Perfect proximal anchorage. Does it solve all the problems?

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On behalf of the ANCHOR trial collaborators

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Disclosures:

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How to manage EVAR with EndoAnchors?

PROPHYLAXIS

Hostile Anatomy

Overcoming concerns for implant stability

- Challenging neck anatomies (e.g. wide, short, conical, angulated)
- Difficult landing (e.g. birdbeaking, close to branched vessels)

Normal Anatomy

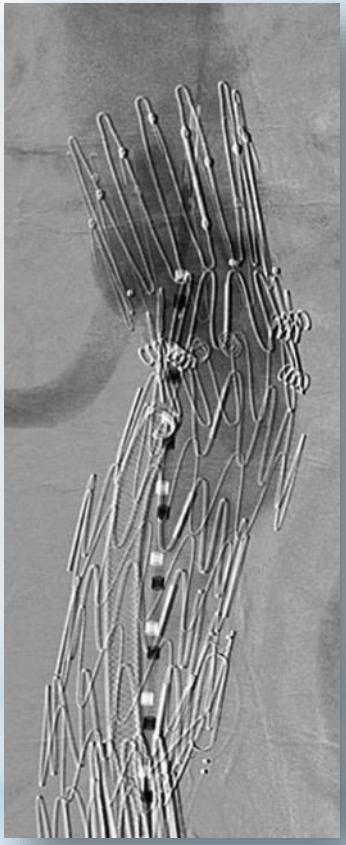
Mitigating risk of re-interventions

- Severe comorbidities that preclude safe re-intervention
- Patients potentially lost during F/U
- Long remaining life expectancy (young pts)

TREATMENT

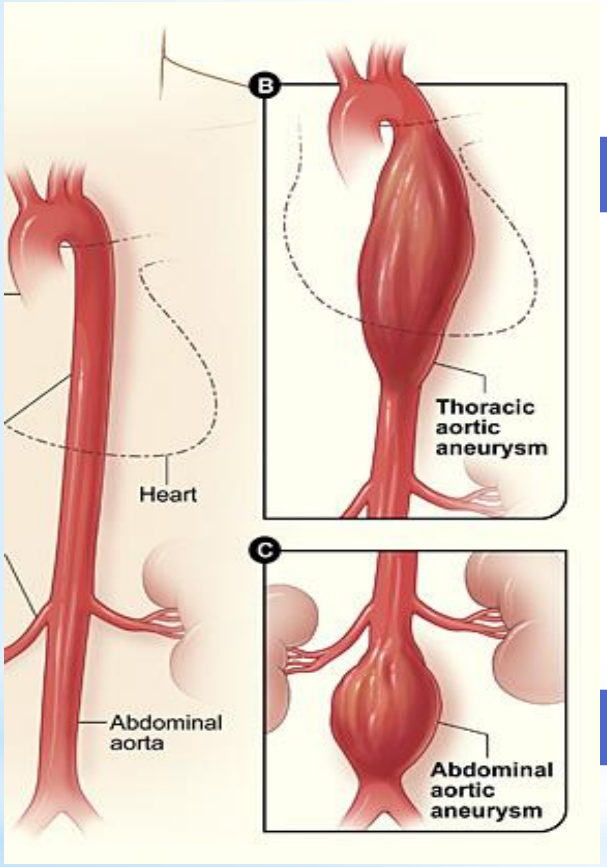
Resolve proximal seal failures

- Targeted sealing of acute type I endoleaks
- Targeted sealing of late type I endoleaks
- Augmented stability in migrated grafts



Case image from Gandhi RT, Katzen BT Treating a Type 1A Endoleak Using EndoAnchors. Endovascular Today March 2012 23:26.

Length of endoguide tip = diameter aortic neck



Aptus™ Heli-FX™ Thoracic EndoAnchor ™System

18Fr OD,
90cm working length

Aptus™ Heli-FX™ Abominal EndoAnchor™ System

16Fr OD,
62cm working length

ANCHOR Registry – Capturing real world-usage

Registry Design	Prospective, observational, international, multi-center, dual-arm Registry
Treatment Arms	"Primary" – Up to 1000 pts, Prophylactic
	"Revision" – Up to 1000 pts, Therapeutic
Enrollment & Duration	Enrollment began 2012 and patients will be followed for 5 years
Follow-up	Per Standard of Care at each center & discretion of Investigator

Registry Principal Investigators	Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital
	US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine

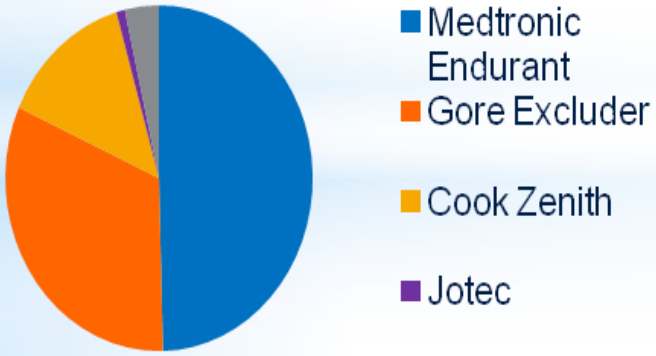
ANCHOR Registry – Enrollment Status (data cut Aug 10, 2015)

ANCHOR Registry
593 Subjects
(74.9% US/25.1% OUS)

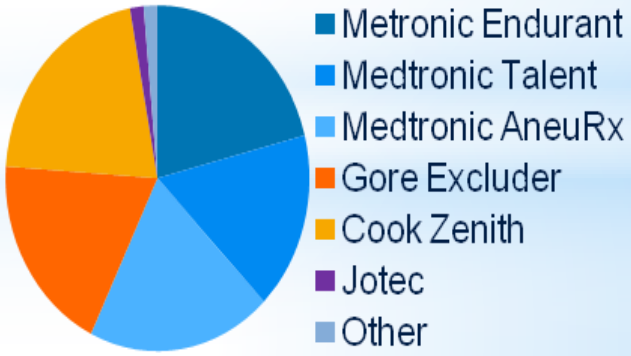
Primary Arm
439 Subjects

Revision Arm
154 Subjects

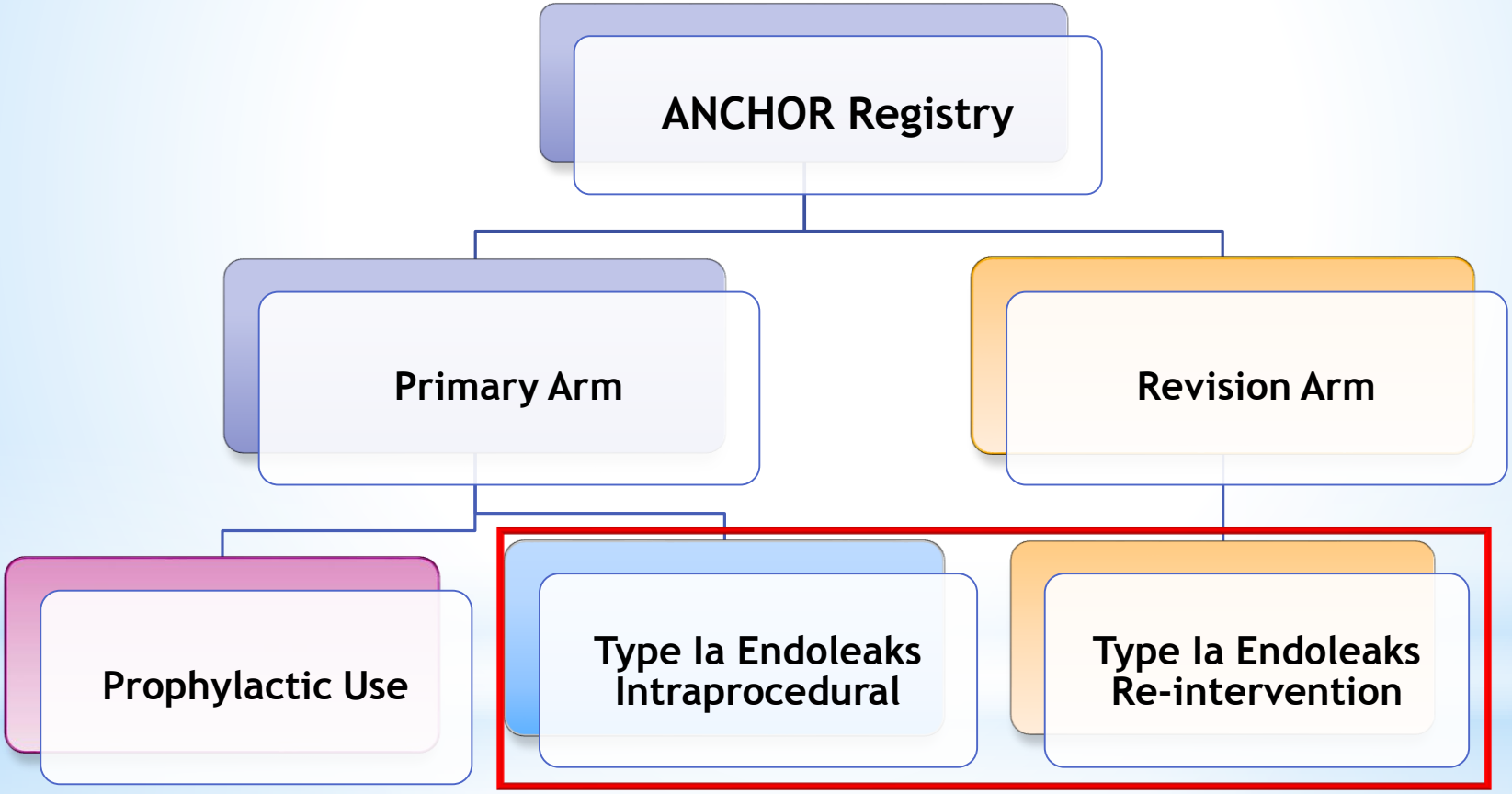
Stent Grafts - Primary Arm



Stent Grafts - Revision Arm



ANCHOR Registry – Therapeutic Use



ANCHOR Registry – Therapeutic Use for Proximal ELs

Anatomic Index	All	Primary	Revision
Number with Baseline CT Scans	161	106	55
Aneurysm Diameter (mm)	61.1	56.6	65.9
Proximal Neck Length (mm)	**16.2**	**16.8**	**14.8**
Suprarenal Diameter (mm)	27.8	27.1	29.1
Infrarenal Diameter (mm)	**27.2**	**26.1**	**29.2**
Suprarenal Angulation (degrees)	16	17.7	12.9
Infrarenal Angulation (degrees)	36	37.8	34.0
Neck Thrombus Thickness (mm)	0.6	0.5	0.9
Neck Calcium Thickness (mm)	1.0	1.3	0.4
Conical Neck (Subjects >10%/10mm)	**42.2%**	**38.7%**	**49.1%**
Hostile Necks	**74.5%**	**73.6%**	**76.4%**

