13th International Symposium on Endovascular Therapeutics

EVAR USING THE ALTURA ENDOGRAFT SYSTEM WITH DOUBLE-D PROXIMAL STENT DESIGN, PRECISE RENAL ARTERY POSITIONING AND RETROGRADE DEPLOYMENT OF ILIAC STENT GRAFT: SINGLE CENTRE CLINICAL EXPERIENCE

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Disclosure

Lombard Medical Ltd., Endologix Ltd.

X I have the following potential conflicts of interest to report:

- X Receipt of grants/research support
- ❑ Receipt of honoraria and travel support
- ❑ Employment in industry
- ❑ Shareholder in a healthcare company
- ❑ Owner of a healthcare company

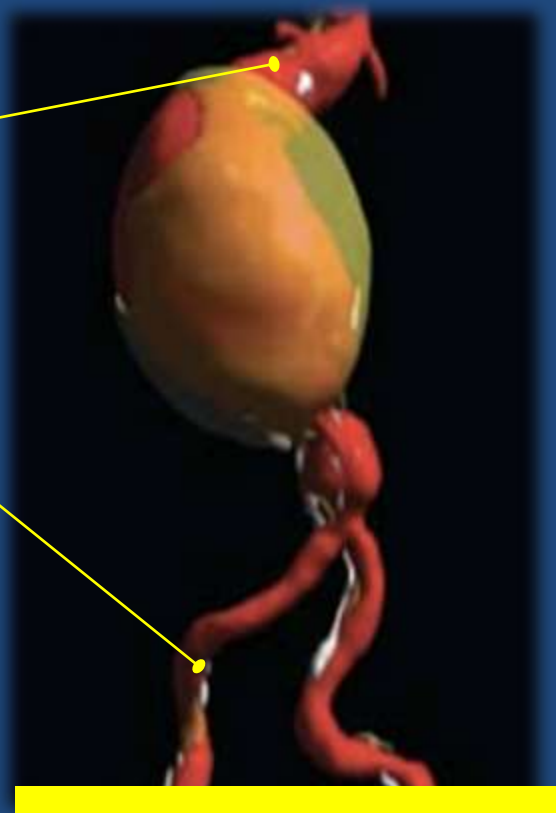
❑ I do not have any potential conflict of interest

Limitations Of Current EVAR

- **Anatomical**
- **Procedural**
  - Unpredictable and time consuming
  - Gate cannulation, Snaring, Polymer
  - Complex procedures
- **Economical**
  - Throughput / efficiency
  - Device costs

Aortic
- Length/shape of neck
- Angulation
- Small distal segment

Iliac
- Tortuosity
- Small caliber access

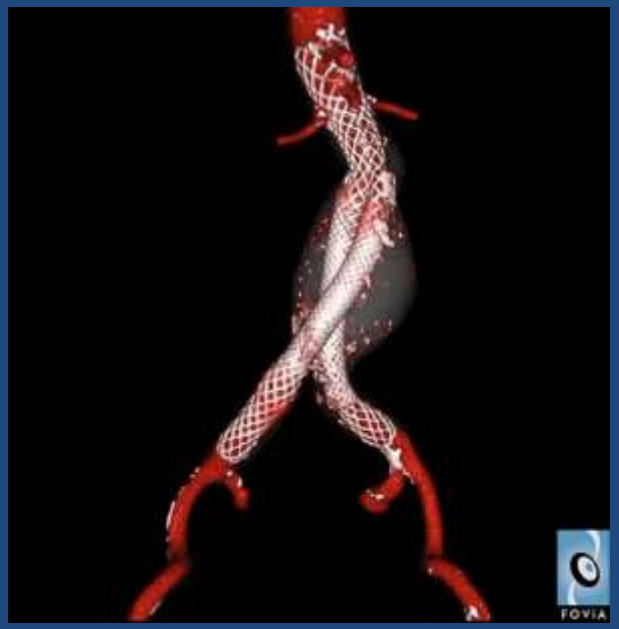


Other
- Landing zone/fixation
- Thrombus/Calcification

Design Goal: Address current EVAR limitations with a simple, low profile system

Parallel / “Kissing” endografts

NELLIX



ALTURA

ALTURA System Concept

- **Stent Graft**
  - "D" endografts (aortic)
  - Flexible Nitinol braid
  - Ribbed woven polyester outside the stent
  - Suprarenal anchors
  - Telescoping iliac endografts

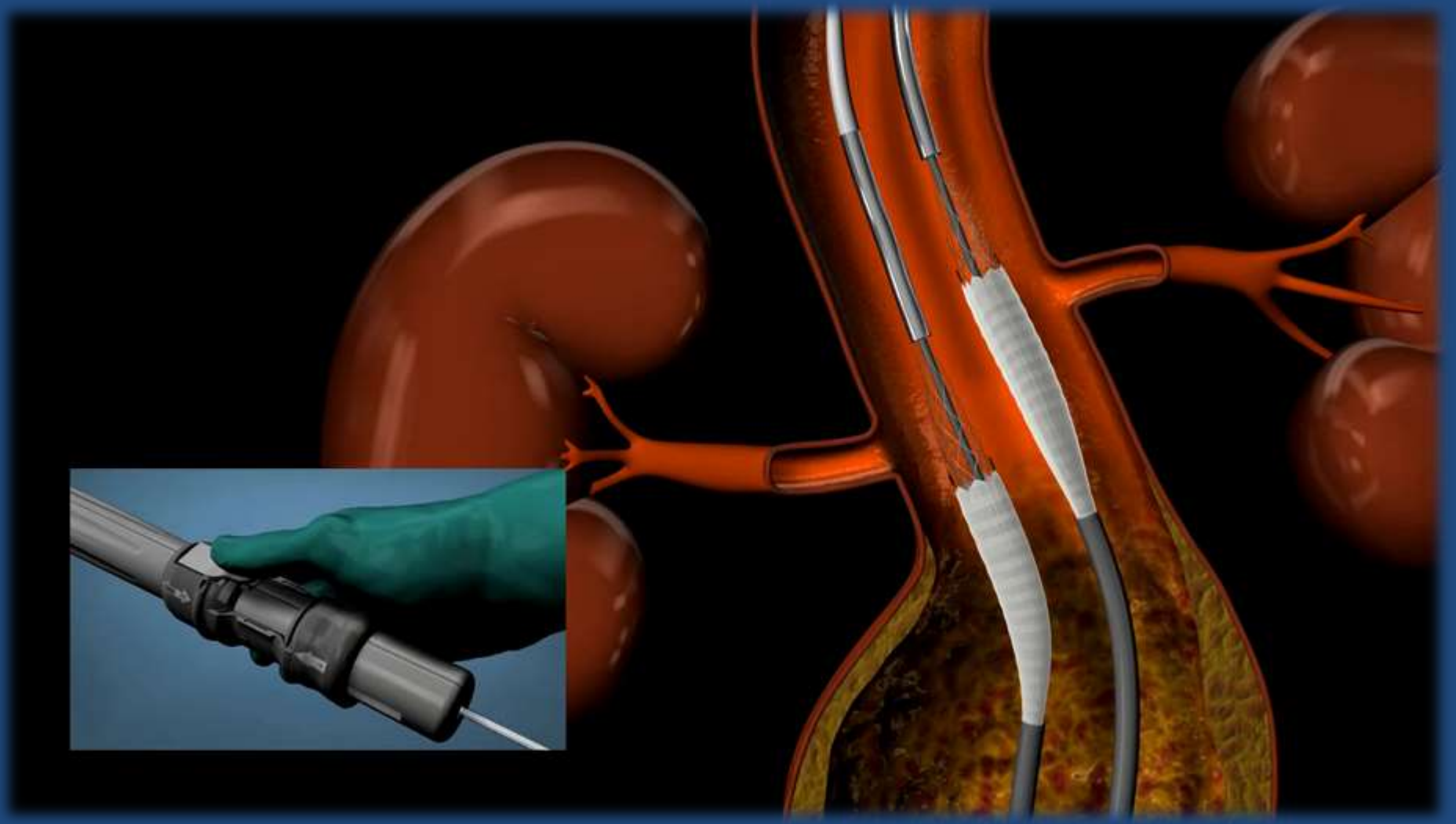
- **Delivery System**
  - Low profile (14F) and flexible
  - Controlled braid deployment
  - No Gate Cannulation
  - Contrast injection capability

