Cordis

InCraft
AAA Stent Graft System

Cordis Symposium

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE

My personal experience with INCRAFT® in standard and challenging cases

G Pratesi, MD

Vascular Surgery

University of Rome "Tor Vergata"

giovanni.pratesi@uniroma2.it

PTV

FONDAZIONE PTV POLICLINICO TOR VERGATA

Università degli Studi di Roma Tor Vergata

Disclosure

Speaker name:

Giovanni Pratesi, M.D.

- ☐ I have the following potential conflicts of interest to report:
- ☑ Consulting: Abbott, Cook, Cordis, Endologix, Medtronic, WL Gore
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest

These presentations have been developed for an educational purpose and represents independent evaluations and opinions of the authors and contributors independently from the operating company sponsoring the present symposium.

Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device(s).

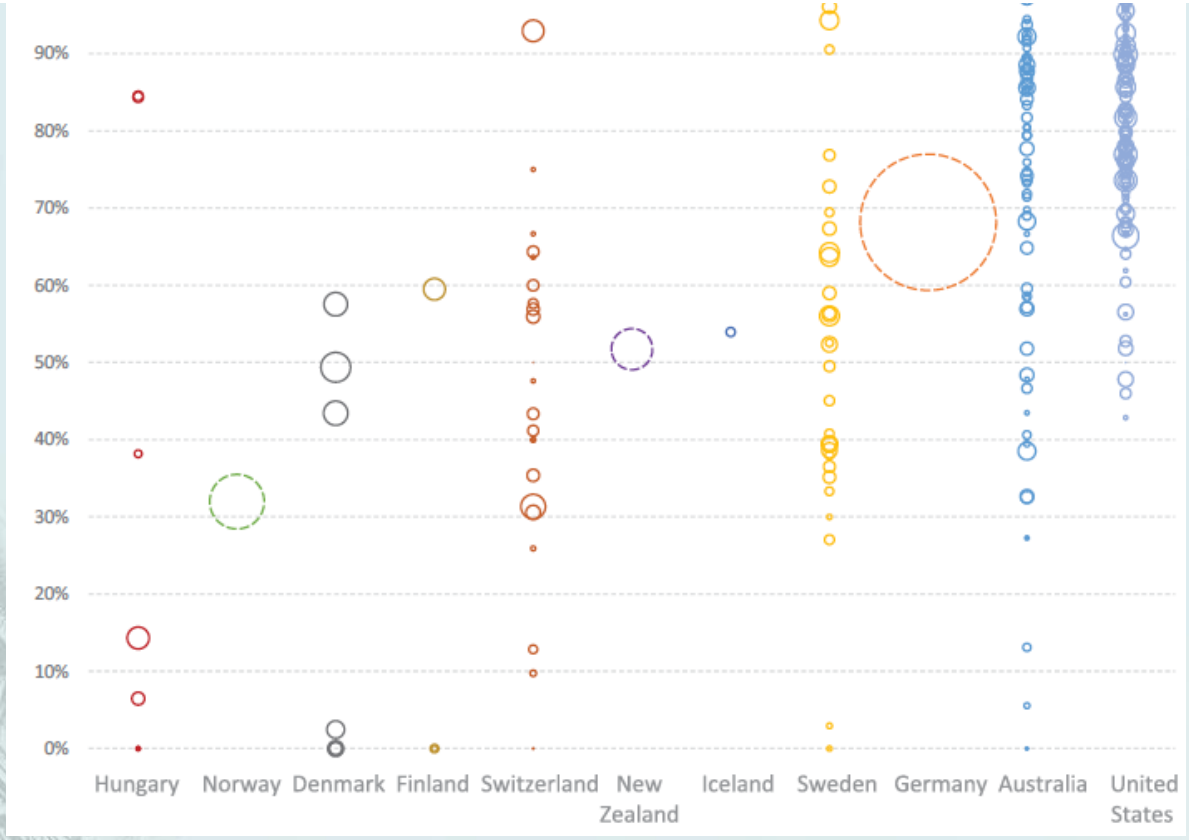
Dr Pratesi is compensated by and presenting on behalf of Cordis, and must present information in accordance with applicable regulatory requirements.

ORIGINAL RESEARCH ARTICLE

Variations in Abdominal Aortic Aneurysm Care

A Report From the International Consortium of Vascular Registries

Variations in modality of repair (open vs endovascular aortic repair [EVAR]).