ANCHOR Registry – Therapeutic Use for Proximal ELs

Details of Index Procedure	Primary	Revision
Duration of Procedure (min)	159	158
Time to Implant EndoAnchors (min)	**20**	**23**
Number of EndoAnchors	**6.1**	**7.7**
Fluoroscopy Time (min)	37	33
Technical Success (Site-Reported)	**95.7%**	**93.4%**
Procedural Success (Site-Reported)	85.1%	82.8%
ICU Admission	25.5%	32.0%
Length of Hospitalization (days)	3.9	6.8

ANCHOR Registry – Therapeutic Use for Proximal ELs

Adjunctive Devices	Primary (N=141)	Revision (N=122)	All (N=263)
Aortic Extender Cuff	25 (17.7%)	62 (50.8%)	87 (33.1%)
Giant bare stent (e.g. Palmaz)	2 (1.4%)	4 (3.3%)	6 (2.3%)
Cuff + Palmaz	0 (0%)	2 (0.8%)	2 (0.8%)
Chimney	0 (0%)	2 (0.8%)	2 (0.8%)
Fenestrated	0 (0%)	1 (0.4%)	1 (0.4%)
Debranching	0 (0%)	1 (0.4%)	1 (0.4%)
EndoAnchors alone	114 (80.9%)	50 (41.0%)	164 (62.4%)

ANCHOR Registry – Therapeutic Use for Proximal ELs

Adverse Events *Mean Follow-Up 18.9m*	Primary (N=141)			Revision (N=122)		
	Events	Subjects With Events		Events	Subjects With Events	
Adverse Events	165	63	45.0%	209	78	63.9%
Serious Adverse Events	93	44	31.4%	107	54	44.3%
Procedure-Related SAE	14	9	6.4%	11	9	7.4%
Endograft-Related SAE	0	0	0.0%	4	3	2.5%
EndoAnchor-Related SAE	0	0	0.0%	3	2	1.6%
Aneurysm-Related SAE	12	3	2.1%	12	9	7.4%
Unrelated SAE	61	32	22.9%	55	36	29.5%
Rupture of AAA	0	0	0.0%	1	1	0.8%
All-Cause Mortality	6	6	4.3%	6	6	4.9%

Persistent / recurrent type IA endoleaks

CORE LAB
MEAN CT FOLLOW-UP 10.4 MONTHS

Cohort	All Cases		
	1a ELs	CTs	%
All	24	142	16.9%
Primary	3	76	3.9%
Revision	21	66	31.8%

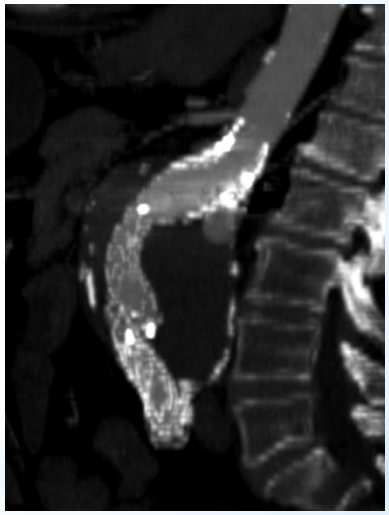
When Endoanchors not to use

Lack of EndoAnchor penetration in aortic tissue may increase risk of developing/re-developing type I endoleaks

CoreLab assessment of etiology of residual type 1A after EndoAnchor placement (N =17)

Reason for persistent type 1a endoleak	Number of cases
Calcified Rim	5
Gap between graft and aortic wall	6
EndoAnchor deployed above graft fabric	3
EndoAnchor deployed in aneurysm sac	4
EndoAnchor not oriented perpendicular to graft wall	2

4 subjects had two reasons identified for persistent type 1a endoleak



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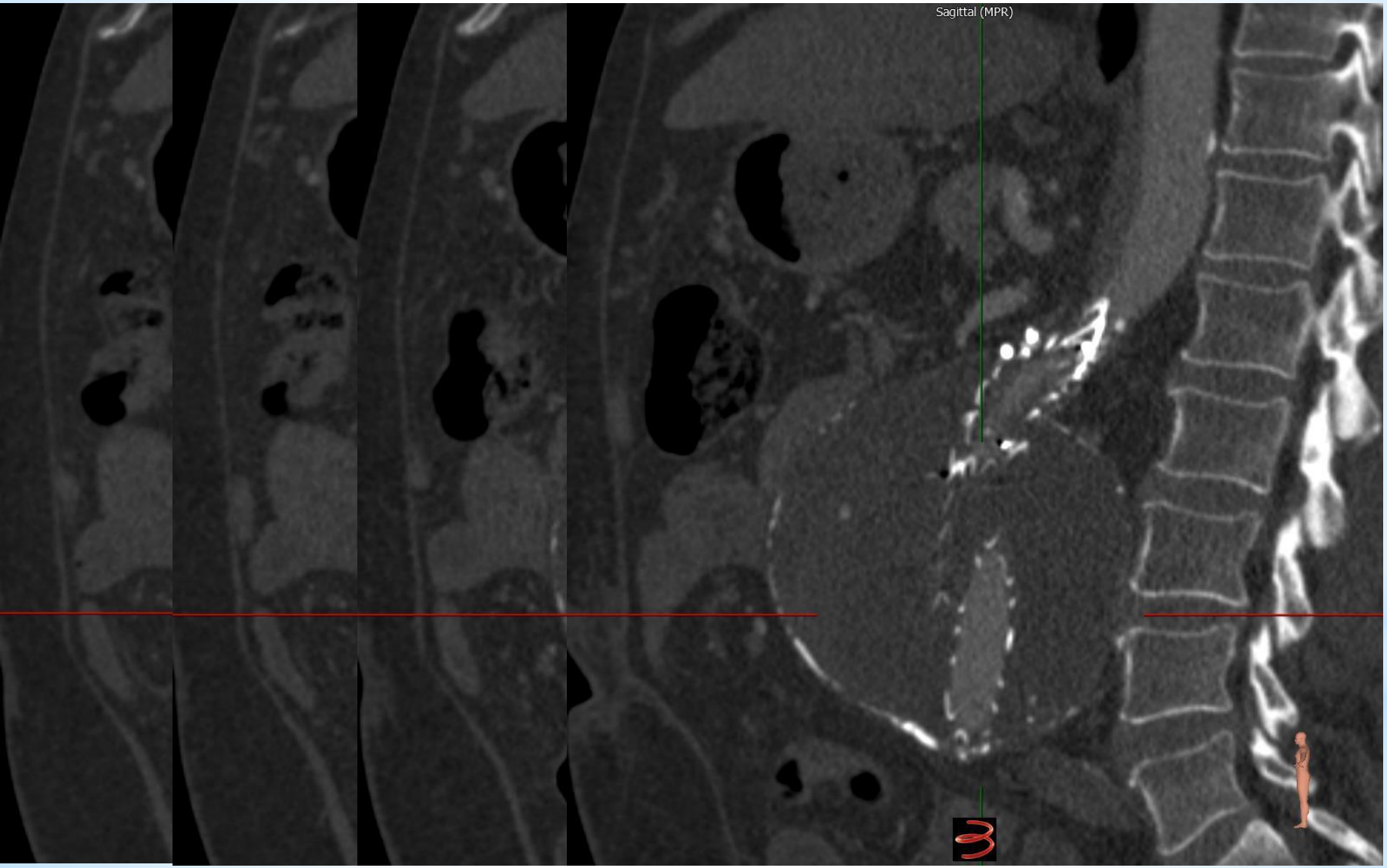