Aortic Deployment

Introduce and align ‘D’ endografts

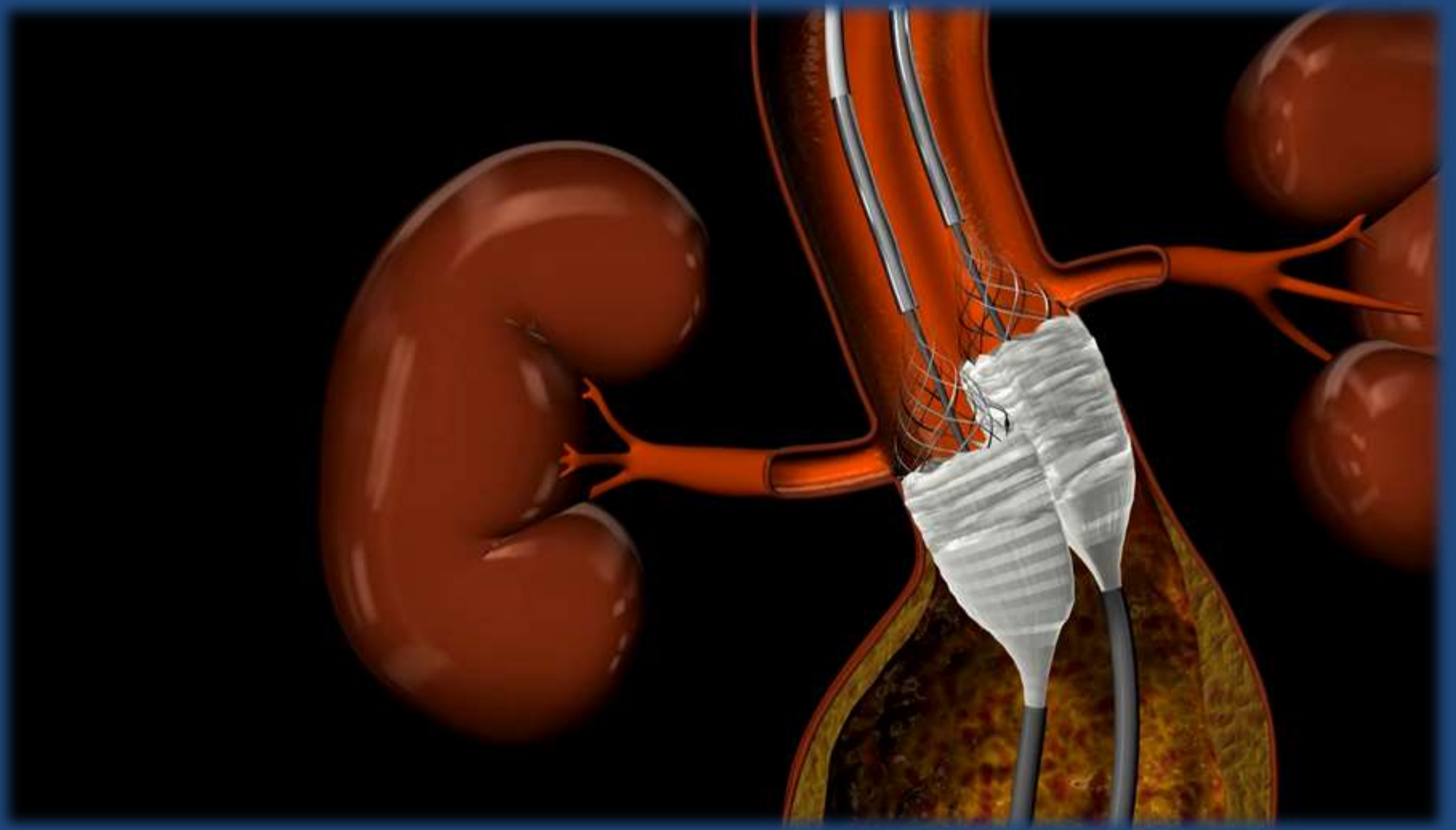
Aortic Deployment

Position endografts below both renals



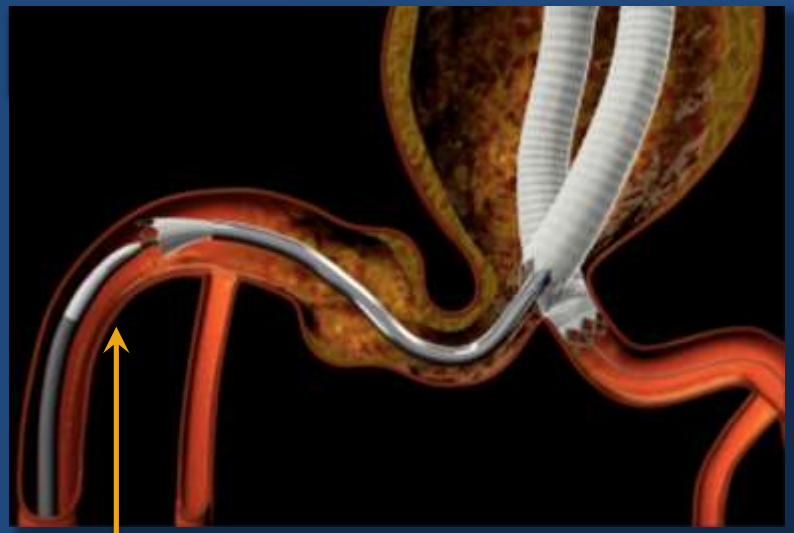
Aortic Deployment

Release suprarenal stent and deploy



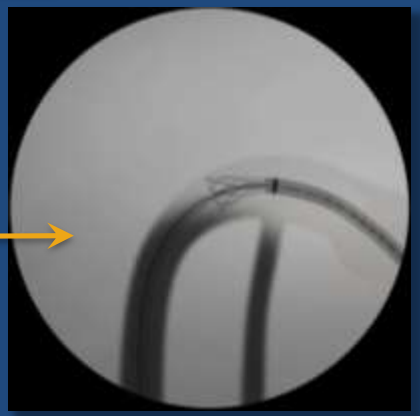
Iliac Deployment

Start at Iliac bifurcation



Reverse deployment
from distal to proximal graft

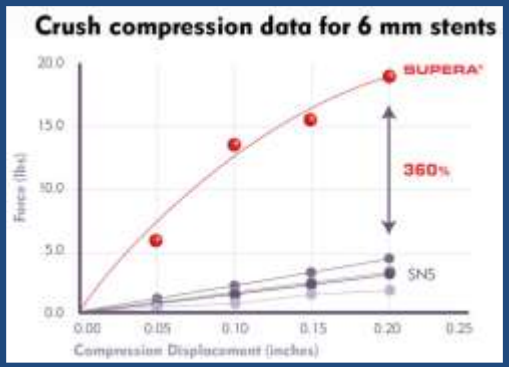
Built-in contrast injection capability to identify internal iliac



Nitinol Braided Stents

- Well known for ***extreme flexibility****
- Successful applications in other challenging vasculature
- Proven long term ***excellent durability*** and fatigue strength*
- Disadvantages
  - Length control
  - Hoop strength (addressed by newer stents)

Braided stent Vs. Laser Cut Nitinol**



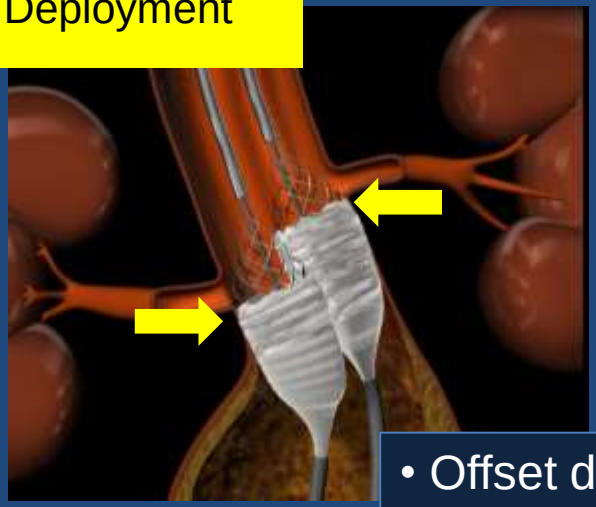
Wouldn't a braided stent be great for EVAR ?

*J Vasc Surg 2013; 57: 1014 - 22 **Vascular Mimetic Technology, P. Goverde, LINC

Bringing Braided Stent Flexibility to EVAR…

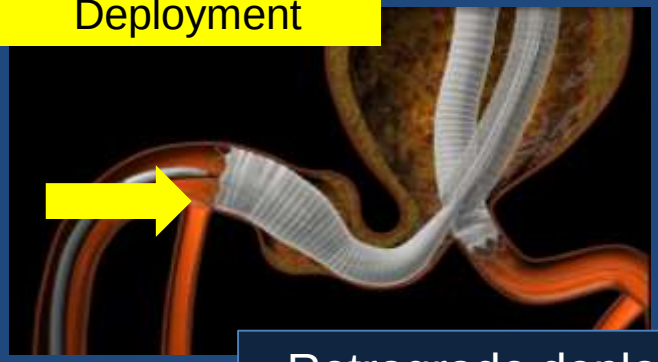
Challenge	Solution
Length Control	Make length variations irrelevant by starting deployment at branch vessels (renals and hypogastric)

Top Down Aortic Deployment

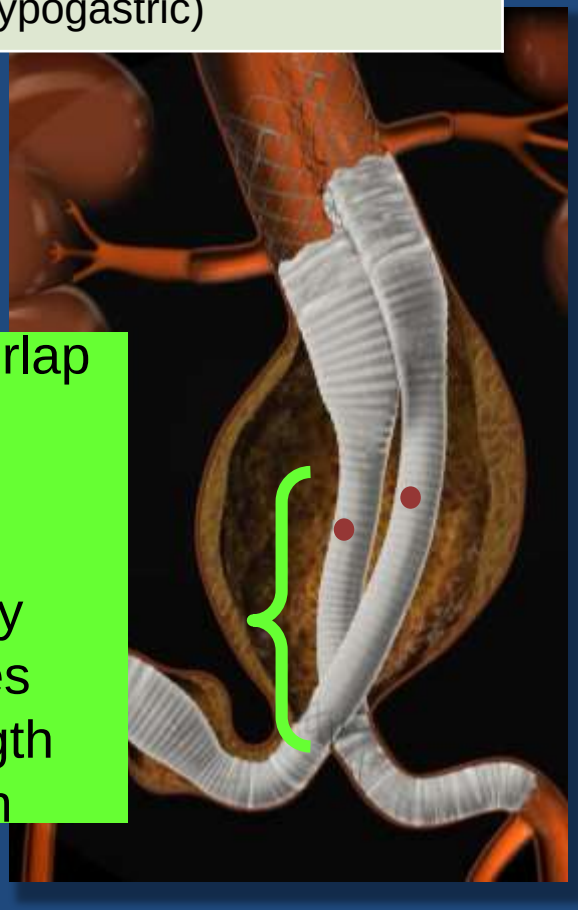


- Offset deployment
- Repositionability

Bottom Up Iliac Deployment



- Retrograde deployment
- Preservation of hypogastrics



Larger overlap zone:

- Absorbs length variability
- Simplifies iliac length selection

Latvia Experience with *ALTURA*

- 1st Case Performed: Jan 2014

Clinical Trial Experience and Evolution

FIH / Feasibility

Standard

- n = 47 enrolled
- Standard anatomy
- Chile & Latvia

⦸ > 4.5cm
Neck ≥ 15mm
Neck ≤ 60°

Complex

- n = 10
- Complex anatomy
- Chile & Latvia

Proof of Concept & Safety Evaluation

ELEVATE registry

Standard & Complex

- n = 46
- Standard anatomy
- OUS sites (8 sites Europe & Chile)

***CE mark* granted July 2015**

Further development

Altitude Registry

Standard

- Enrollment 2017
- International prospective registry
- N= up to 1000
- Capture real world use of Altura Endograft system and its impact on:
  - Safety and efficacy
  - Unique features of the design
    - Impact on procedure
    - Impact on patient care

Latvia Experience with *ALTURA*

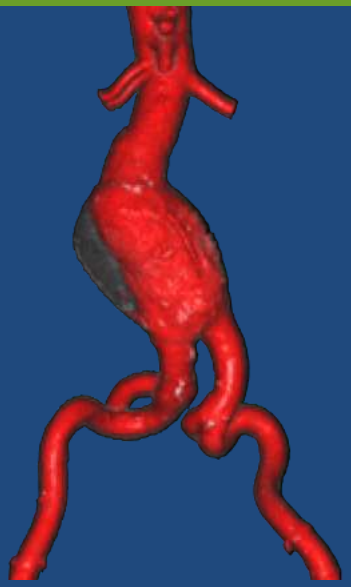
- Total 104 cases to date

FIM (Standard/Extreme)

- n = 12
- Standard/Complex anatc

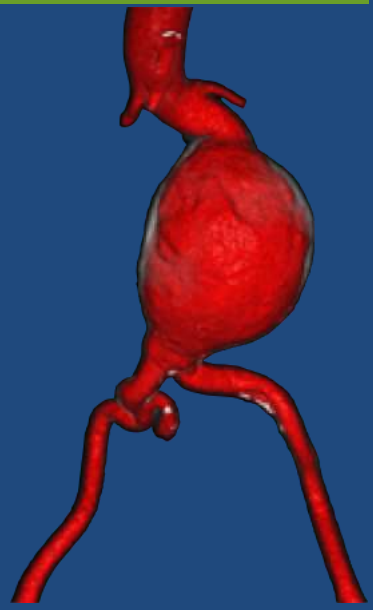
ELEVATE International (Standard)

- n = 16
- Standard anatomy



ALTITUDE (Standard)

- n = 35
- Standard anatomy



ALTURA Clinical Trial Experience
Latvia RESULTS

Demographics & Baseline Characteristics	104 Patients
Male Gender (%)	87.8
Age, Years, Mean, Range	72.8 ± 8.3
History of Coronary artery disease (%)	66.3
Hypertension (%)	62.5
Family history of AAA (%)	5.7
Mean AAA Sac Diameter, cm	5.7 ± 0.6
Mean Neck Vessel Diameter, mm	22.0 ± 8.5
Mean Neck Length, mm	22.3 ± 7.7

Krievins D, Savlovskis J, et al. EVAR using ALTURA endograft system with double D-proximal stent design, precise renal artery Positioning and retrograde deployment of iliac stent graft: initial clinical experience. JEVT: 2018

ALTURA Clinical Trial Experience
Latvia RESULTS

Procedural / In-Hospital Outcomes	104 Patients
Procedural Technical Success, N	104/104 (100%)
Mean Fluoroscopy Time, min	24 ± 11
Mean Total Procedure Time, min	52 ± 36
Vessel Access Type percutaneous (%)	98.8
Anesthesia Type (%)	
Local	4.8
Regional/Spinal	85.6
General	9.6
Post-procedure ICU, N	8/104
Time to Hospital Discharge, days	2.8 ± 1.4

ALTURA Clinical Trial Experience
Latvia RESULTS

Evaluation (mean 31.5 months)	30 Days (N = 104)	1 YR (N= 64)	2 YRS (N = 33)	3 YRS (N = 20)	4 YRS (N = 14)
Aneurysm Rupture	0	0	0	0	0
No AAA related M	0	4	0	2	1
Device Migration (>10mm)	0	0	0	0	0
Endoleak – Type Ia	1[1](1.0%)	1[2] (1.5%)	1[3] (3.0%)	0	0
Endoleak – Type Ib	0	0	1[4] (3.0%)	0	0
Endoleak – Type III	0	0	0	0	0
Endoleak – Type II	11 (11%)	6 (9.3%)	4 (12%)	2 (10%)	0
Stent Occlusion	0	1[5] (1.6%)	0	0	0
Stent stenosis	2(1.9%)	0	0	0	0
Fracture or Fatigue	0	0	0	0	0
Rate of Secondary Procedures	1 (1.2%)	2 (3.4%)	4[6] (12.1%)	1[6](5.0%)	0

[1] Intra-operative misplacement; Treated additional prox D-shapes
[2] Prox angle 90[0]; Treated coils + glue at 1 year
[3] Prox neck degeneration; Treated coils + glue at 2 years
[4] Large left iliac with thrombus and connection to lumbar, Treated: left iliac Coils+glue
[5] Intra-operative stent damage with stenosis; stent thrombosed; explant with Ao-Biiliac graft

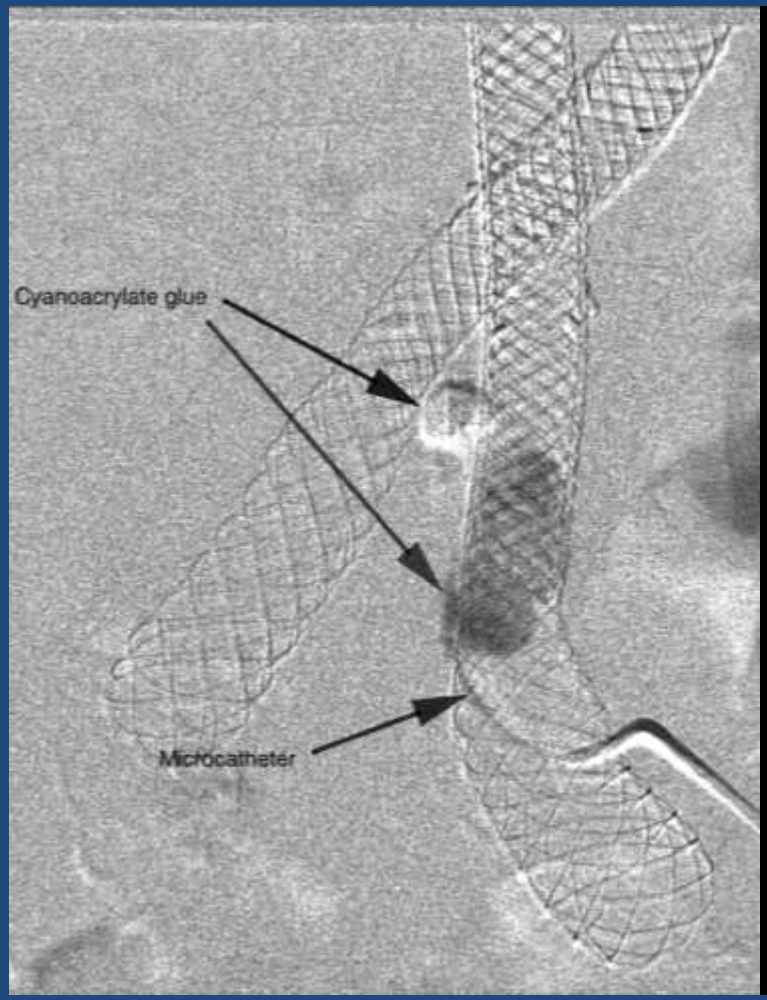
ALTURA Clinical Trial Experience
Iliac segment stenosis (*PTA*)