US:79 % EVAR

Beck AW et al., Circulation 2016

The low invasiveness of EVAR: our strategy

- Preoperative work-up
- Intraoperative
- Postoperative management
- Follow-up surveillance

↑↑↑ **Patient outcome**

↑↑↑ **Cost effectiveness**

Standard vs complex cases: is EVAR always a low invasiveness TX?

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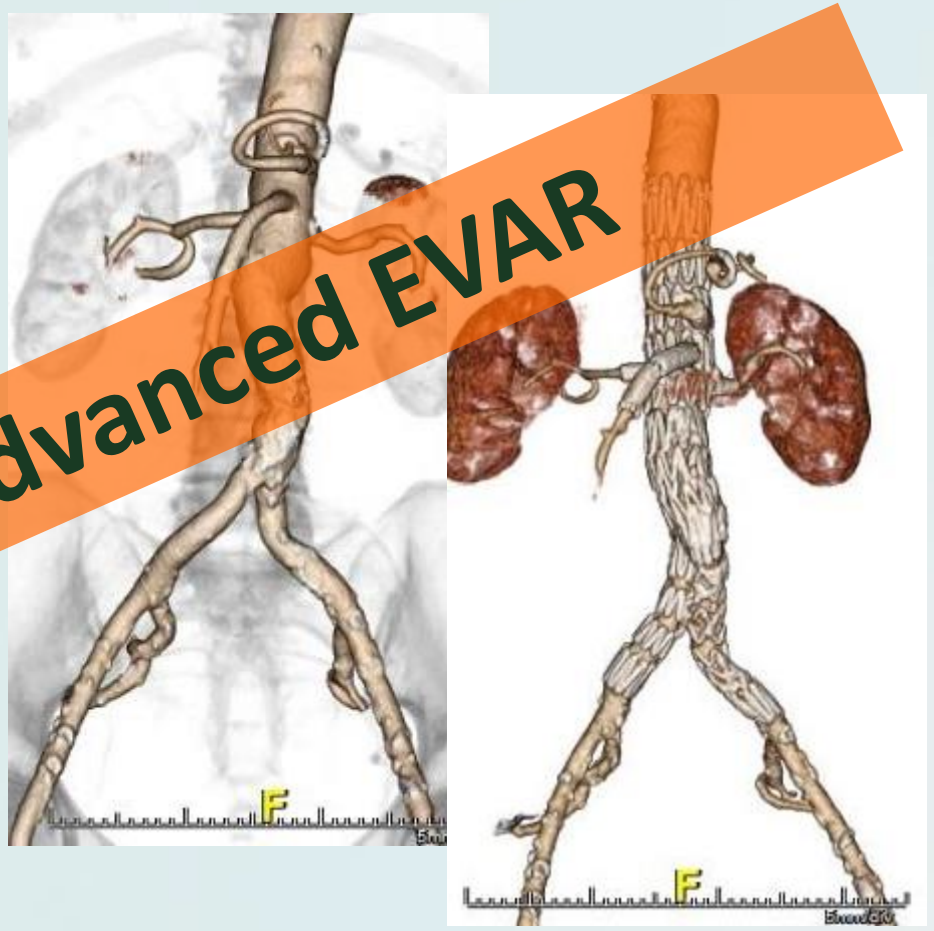
- Patient clinical condition (age, risk factors, comorbidities)
- Aneurysm morphology (proximal aortic neck, distal landing zone, access vessels)
- Kind of repair (open surgery, EVAR, ChEVAR, fbEVAR)

