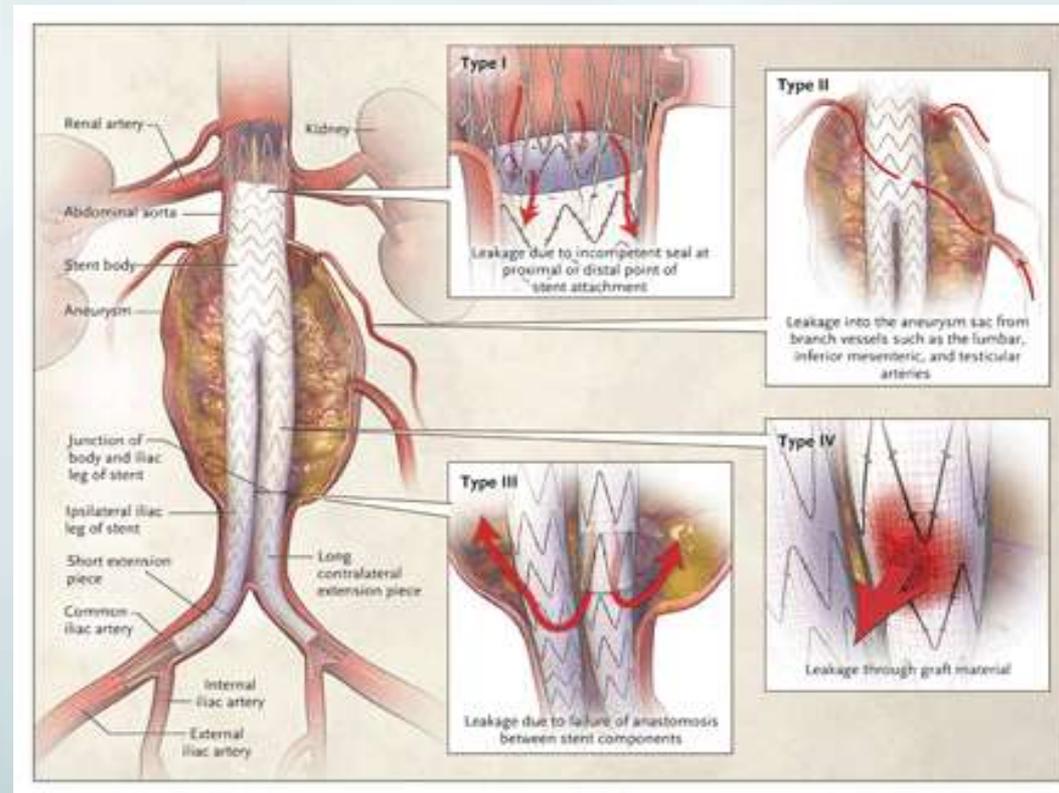


Post-Procedure

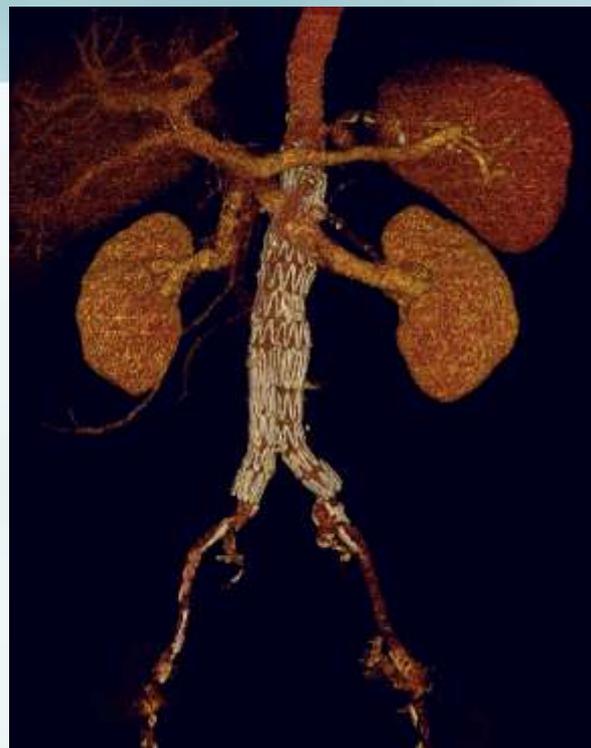
- Discharge the following day
- Follow-up CTA of abdomen and pelvis in one month
- If satisfactory results achieved – Duplex ultrasound follow-up thereafter
 - 6 months, 12 months, then annually
 - Measurements of maximal aneurysm diameter and circumference
 - Evaluation for evidence of endoleak