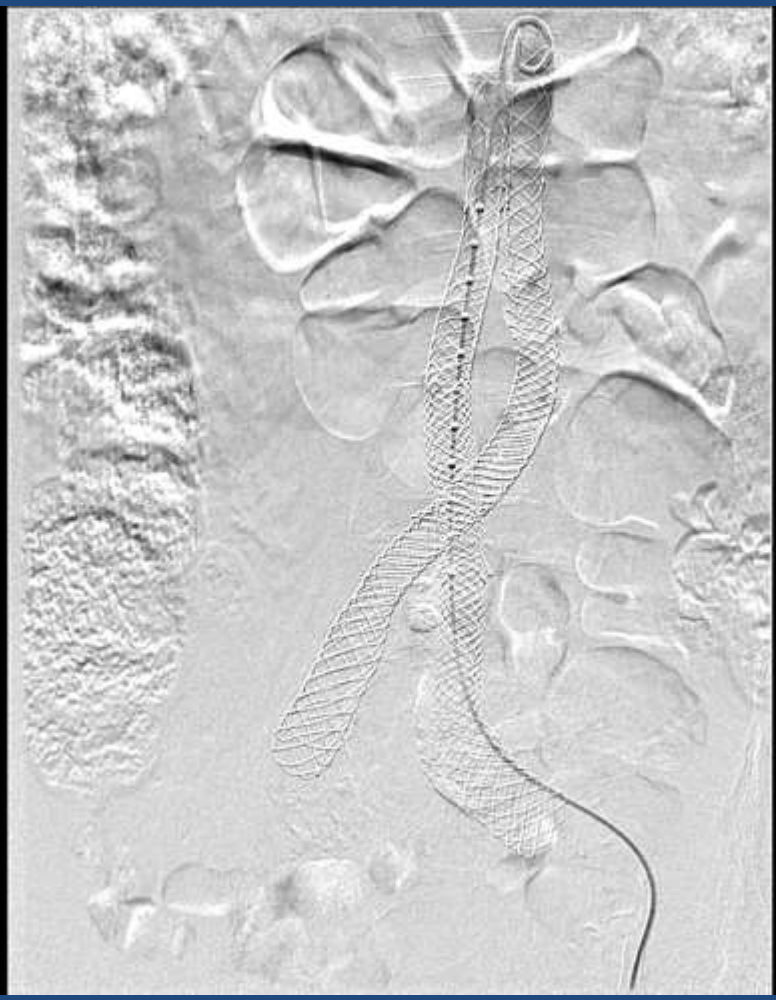
30 days

2 years

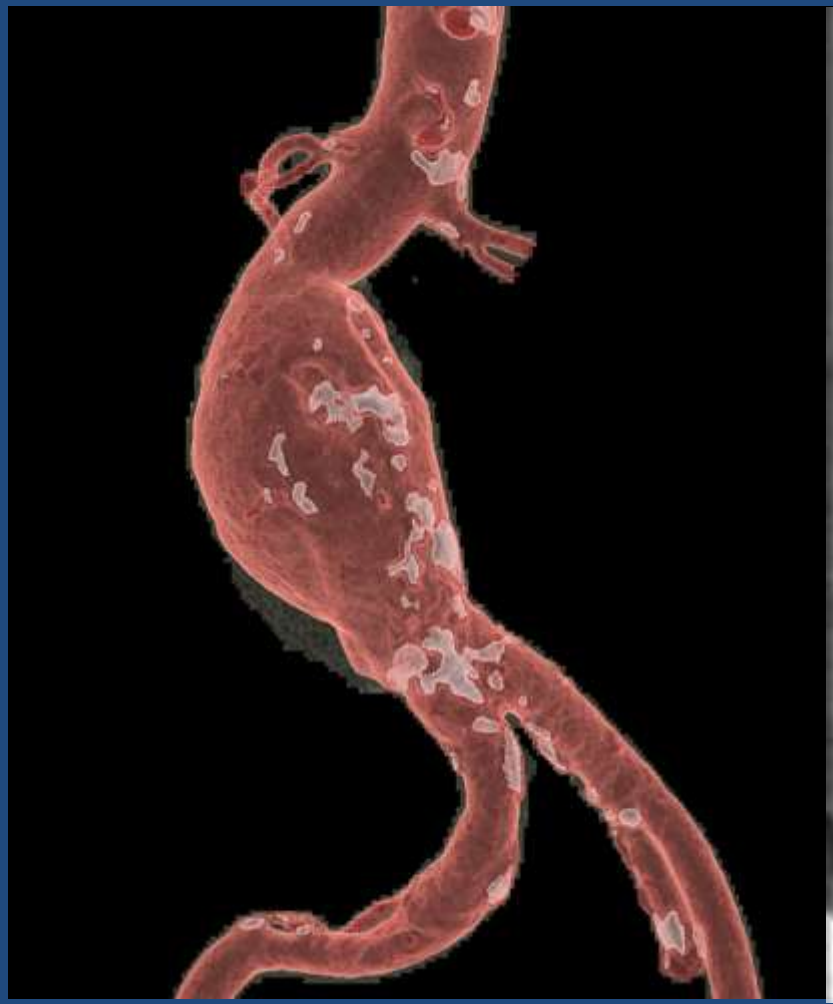
ALTURA Clinical Trial Experience
IB endoleak (*Out of IFU CIA*)

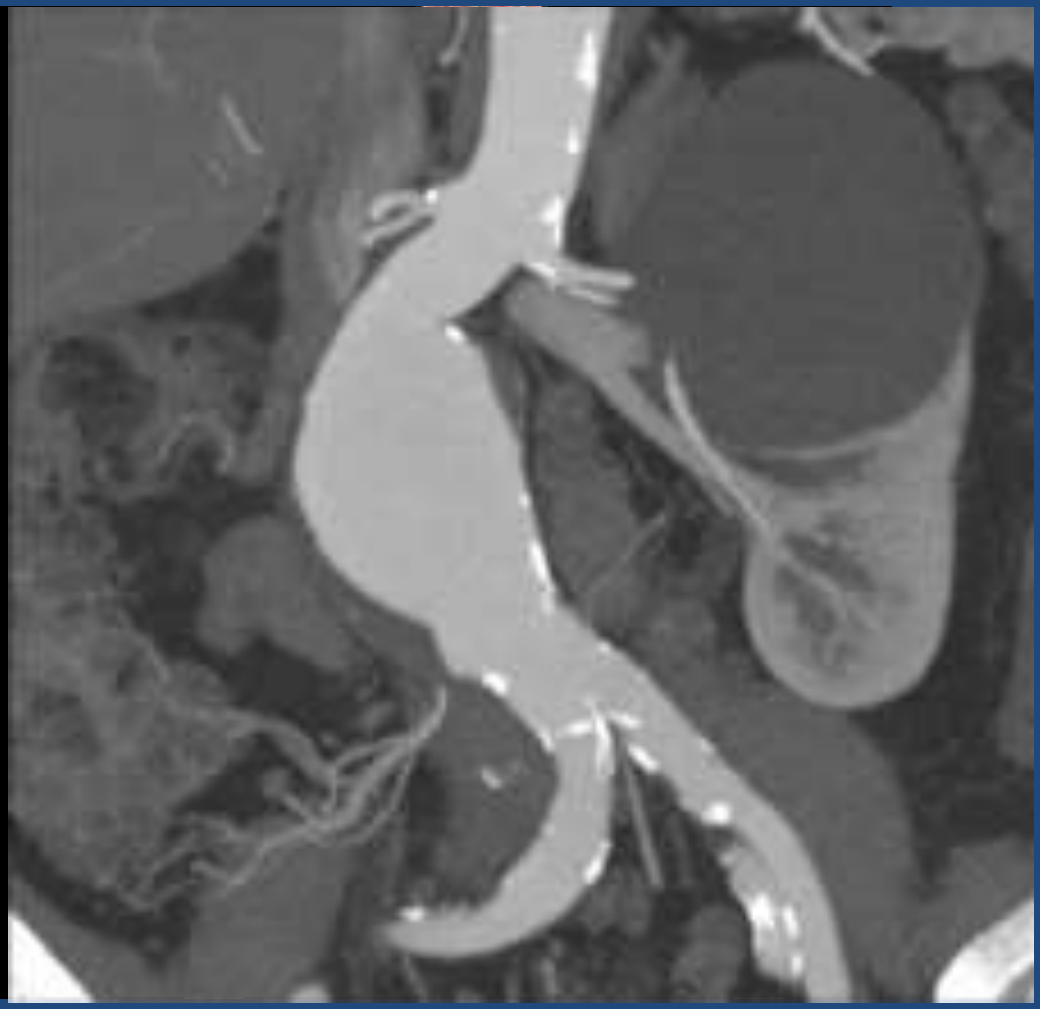
ALTURA Clinical Trial Experience
IB endoleak (*Treated with coils+glue*)