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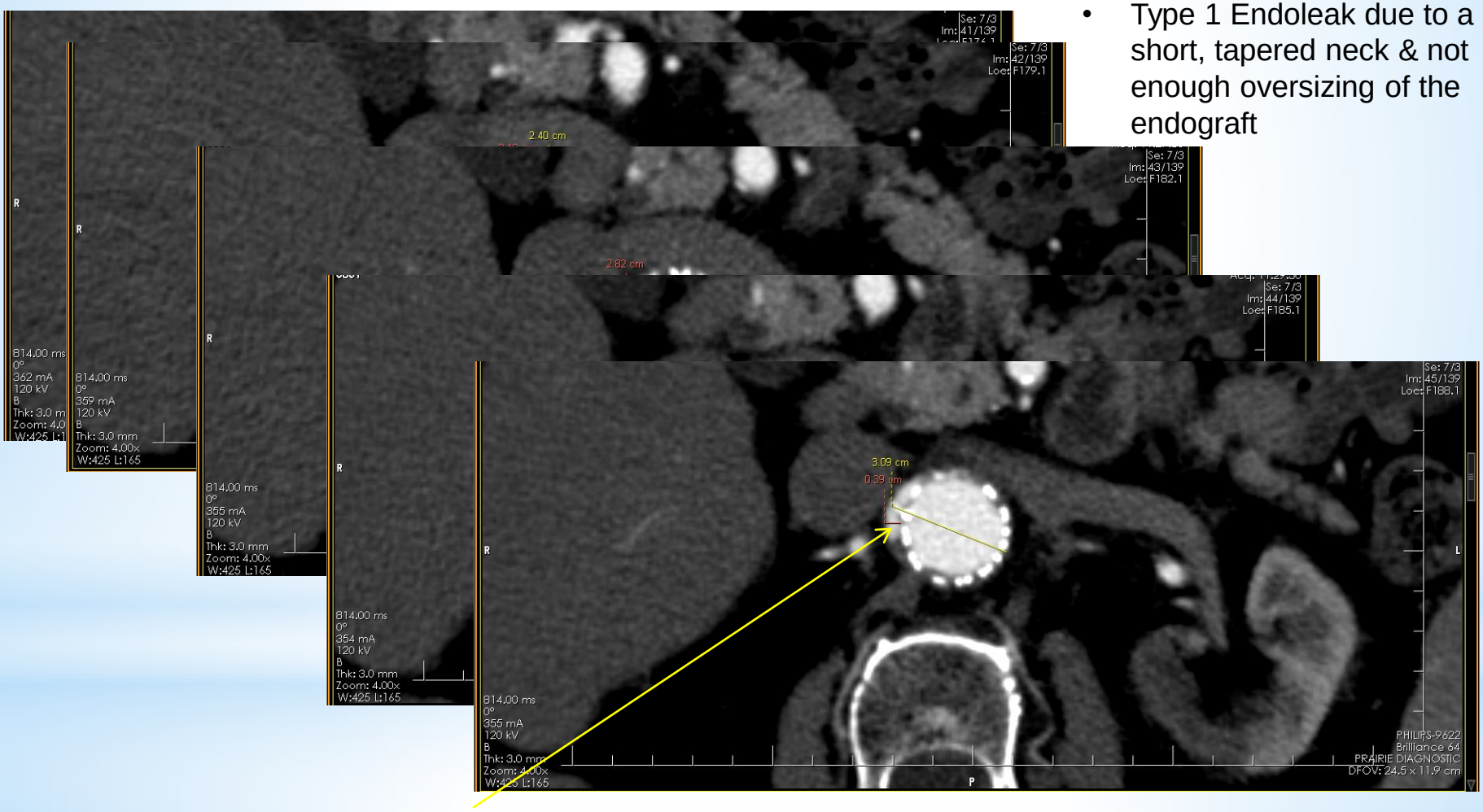
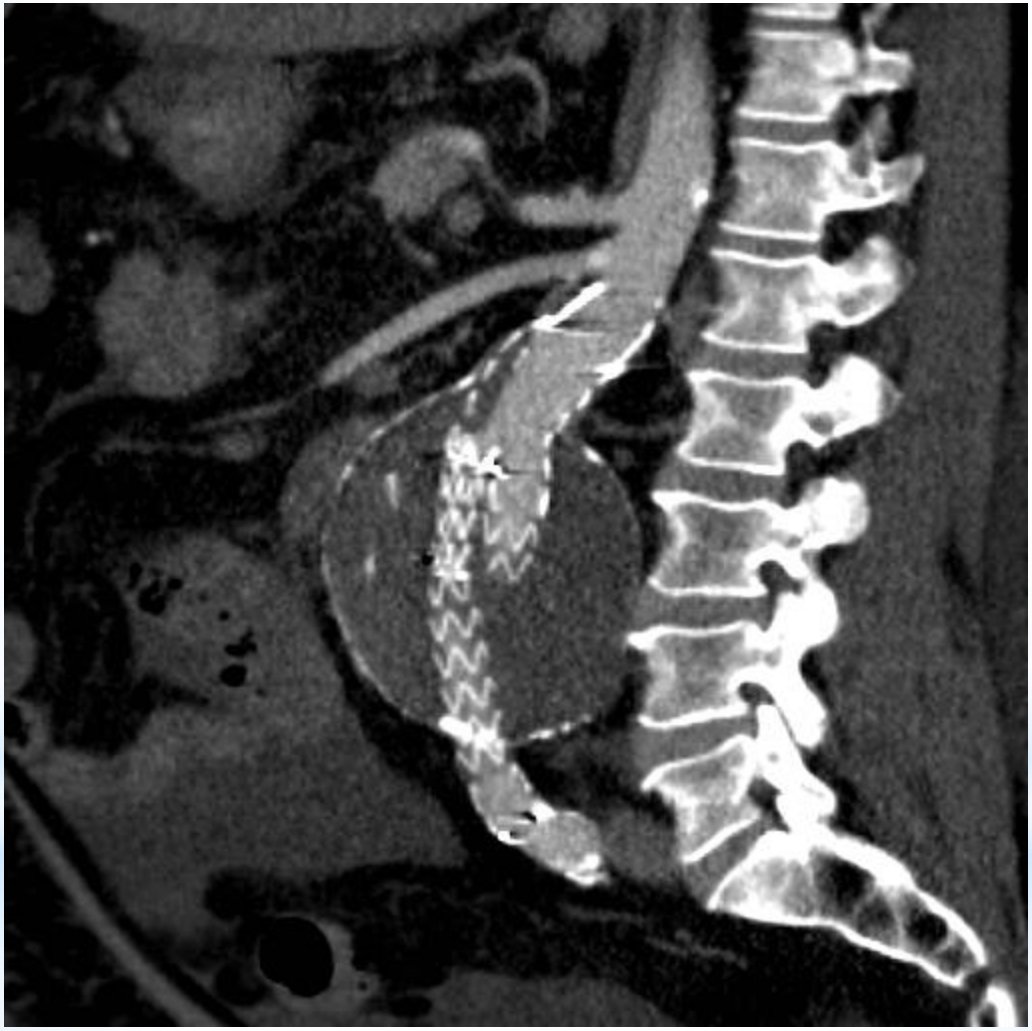


- Type 1 Endoleak due to a short, tapered neck & not enough oversizing of the endograft

- A 4mm gap where the neck is dilated beyond the graft. Anchors were not used because the gap was too wide for the anchors to penetrate the adventitia

Case #1: type IA endoleak 2 years post-implant



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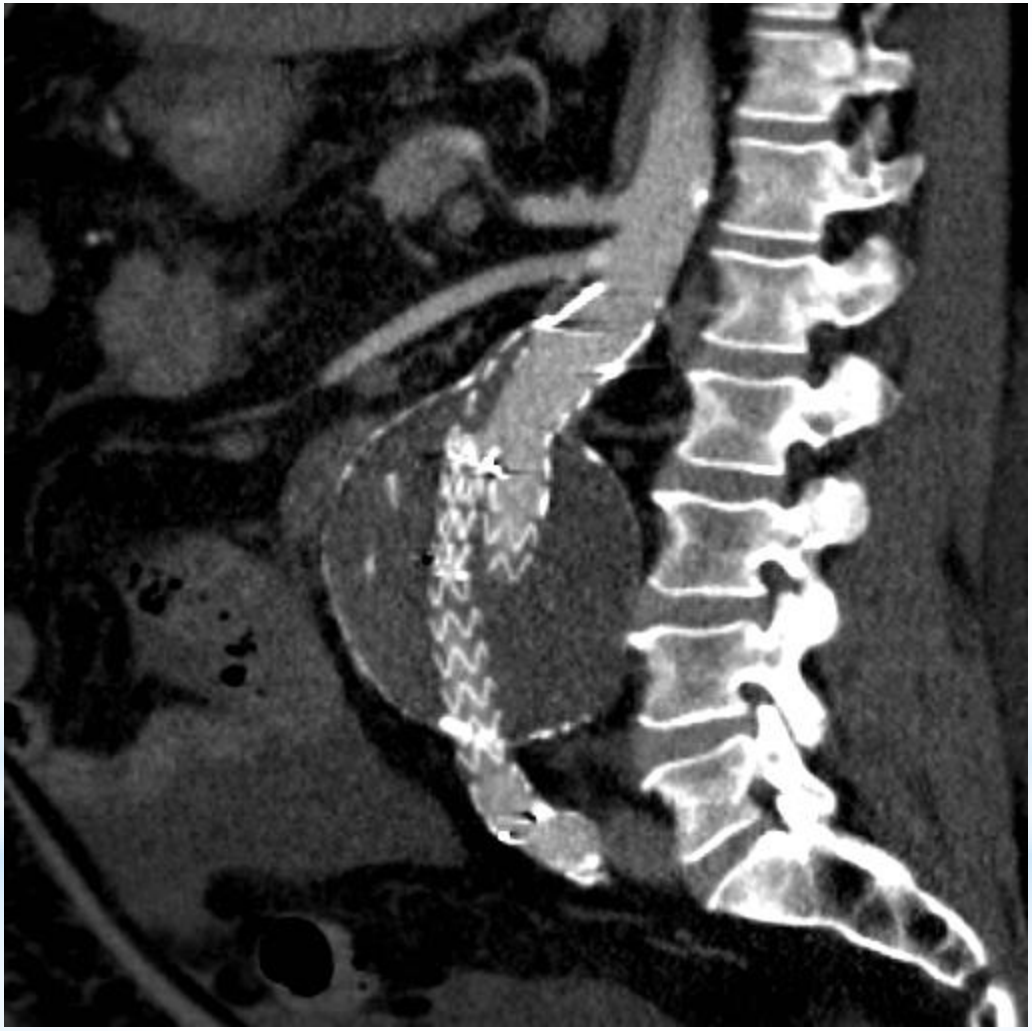