Standard vs Advanced EVAR



New technologies in standard EVAR: increased applicability

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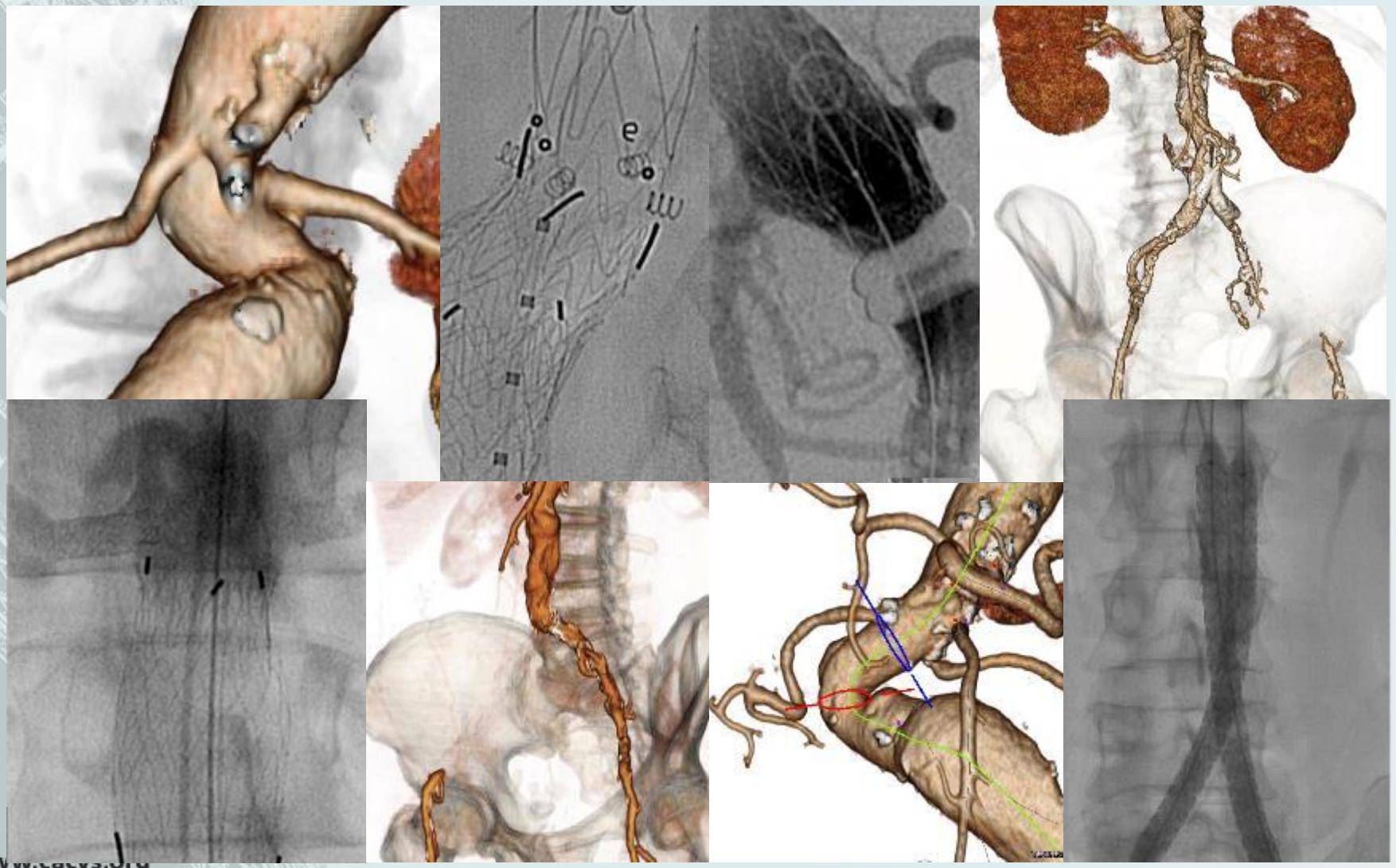

New technologies in standard EVAR: what about durability???