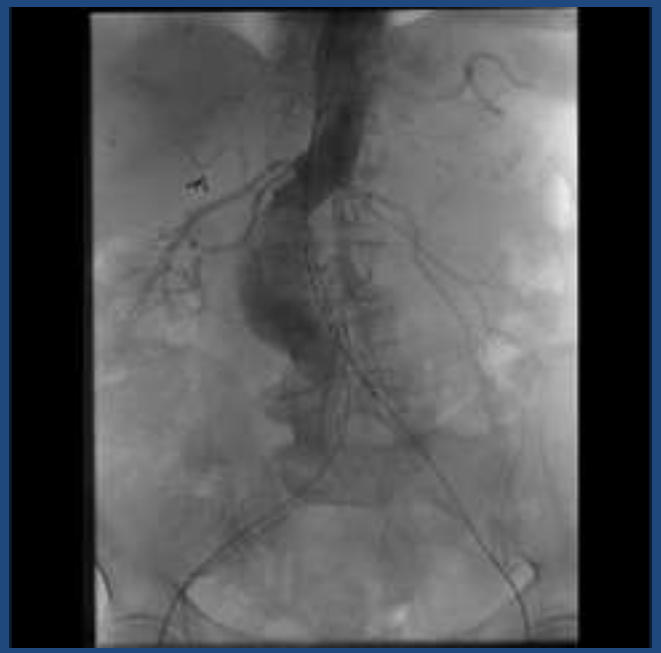


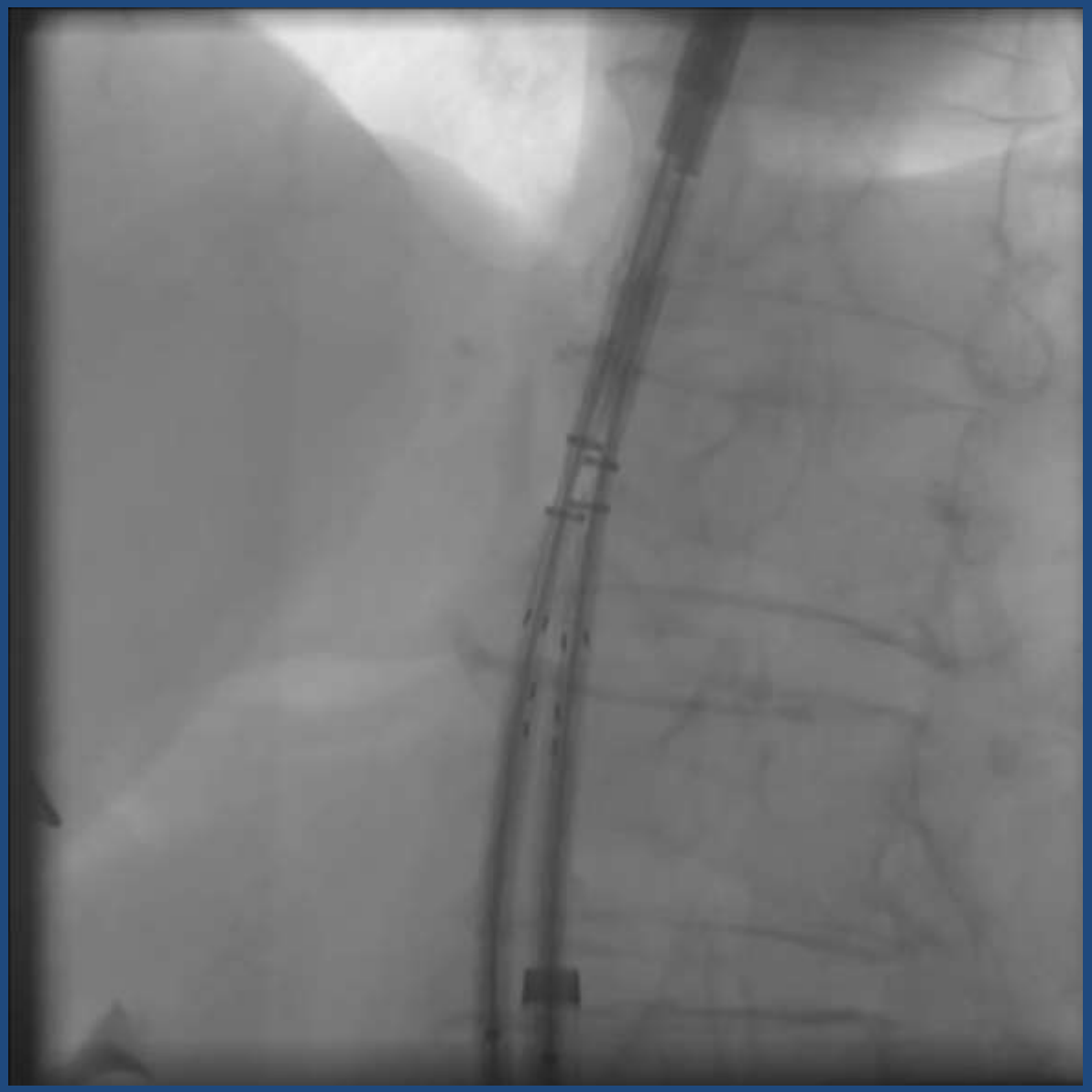


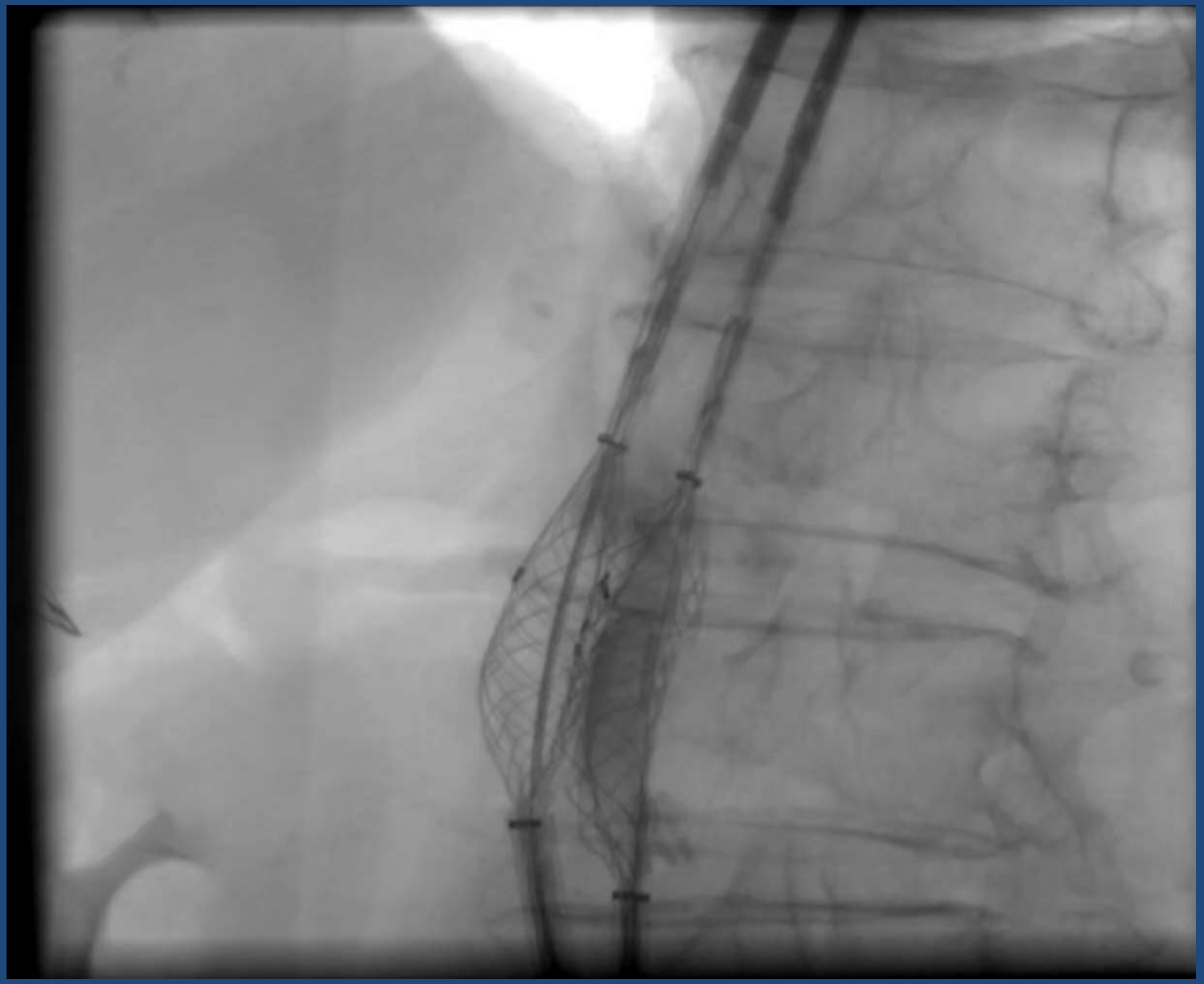
82 year old patient

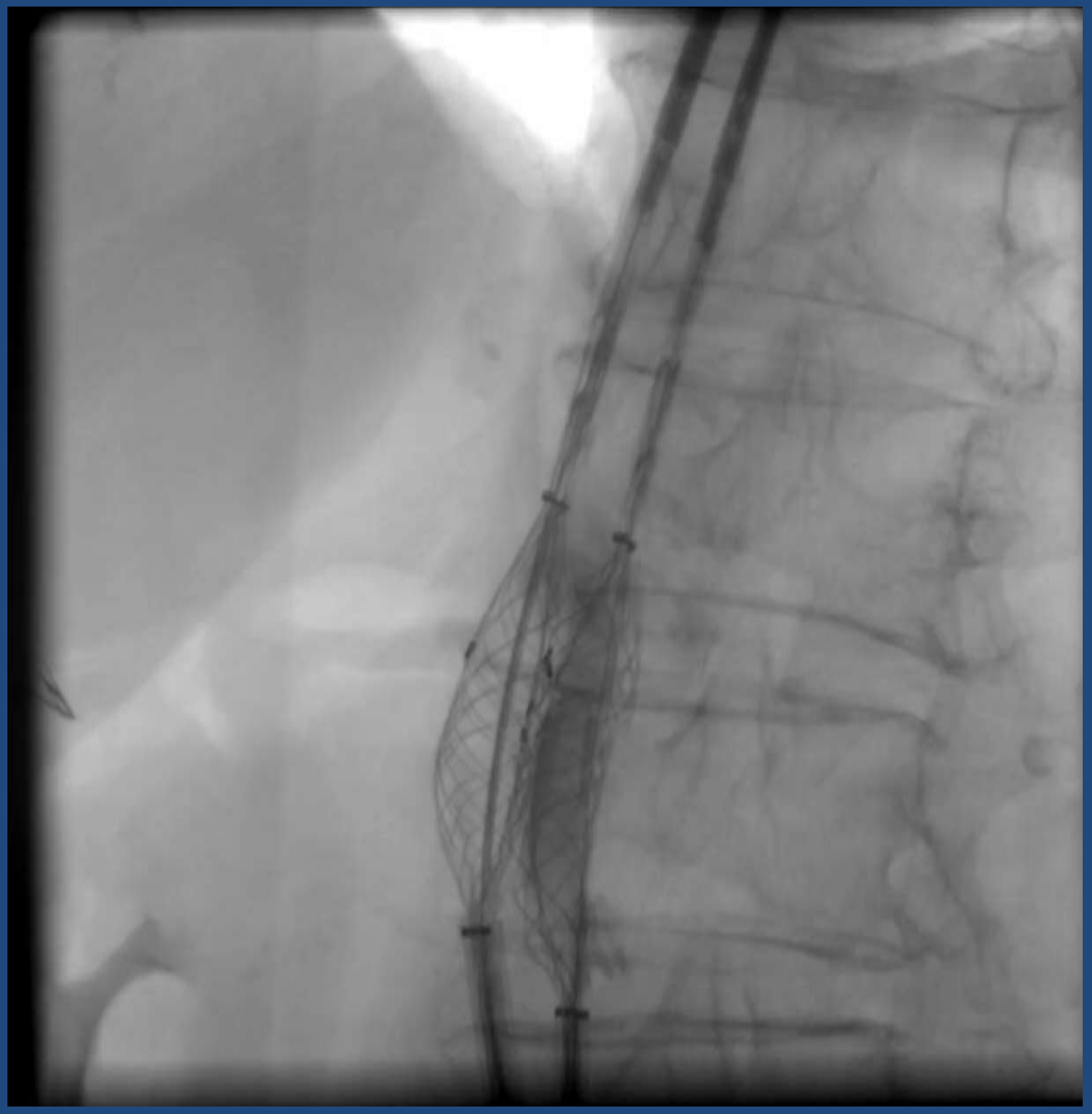


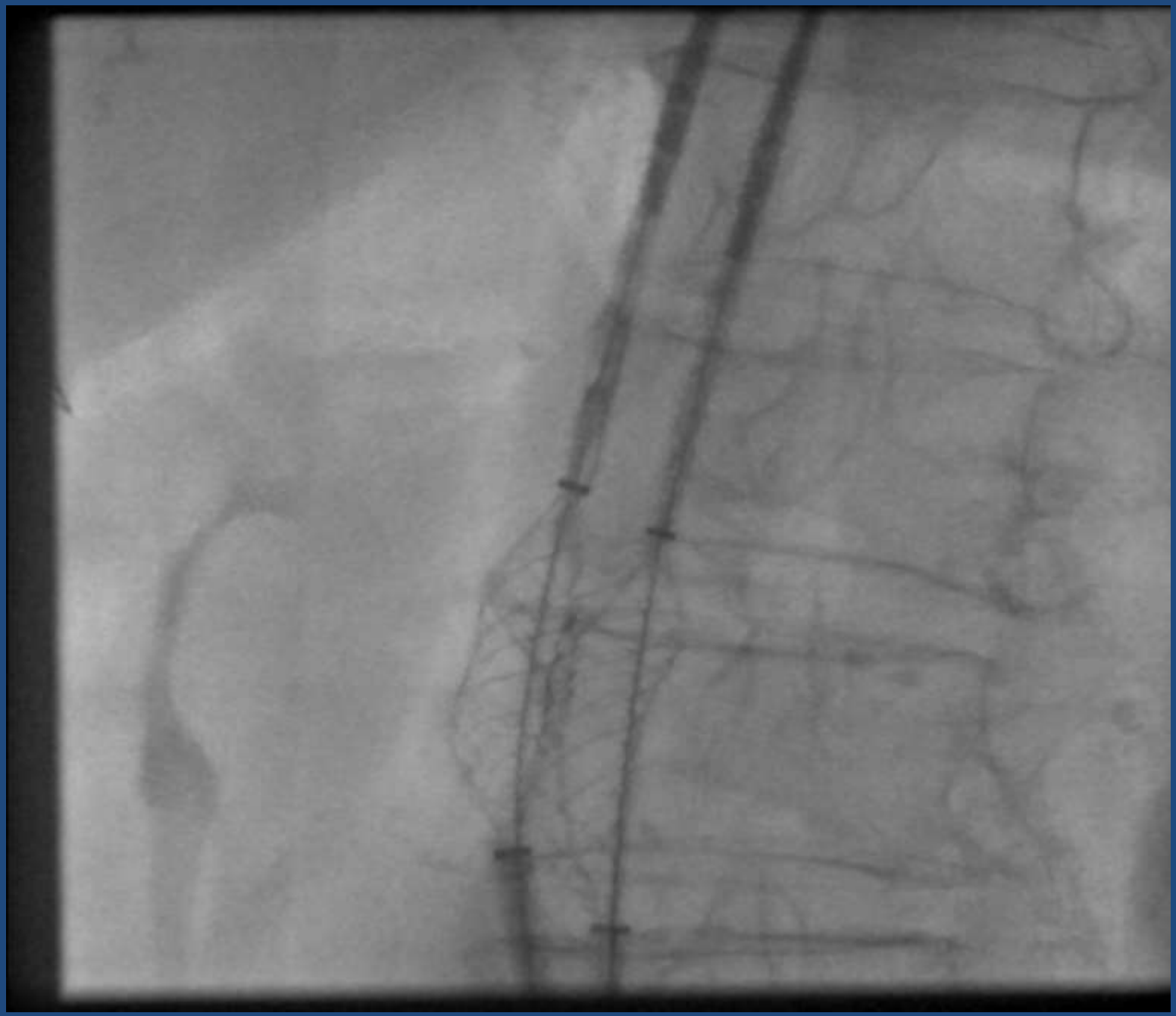


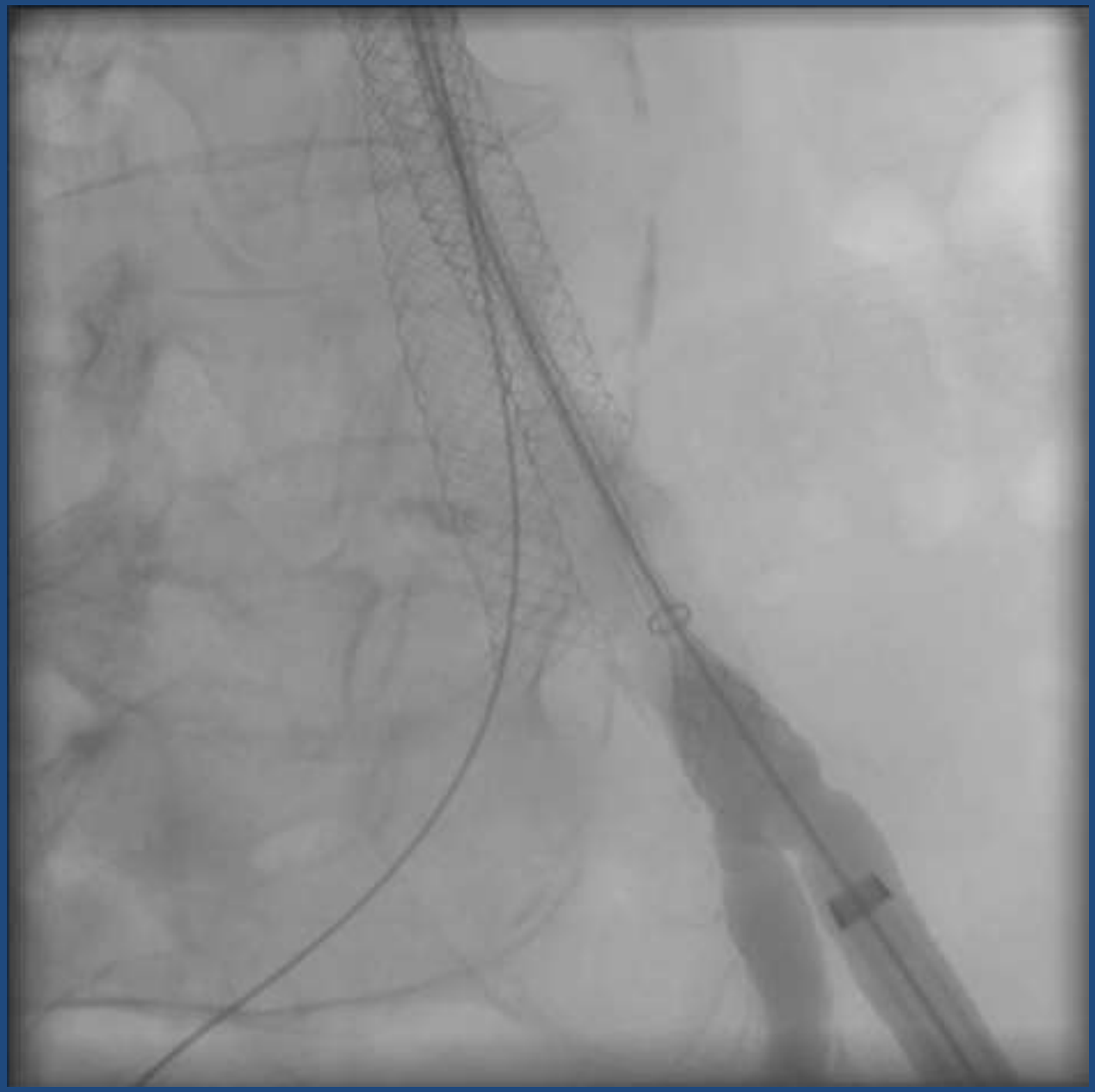


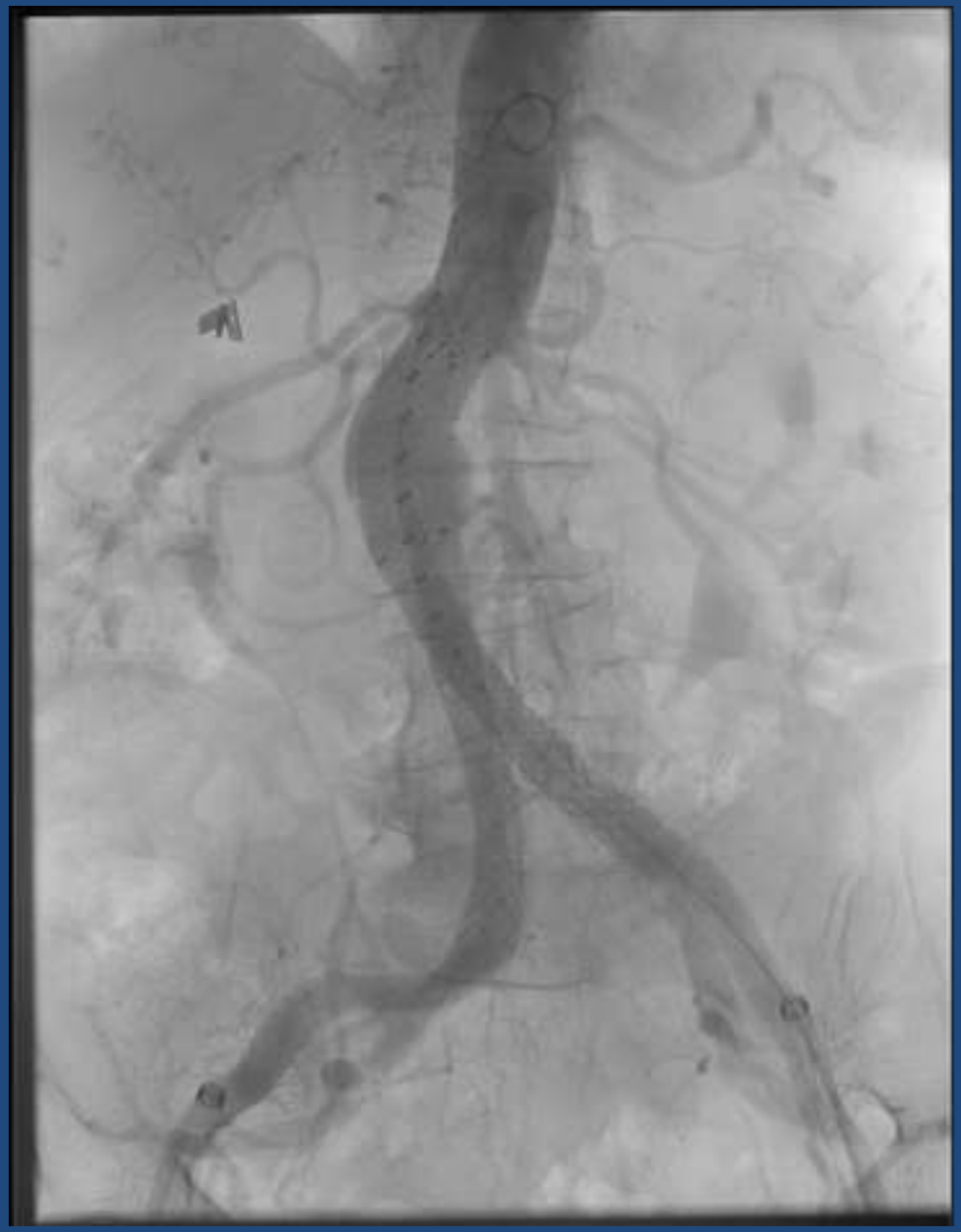


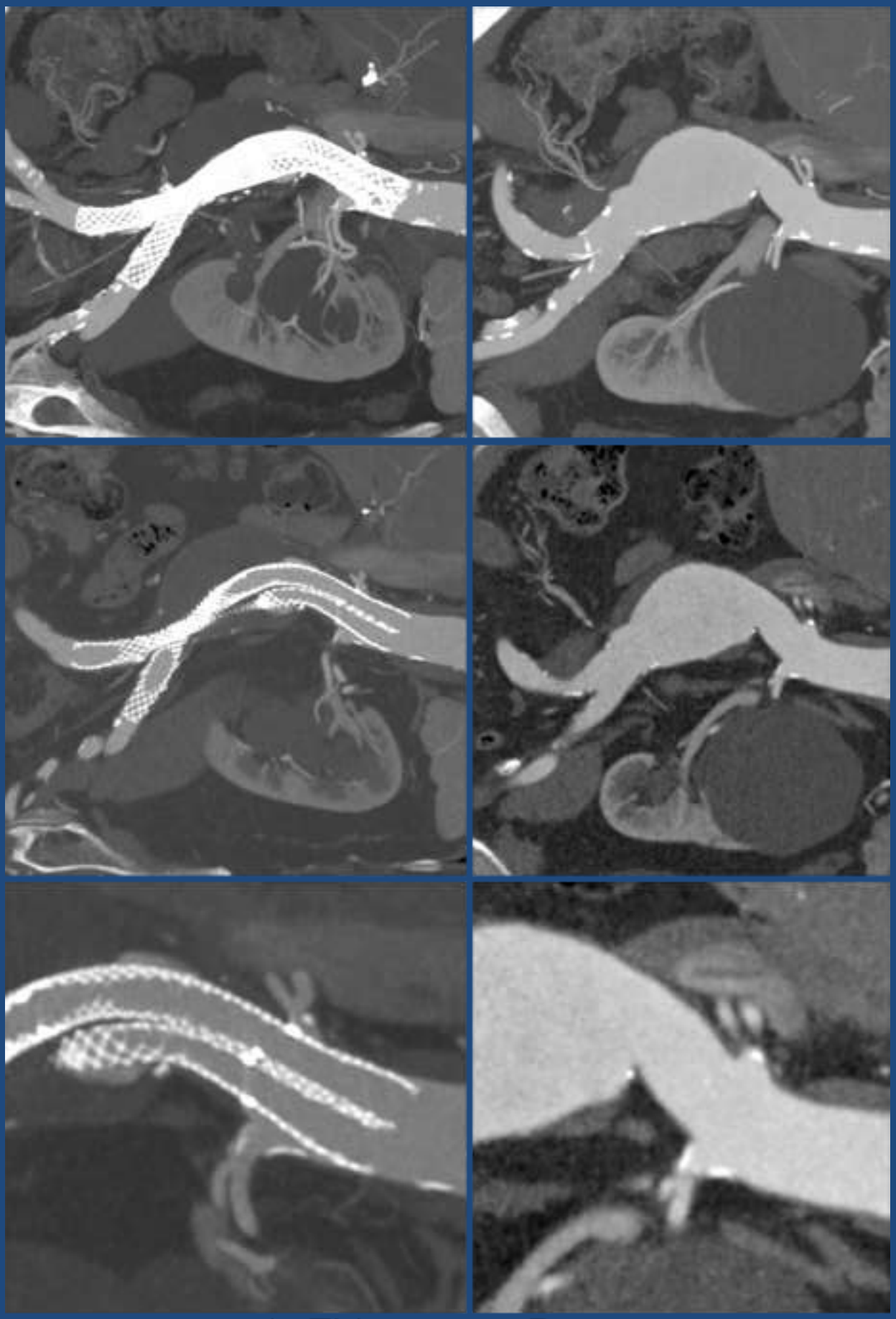




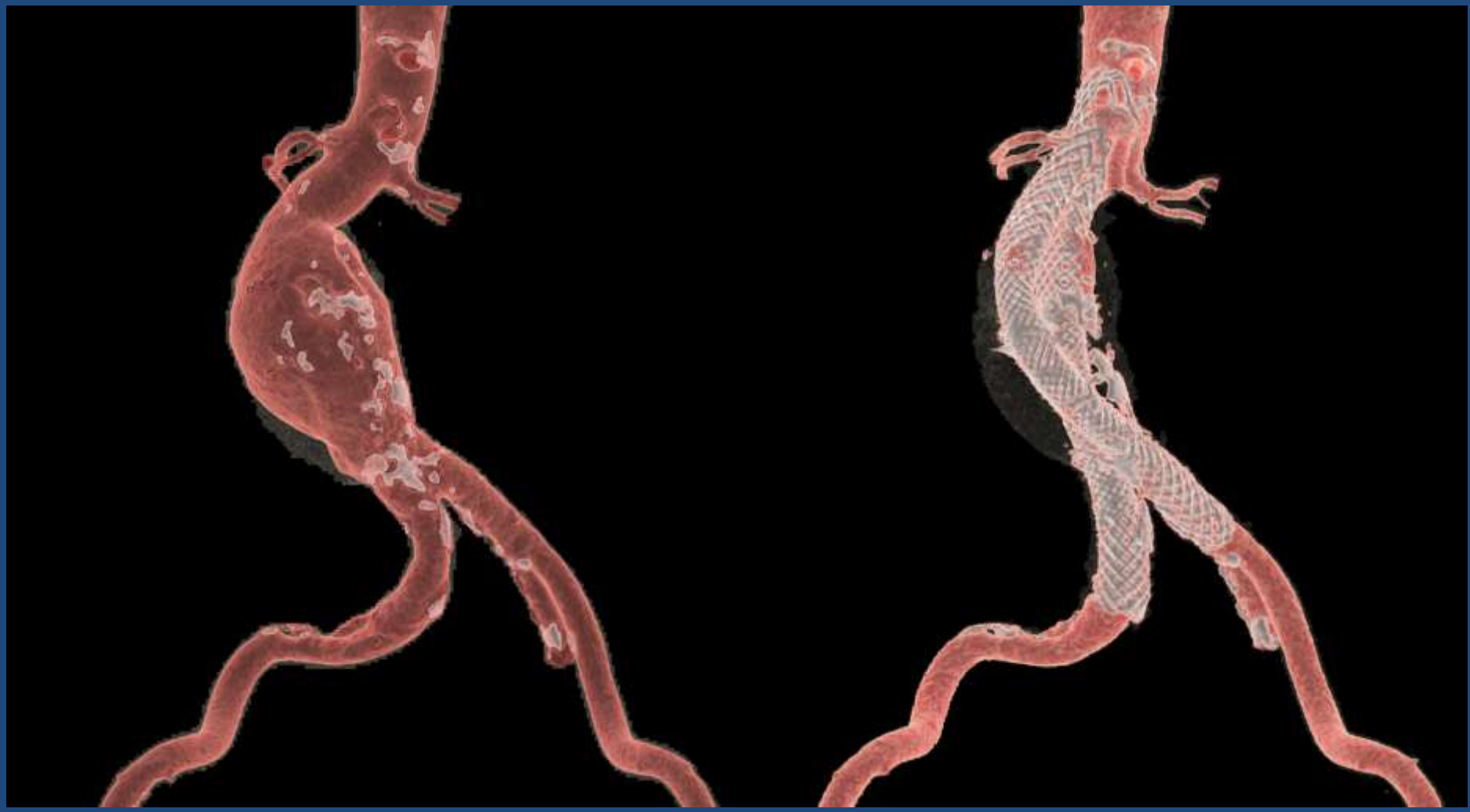