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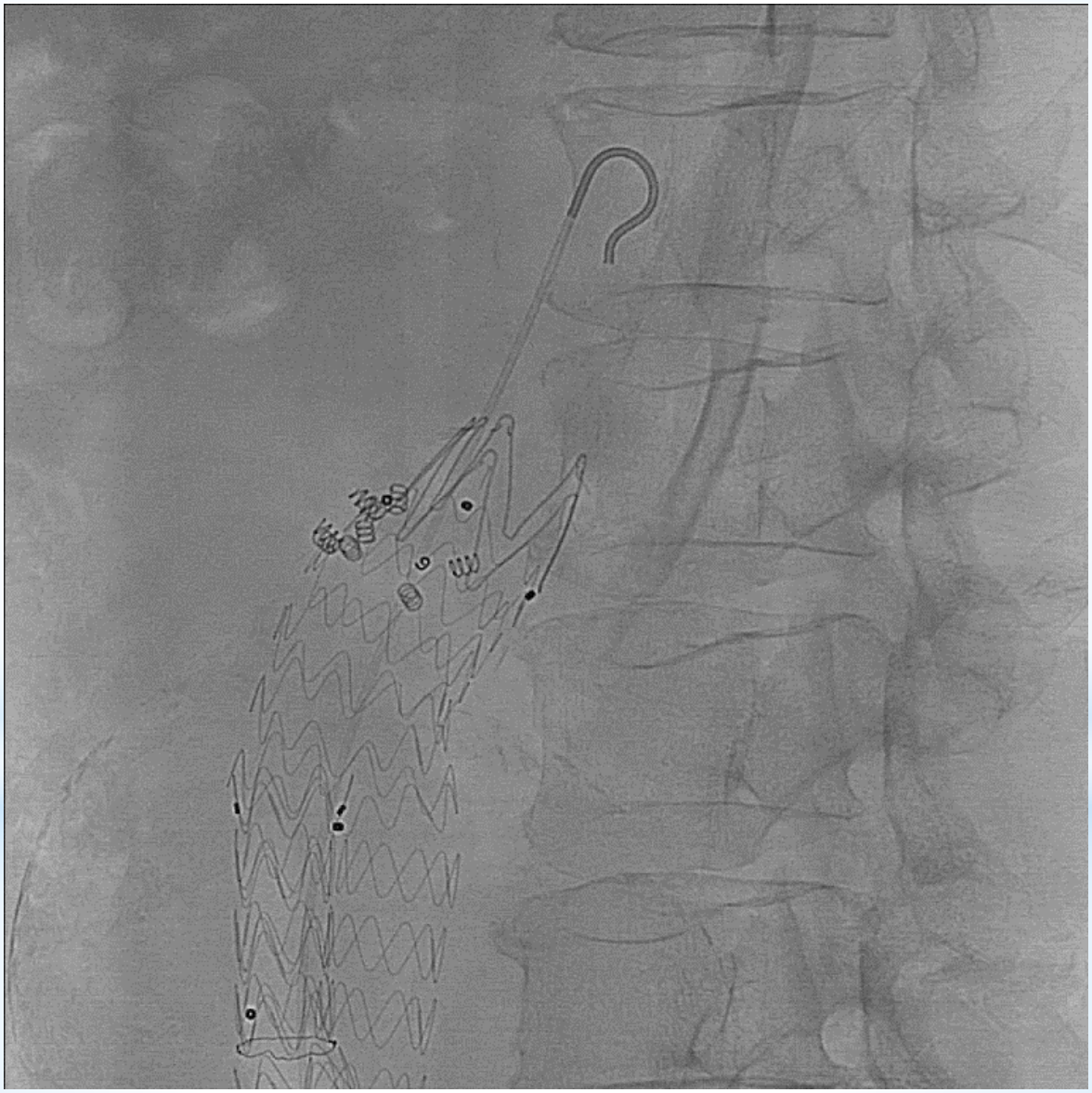
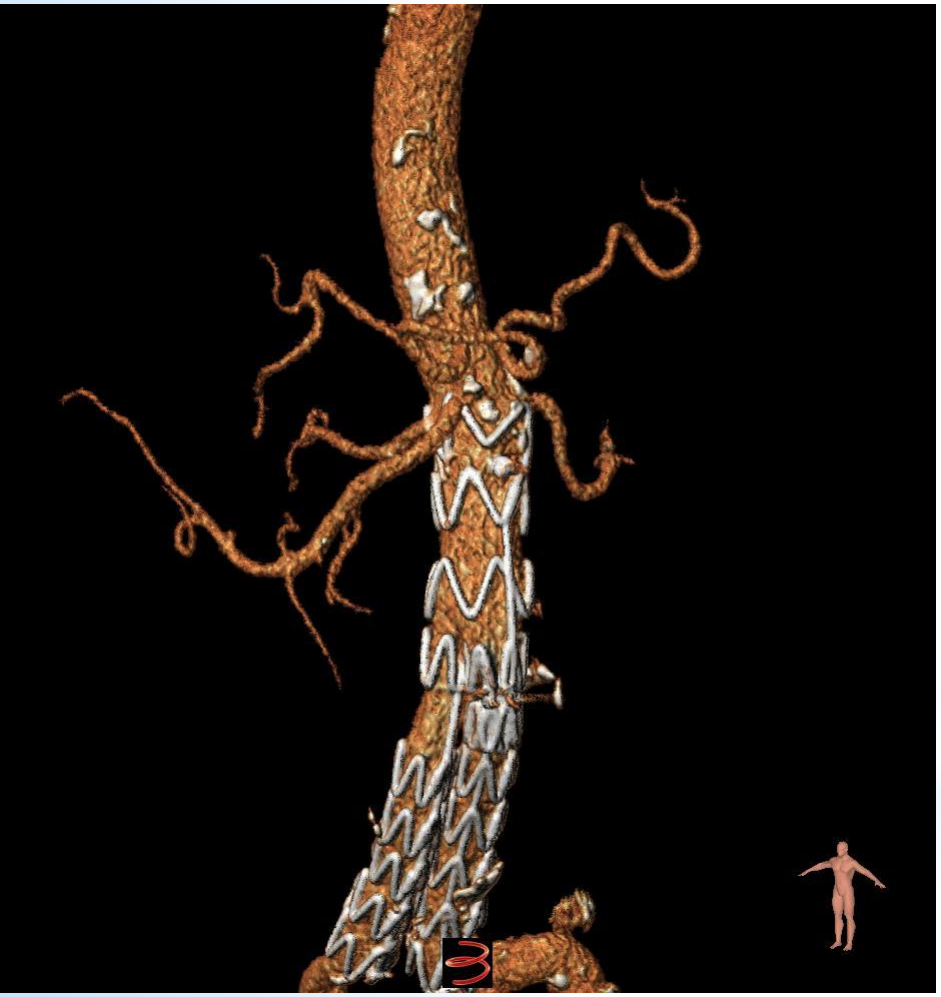
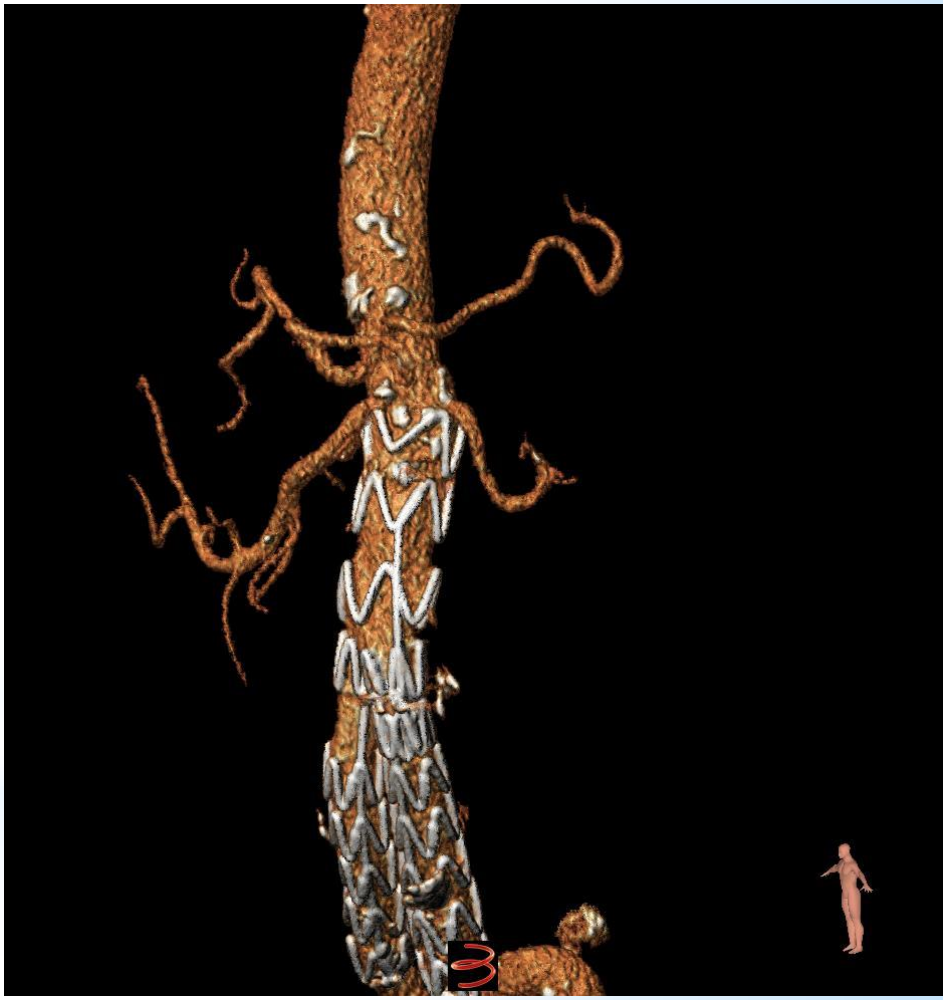


Case #2: migrated Talent endograft





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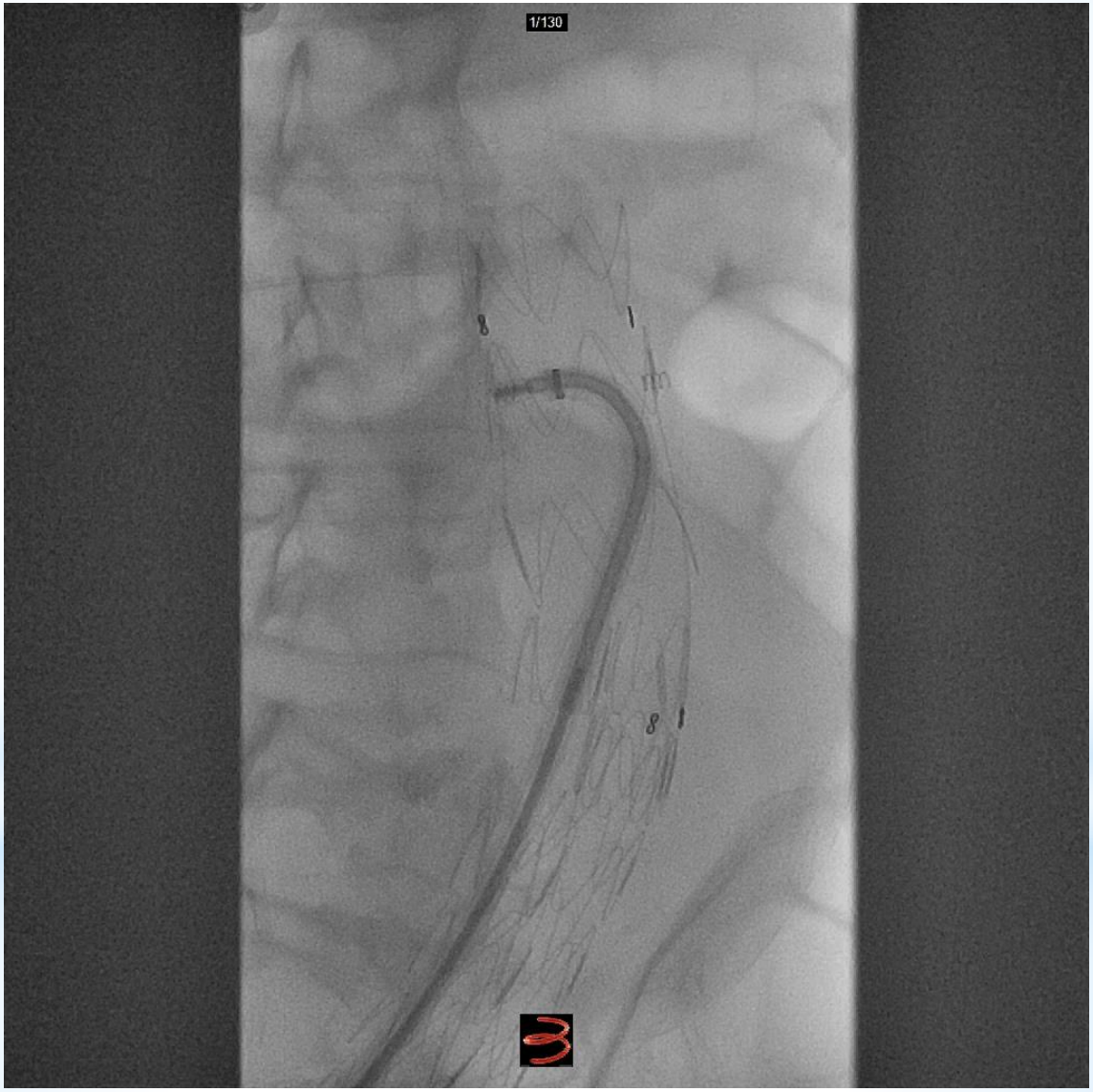