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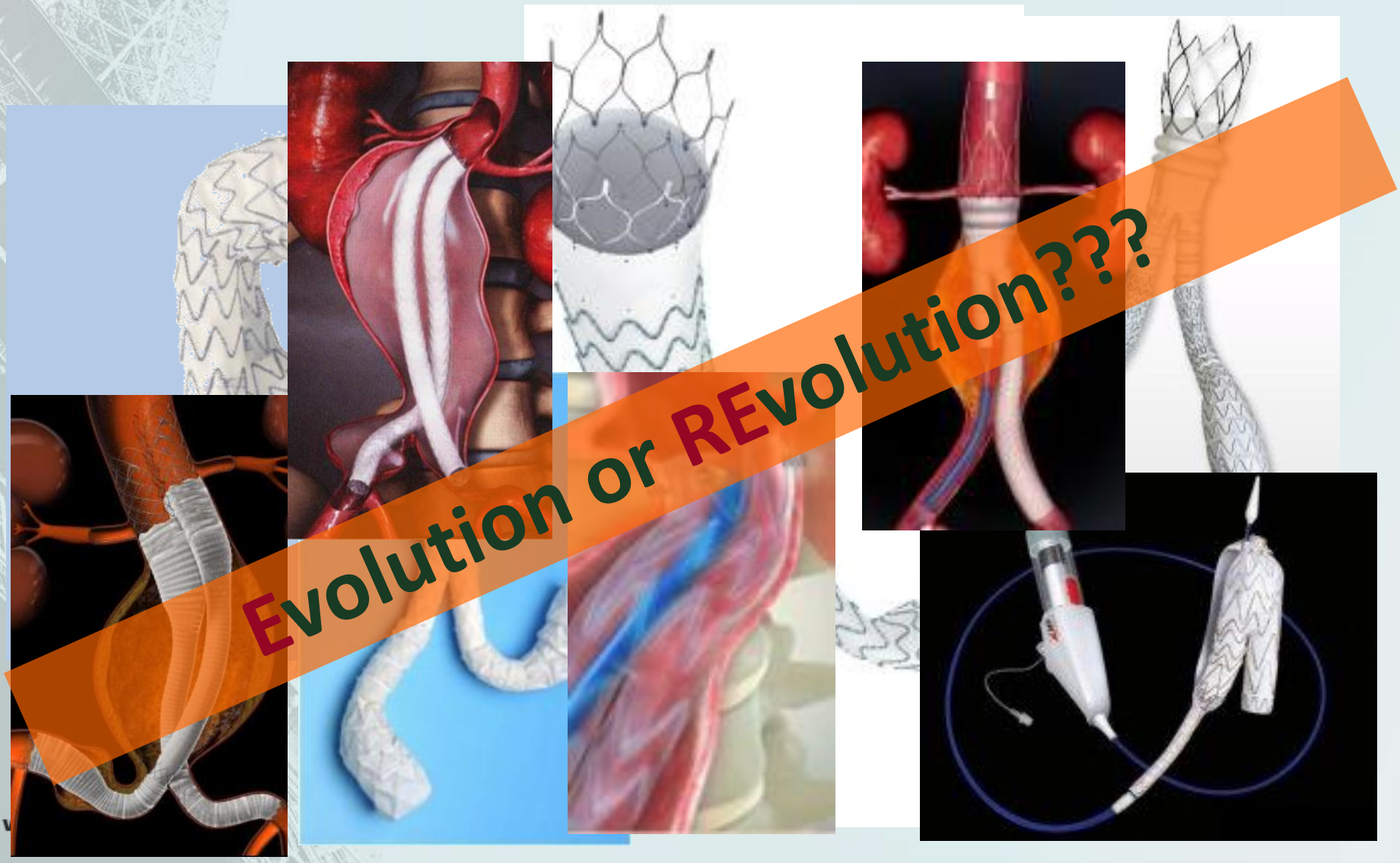
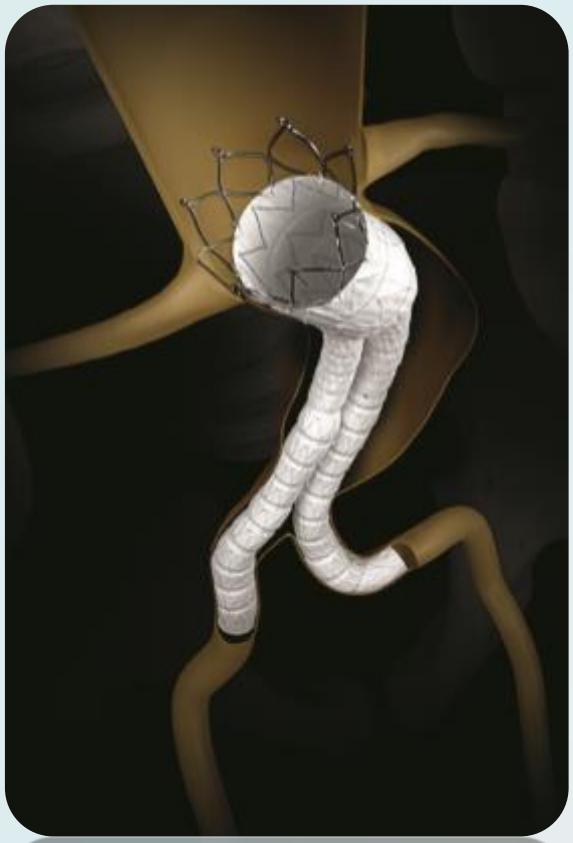