EVAR Surveillance: Purpose

- Prevent Rupture
 - Evaluate for the presence of endoleak
 - Monitor AAA sac size
- Device Status
 - Migration
 - Structural failure
- Outflow
 - Graft Limbs
 - Distal perfusion
- Intervention?



Preoperative



1 month post-EVAR
5.2 cm

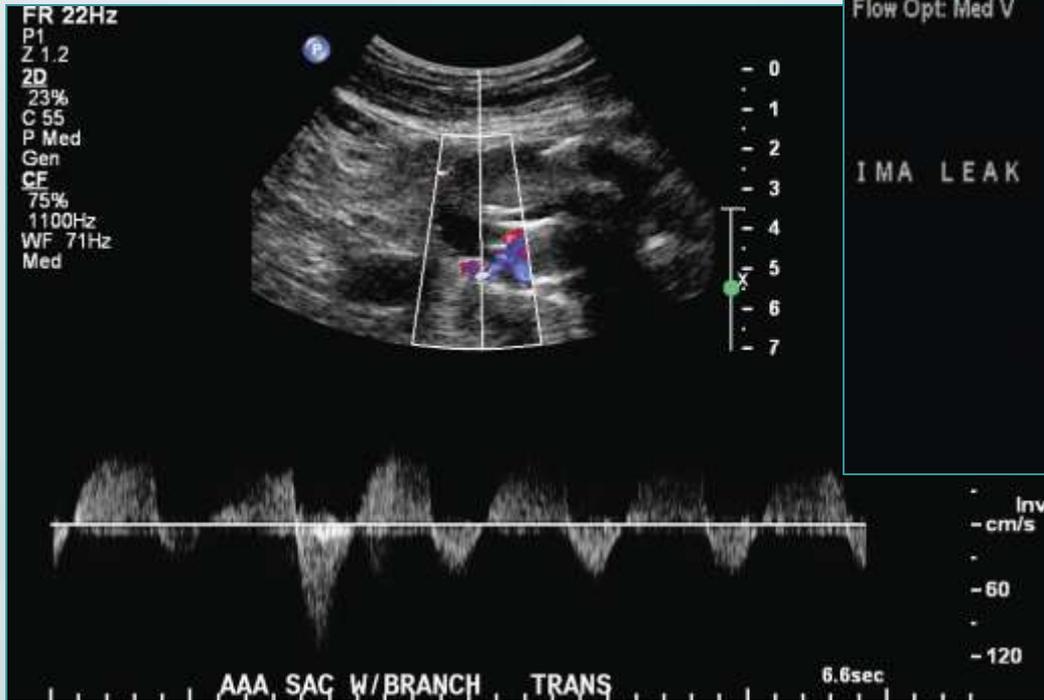


4 months post-EVAR
5.2 cm

7 months post-EVAR
3.7 cm

13 months post-EVAR
2.9 cm

Duplex Surveillance: Type II Endoleaks



Type IIa: IMA

Type IIb: To-fro flow

Summary

- Good preoperative CT imaging is essential for procedure planning and device selection
- Percutaneous delivery of devices now possible in the majority of cases
- Life long surveillance required post EVAR
 - CTA vs Duplex
 - Evaluation for device migration or endoleak
 - Monitoring of sac dimensions

EVAR at TCT AP