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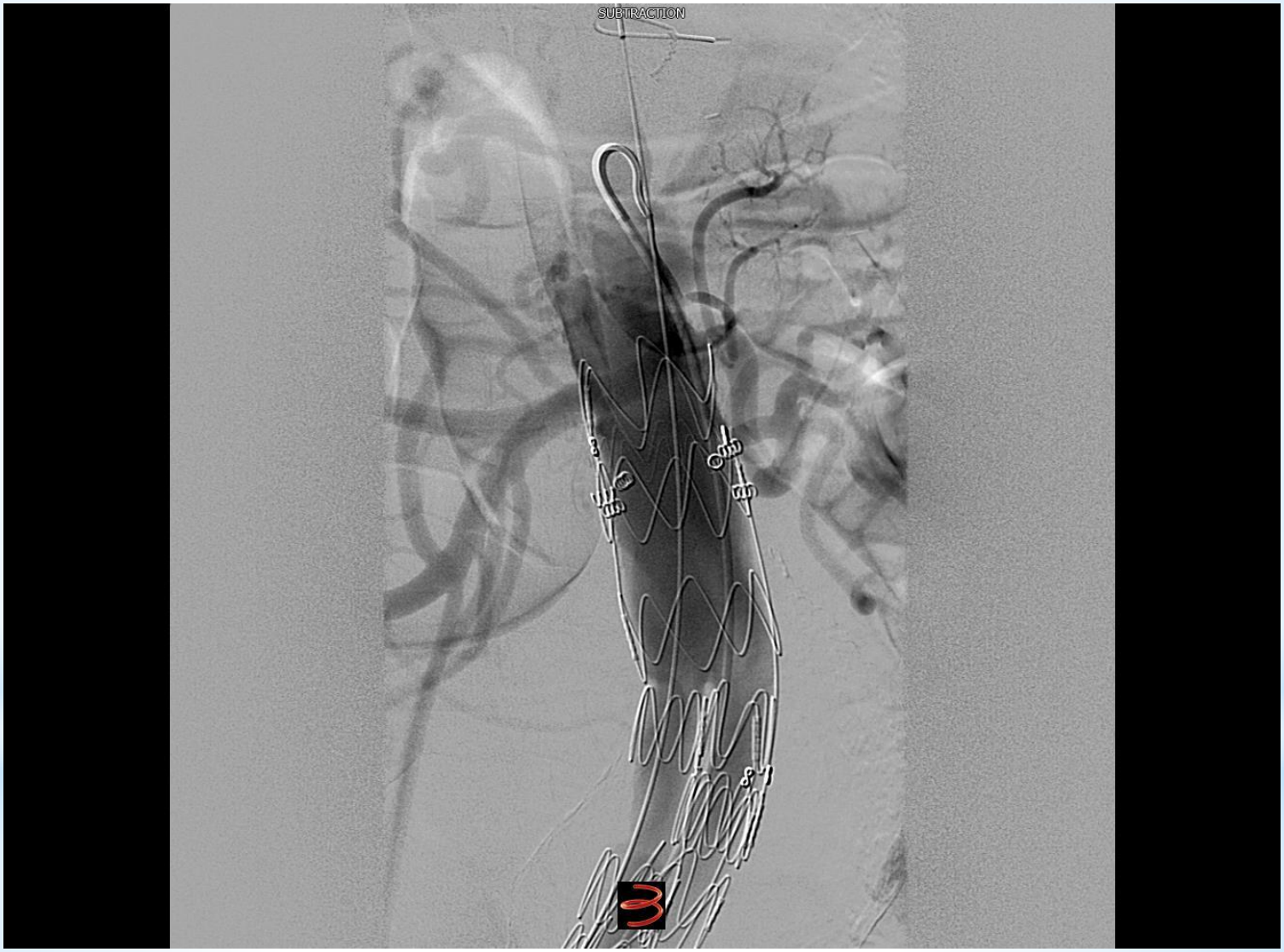

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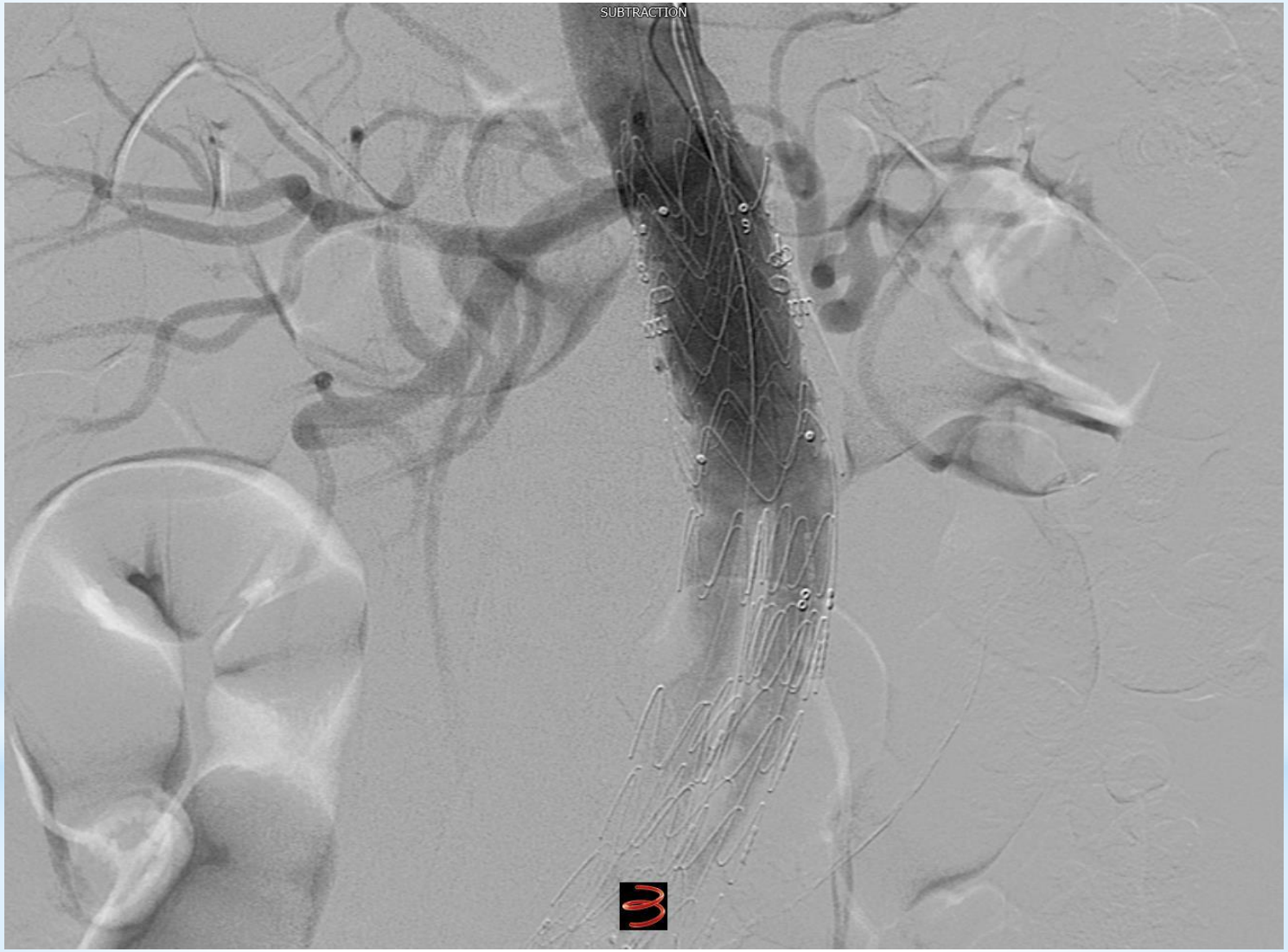