INCRAFT®: a lower profile device for EVAR

- **3-Piece Modular System**
  - Low porosity polyester graft
  - Segmented nitinol stents
  - Supra-renal fixation
- **Customization**
  - Bilateral in-situ length adjustment up to 3cm
  - Partial proximal re-positioning
  - Few units to fit broad anatomical coverage
- **Ultra-Low Profile**
  - 13Fr Integrated Delivery System -14Fr O.D.
  - Catheter-like shaft flexibility



167 standard EVAR

(September 2014 – December 2016)

42 INCRAFT® endograft

	Mean	Range
Infra-renal angle	20.1 °	5-90°
Proximal neck Ø	23.1 mm	18.3-29.1
Neck Length	17.1 mm	5-40
AAA maximum Ø	59.2 mm	48-93
Min. Aortic bifurcation Ø	29.9 mm	14.5-50
Right iliac seal zone Ø	14.9 mm	7-25
Left iliac seal zone Ø	13.9mm	8-22
Right min. access Ø	6.9 mm	4.7-12.1
Left min. access Ø	6.8 mm	4-10.8

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INCRAFT® experience

(September 2014 – December 2016)

	Operative	12 M	24 M
Technical success	100%% (42/42)	-	-
Freedom from Endoleak Type I Type II Type III Type IV	 100% (42/42) 69.1% (29/42) 100% (42/42) 94.7% (40/42)	 100% (22/22) 81.8% (18/22) 100% (22/22) 100% (22/22)	 88.9% (8/9) 66.7% (6/9) 100% (9/9) 100% (9/9)
Freedom from Limb occlusion	100% (42/42)	95.4% (21/22)	100% (9/9)
Freedom from Reintervention	-	95.4% (21/22)	88.9% (8/9)
Freedom from Migrations	-	100% (22/22)	100% (9/9)
Freedom from Sac Enlargement	-	100% (22/22)	100% (9/9)
Freedom from MAE (death, QMI, CVA, renal failure)	100% (42/42)	90.9% (20/22)	88.9% (8/9)