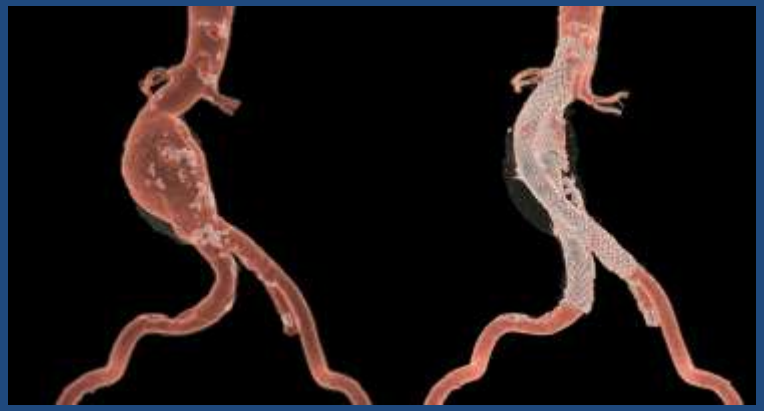
1st month FU Pre treatment



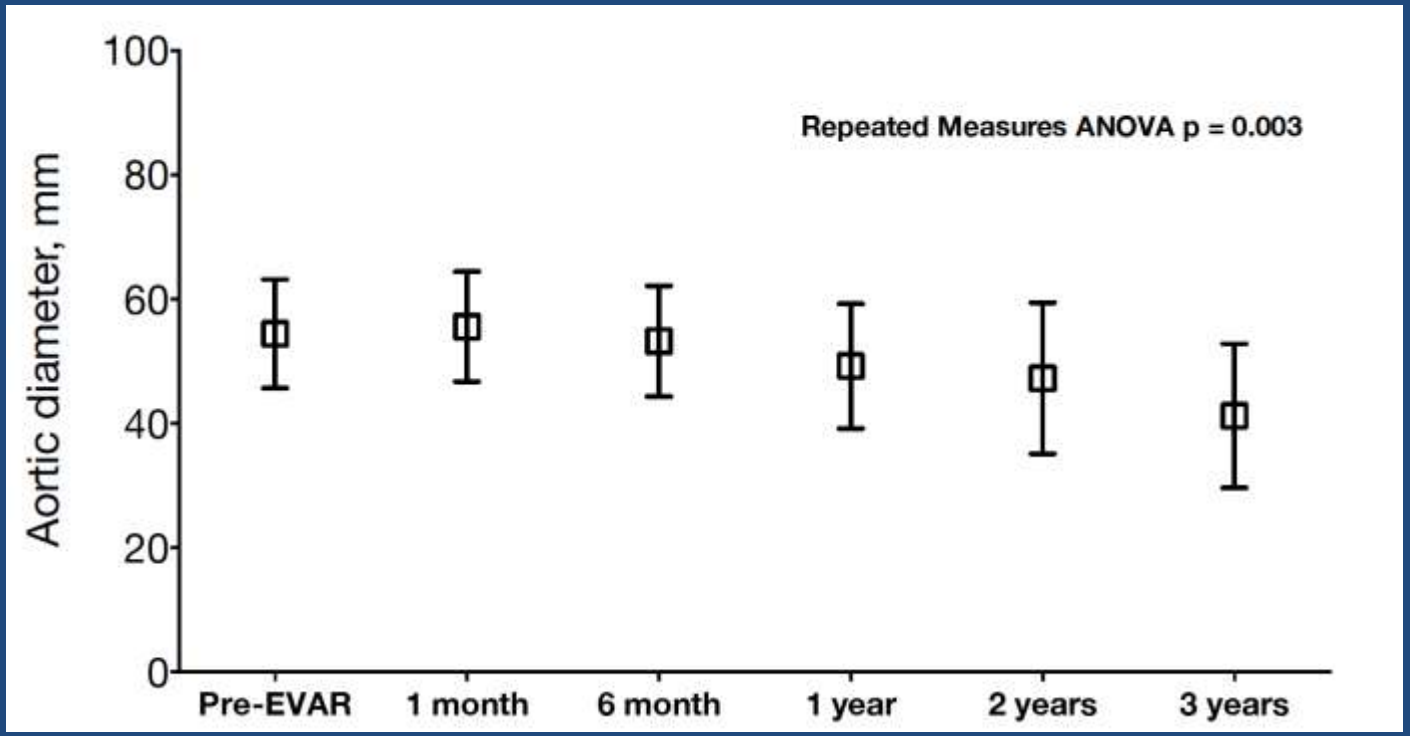
Pre-op

4 Year follow-up

Surveillance Appearances

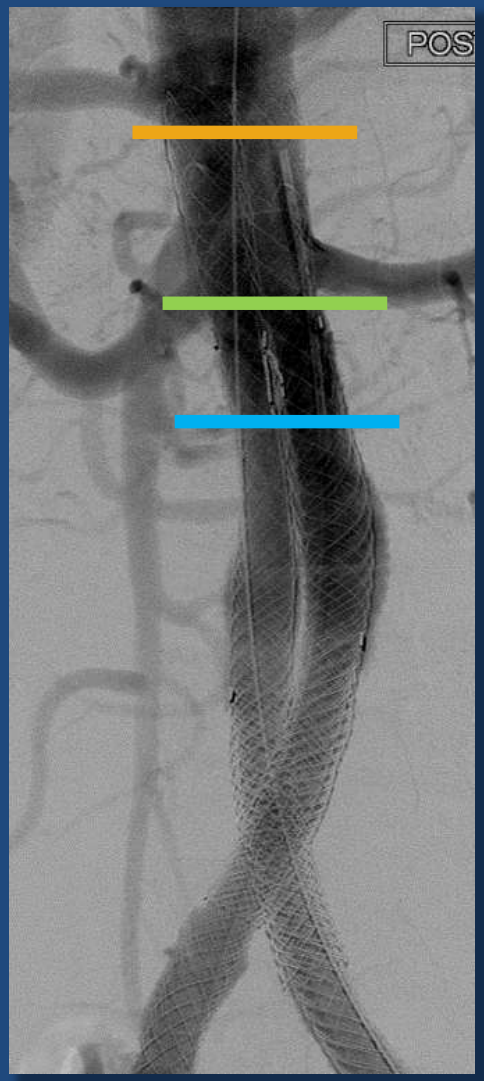


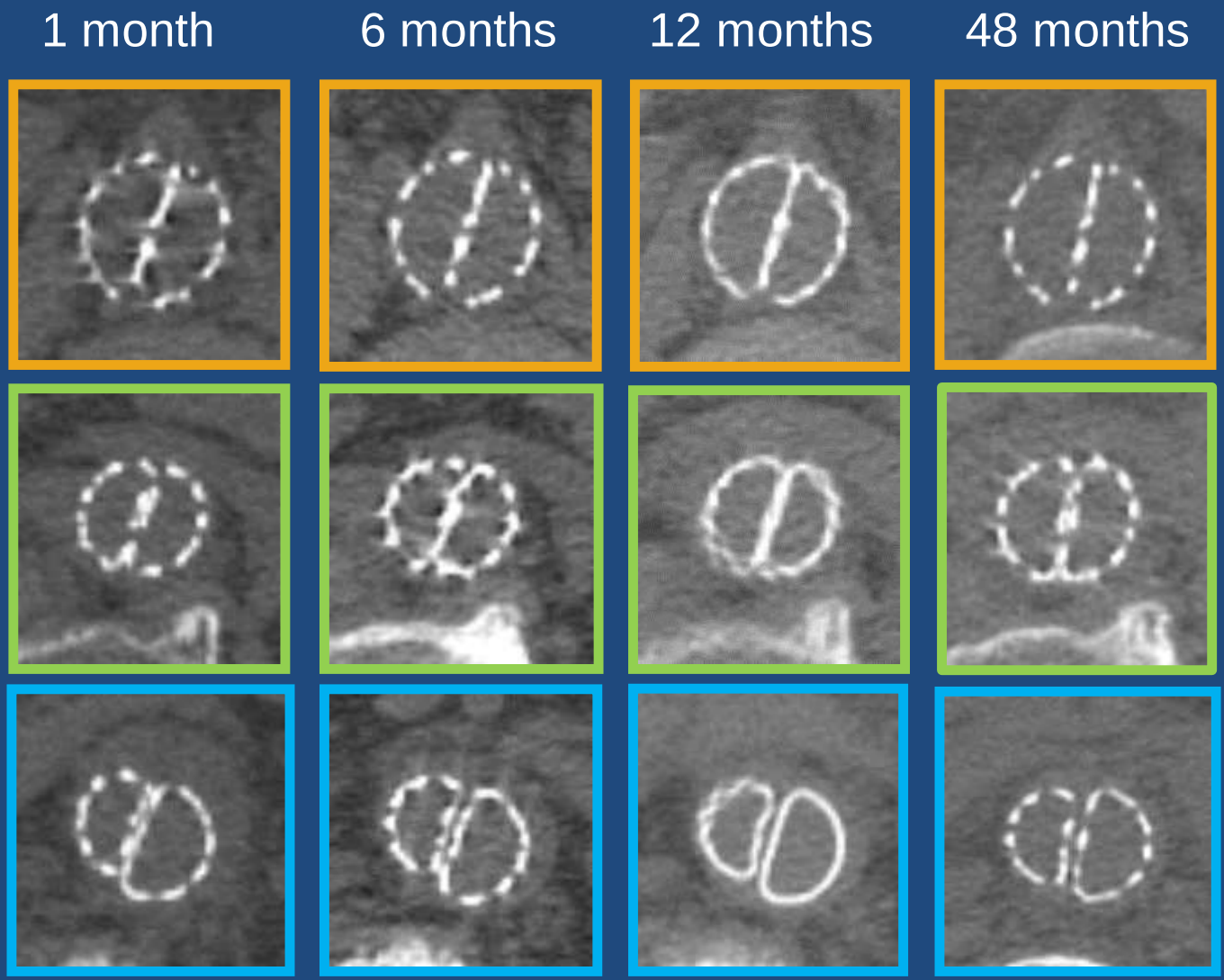
- Majority of patients had sac shrinkage



“D” Endograft Stability

No septal endoleaks





Summary

- The initial safety and effectiveness of the ALTURA device is very encouraging
  - Absence of rupture
  - Pleasing Endoleak and Occlusion performance, attributable to device/patient selection
  - Low rate of device-related secondary procedures

Conclusions

- Predictable, precise and easy to use
- Potential benefits include:
  - Tortuous, short iliacs
  - Narrow bifurcations
  - Offset renals
- Accurate placement due to repositionability
- No cannulation
- Quicker procedures
- Potential option for rAAA
- Potential option for EVAR day surgery patients

There is need for KISSING endografts

Thank You


Islande
Norvegija
Zvedrija
Somija
Latvija
Krievija
Lietuva
Baltkrievija
Polija
Vācija
Nīderlande
Beļģija
Luksemburga
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Ungārija
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Grieķija
Turcija
Alžīrija
Tunisija