Case #3: type IA endoleak: cuff → Endoanchors

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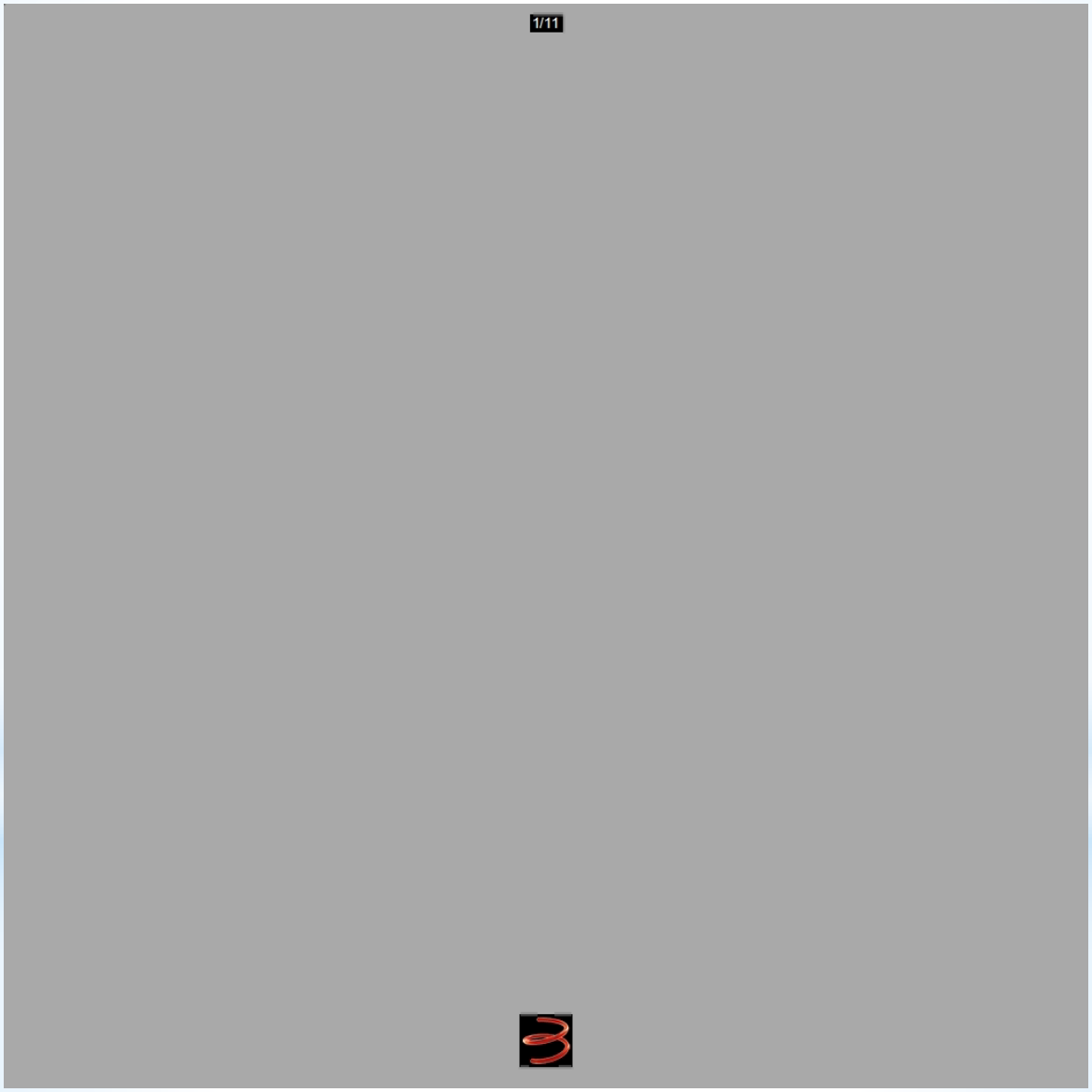

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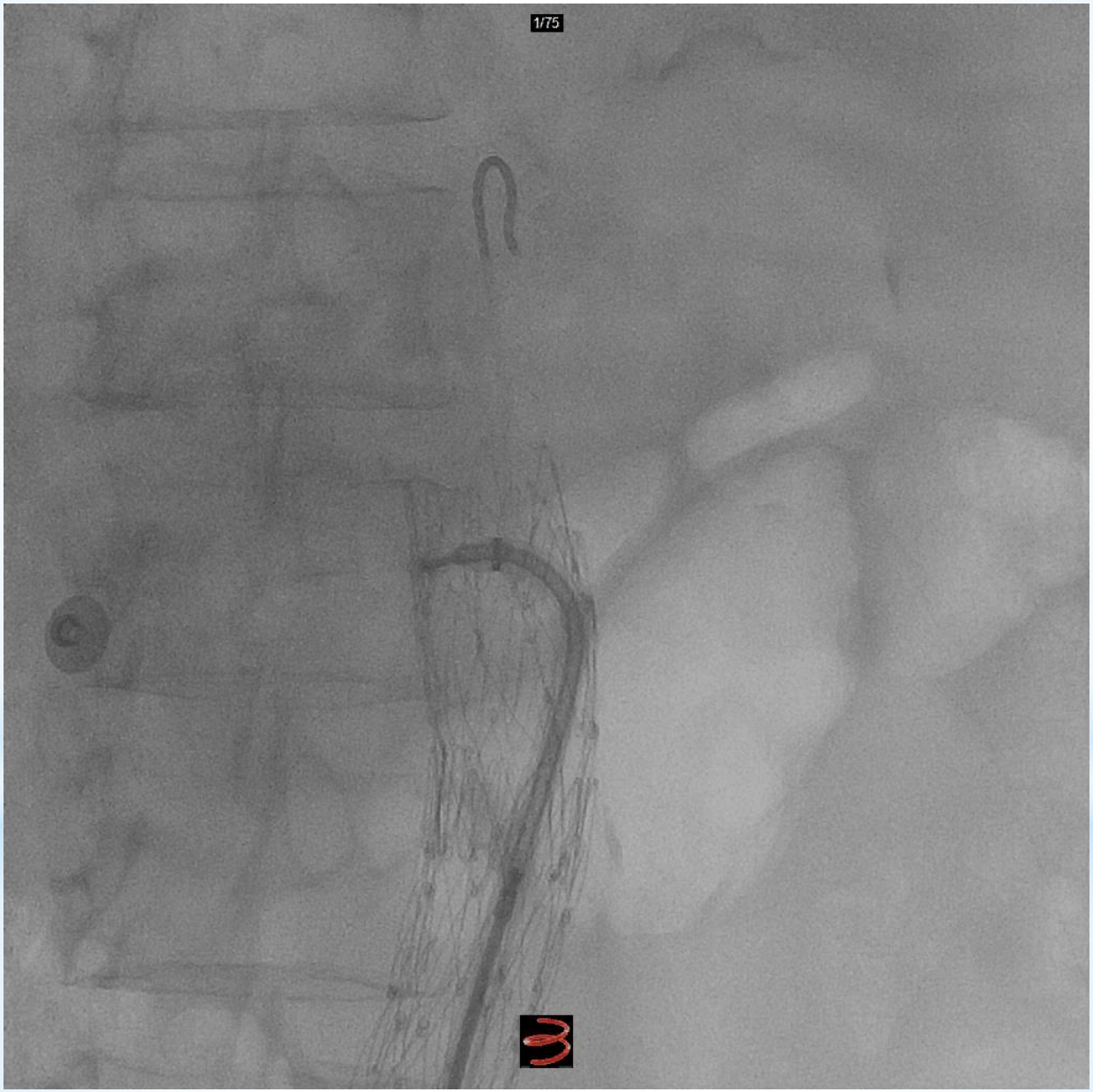

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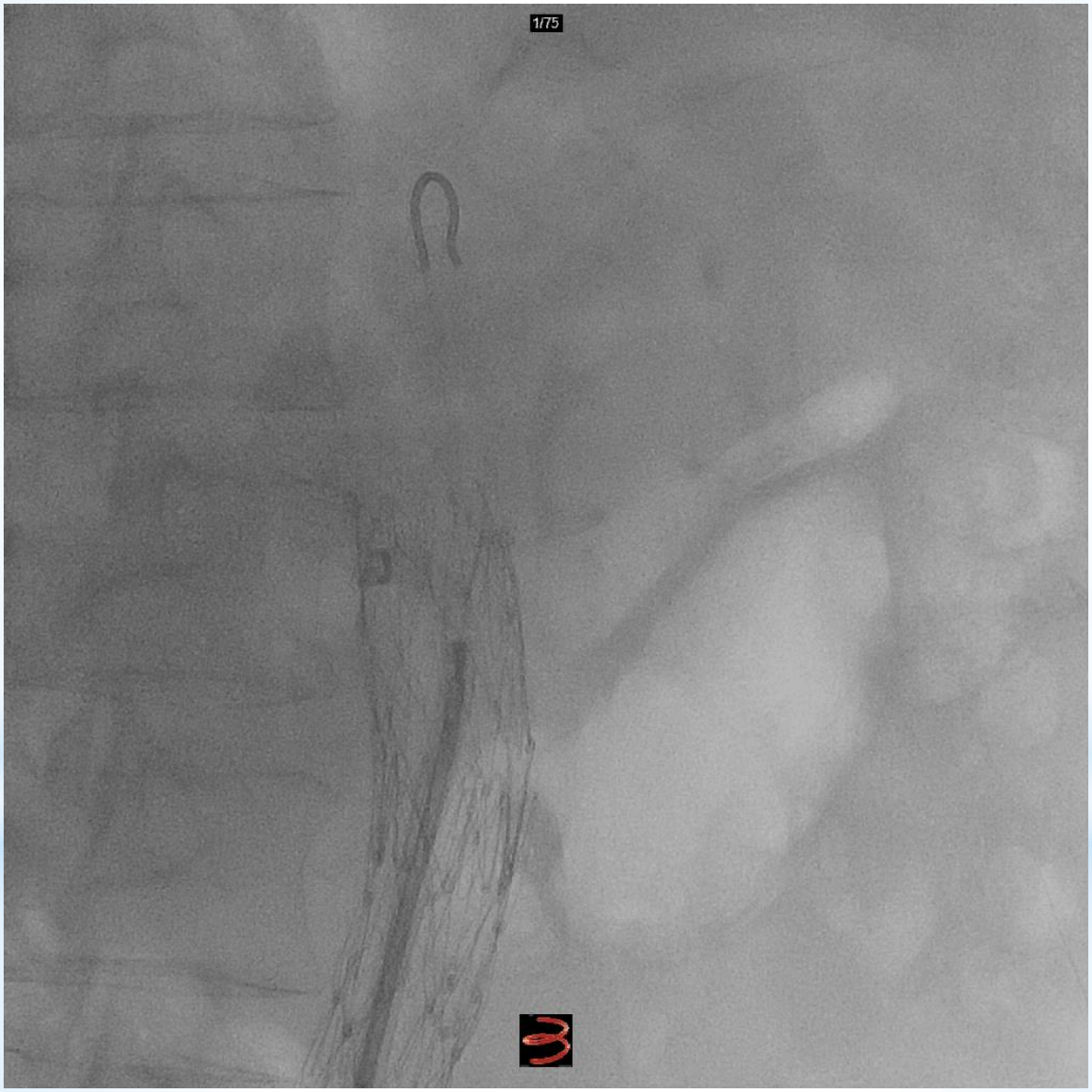
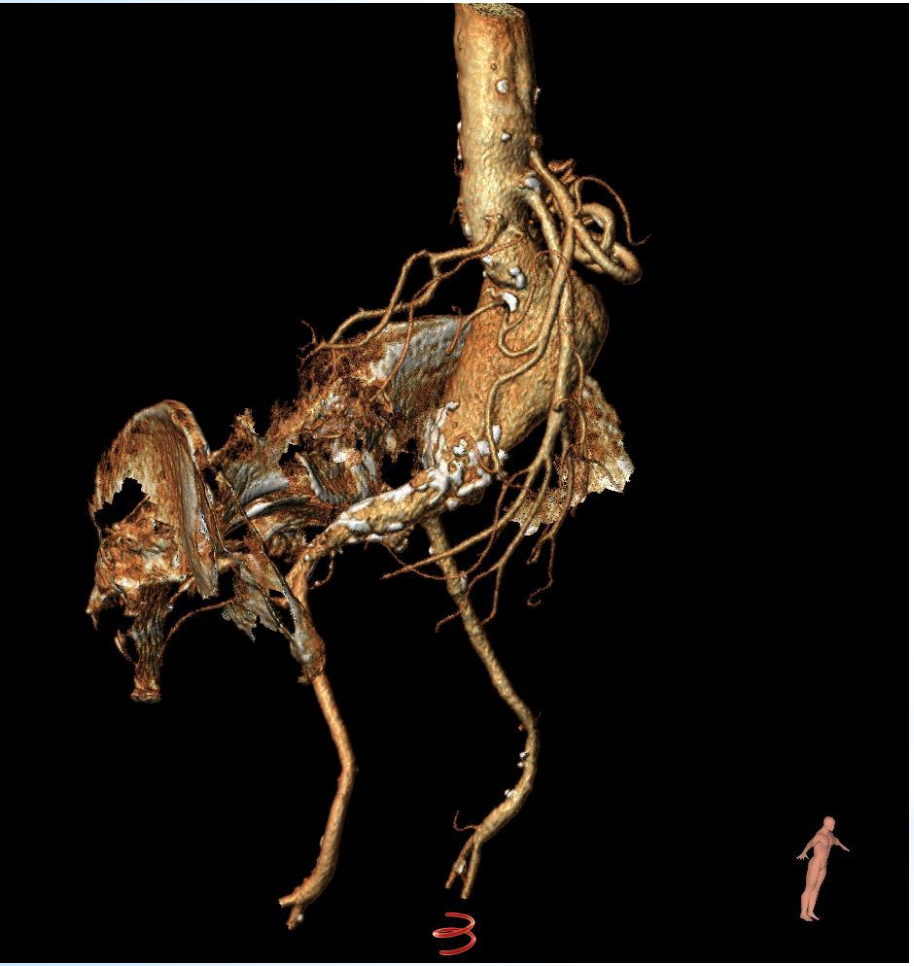
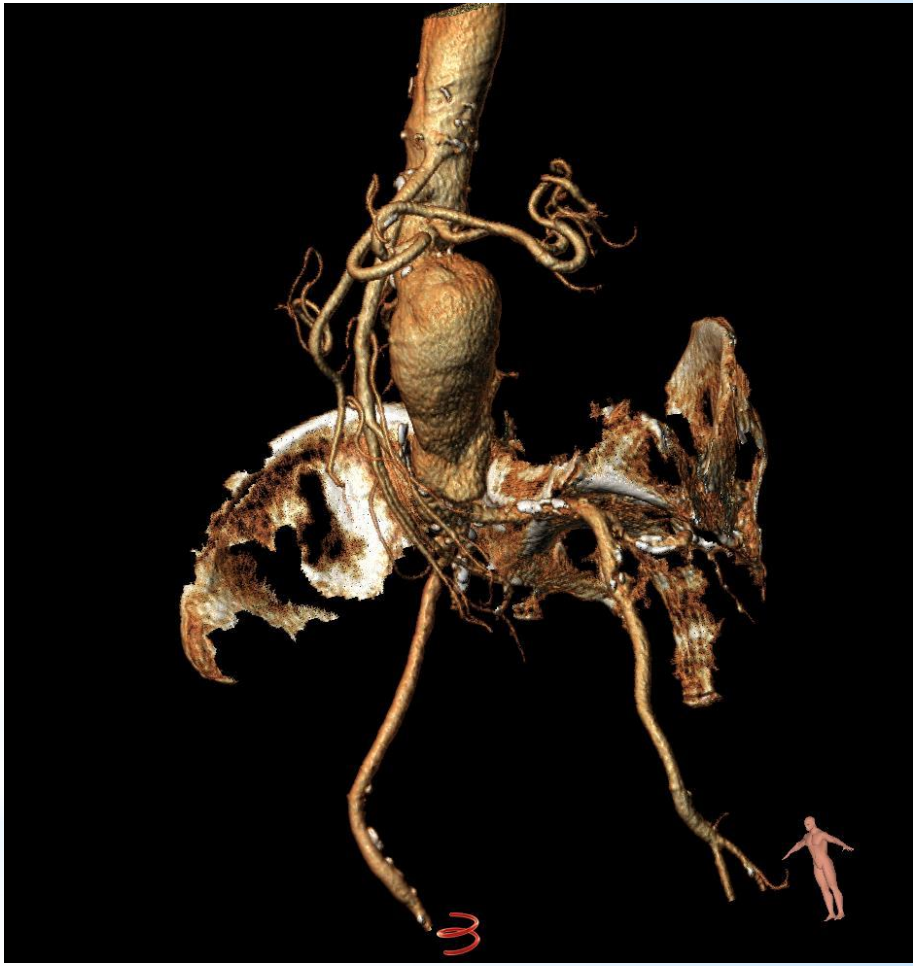


Case #3: type IA endoleak: cuff → Endoanchors

Case #4: acute type IA endoleak





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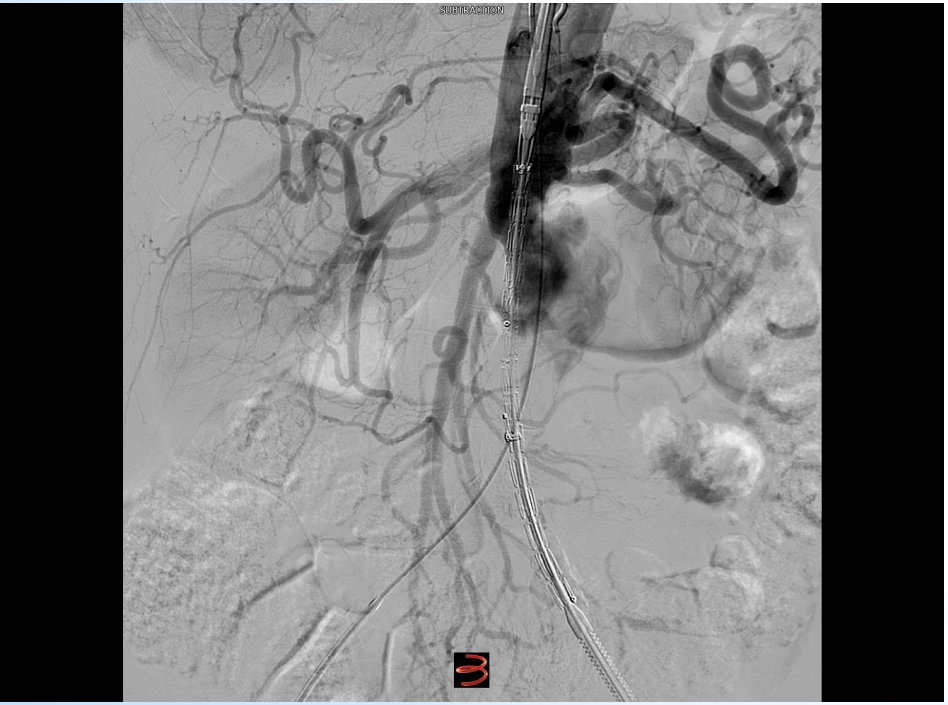

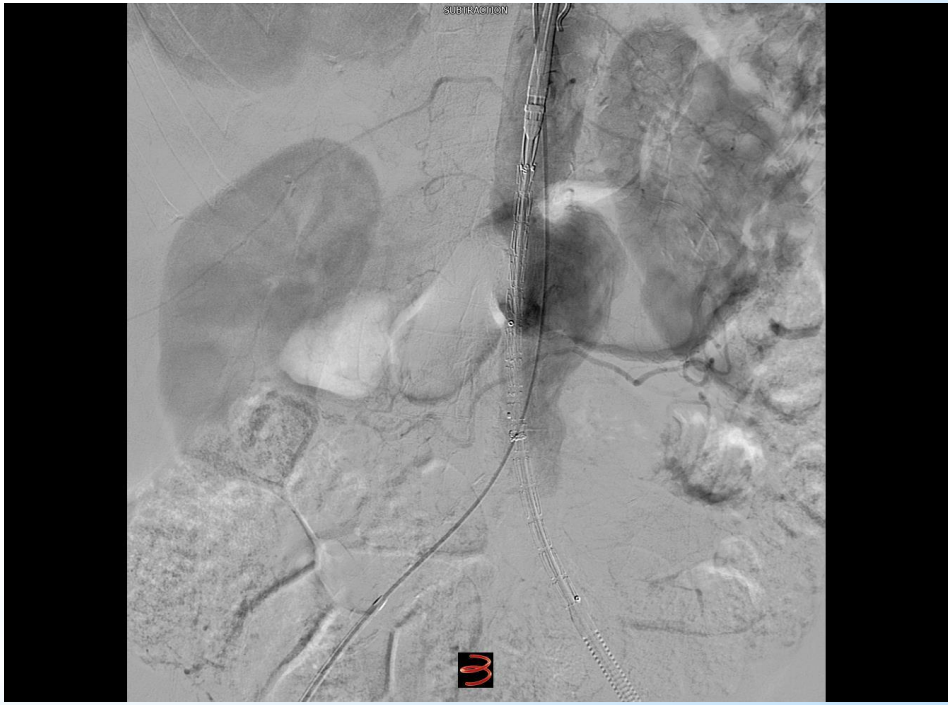

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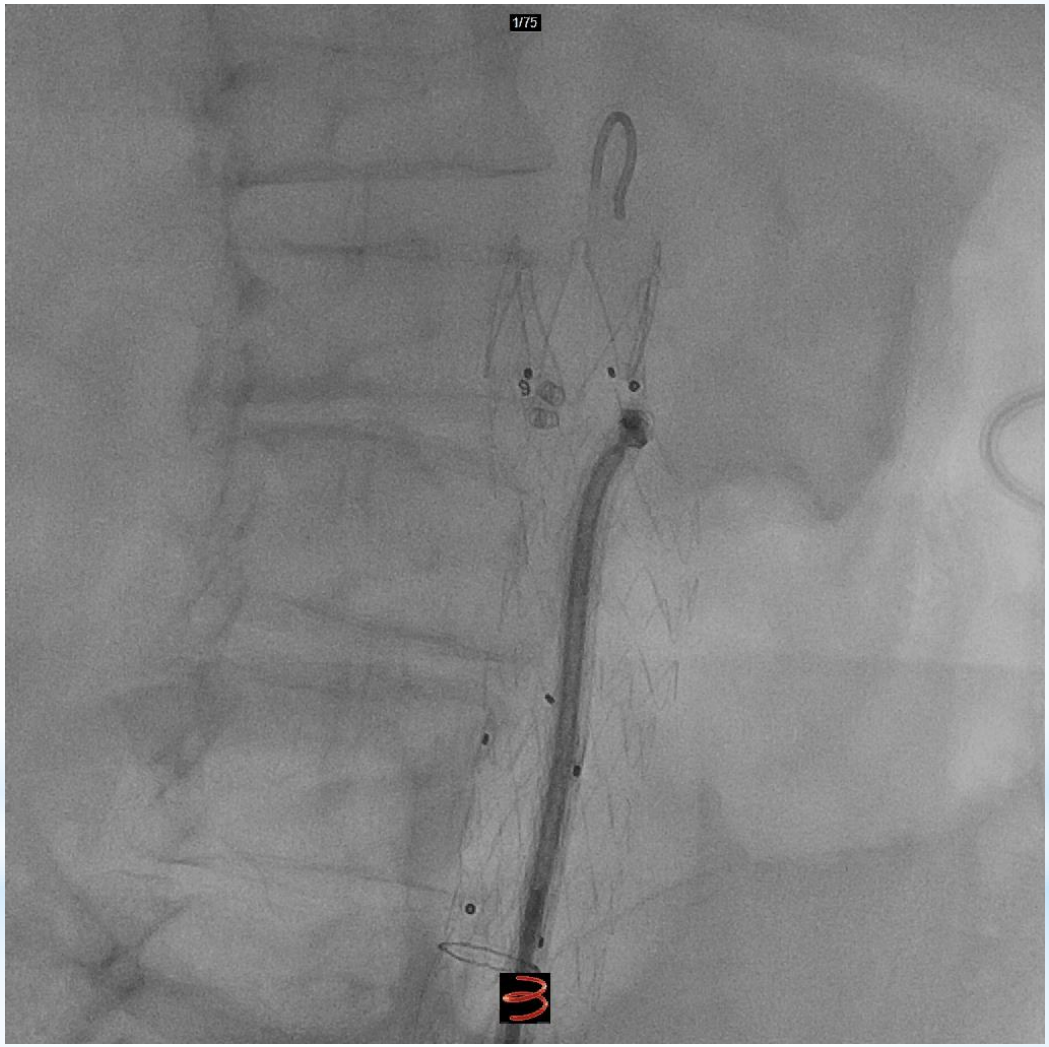

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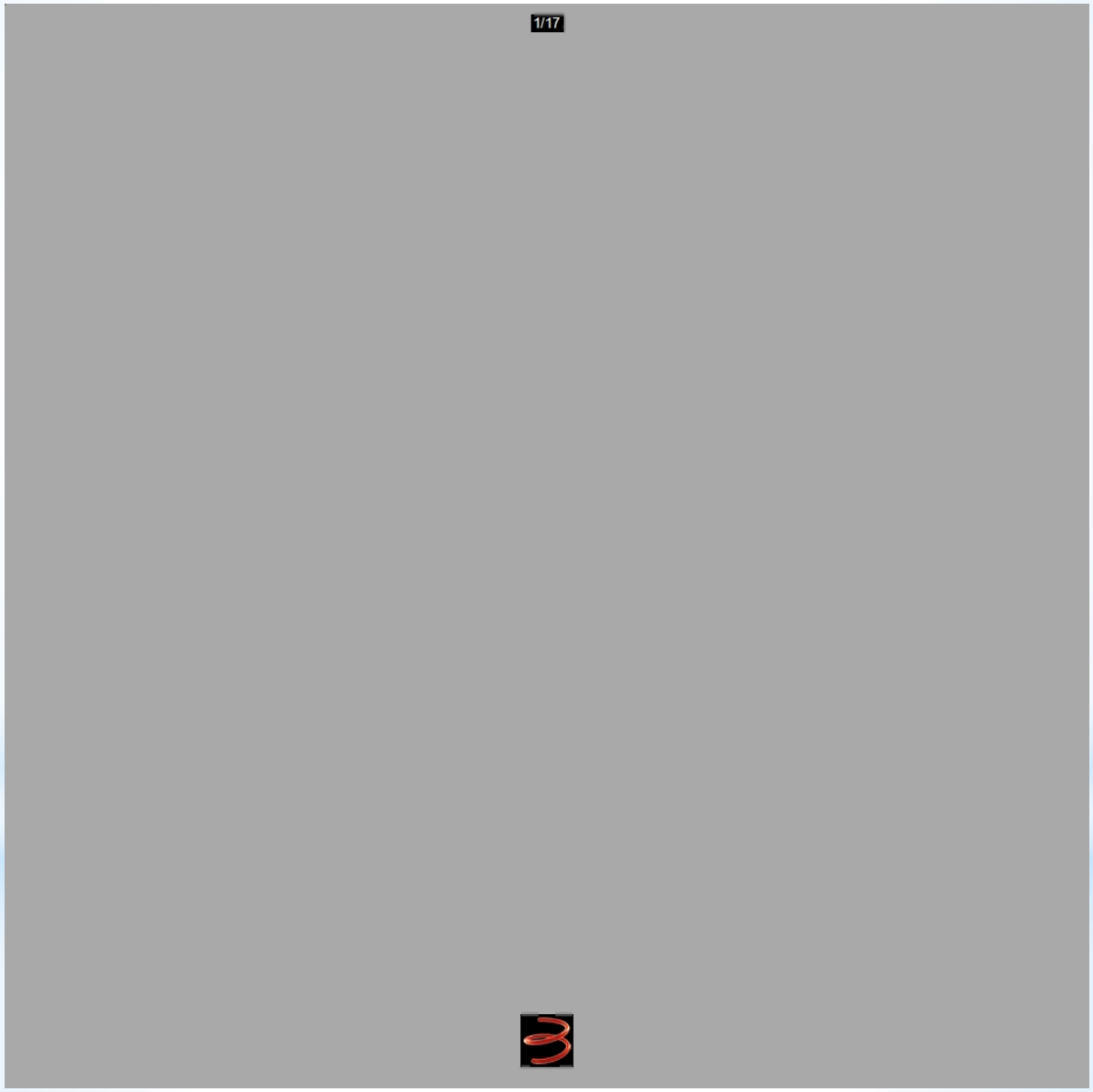

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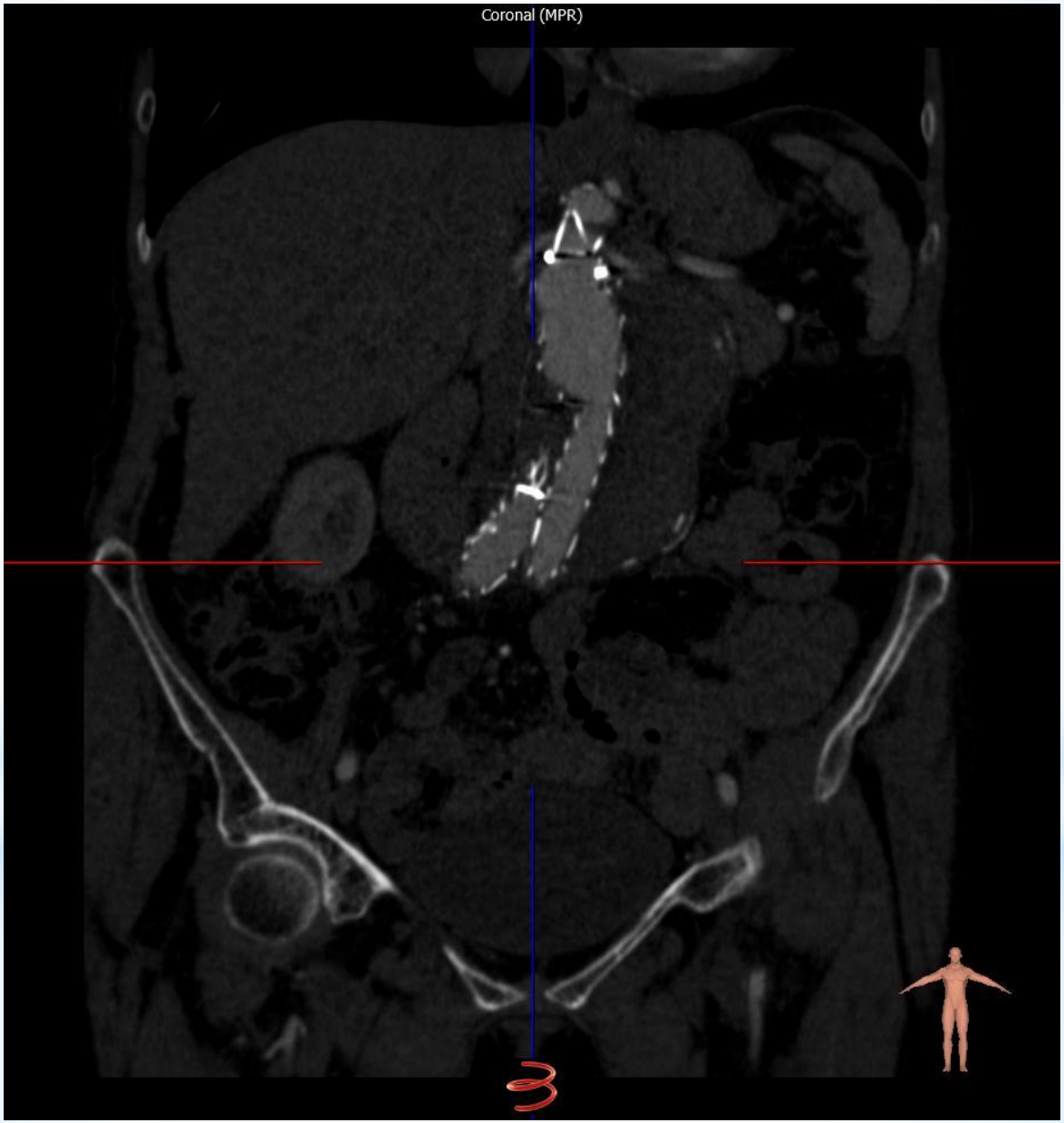

Conclusions

Use of EndoAnchors for treatment of acute type IA endoleaks is associated with excellent results (96% freedom of renewed type IA endoleaks at 1 year FU)

Use of EndoAnchors for treatment of type IA endoleak remote from an EVAR procedure successful in 68% of patients (75% of patients with persistent leaks do not undergo further interventions)

40% of type IA endoleaks in the revision group can be treated with Endoanchors alone

Planning and sizing essential for technical success (endovascular suture)

Be aware of the limitations of the use of the Endoanchors