INCRAFT
in standard cases

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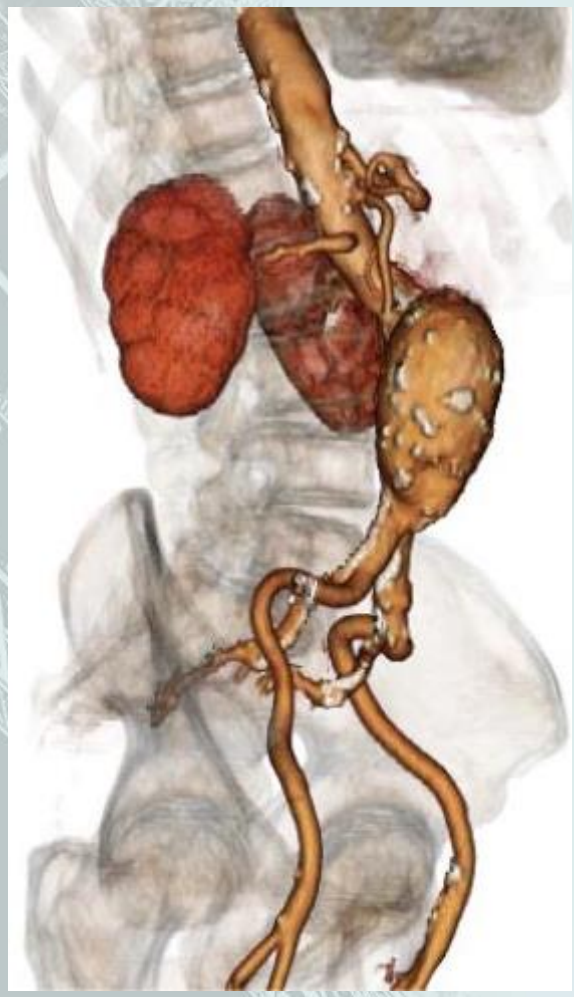
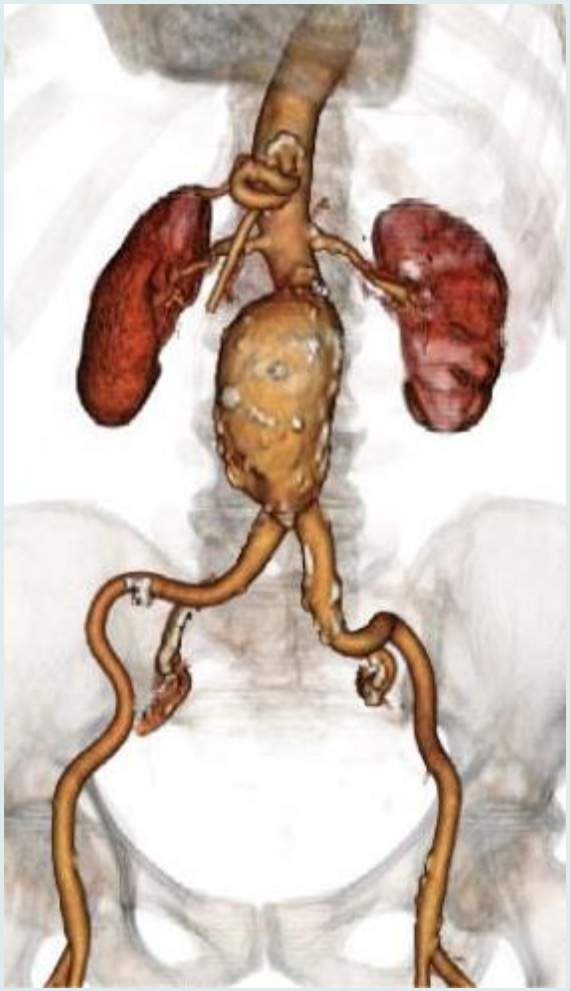
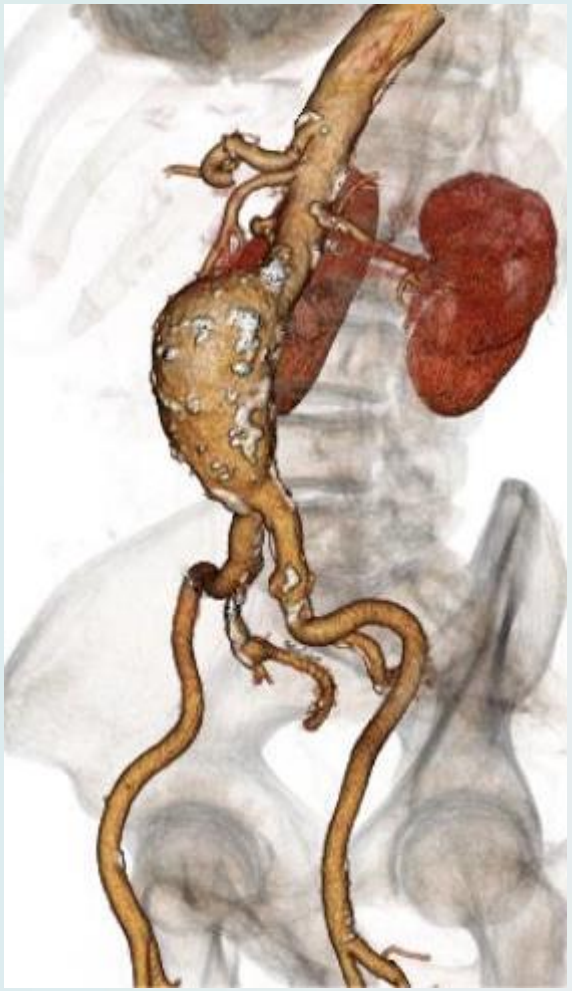




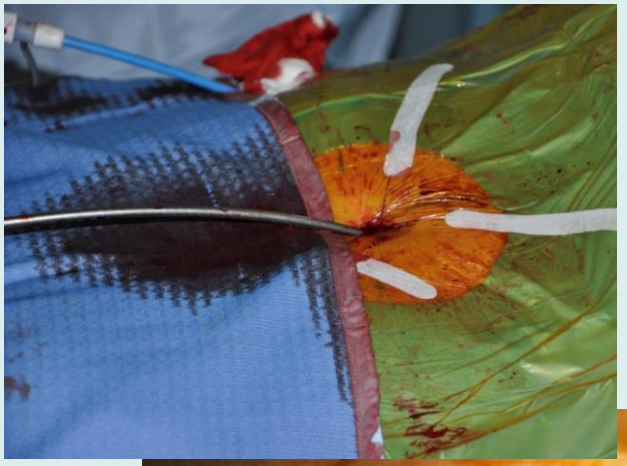


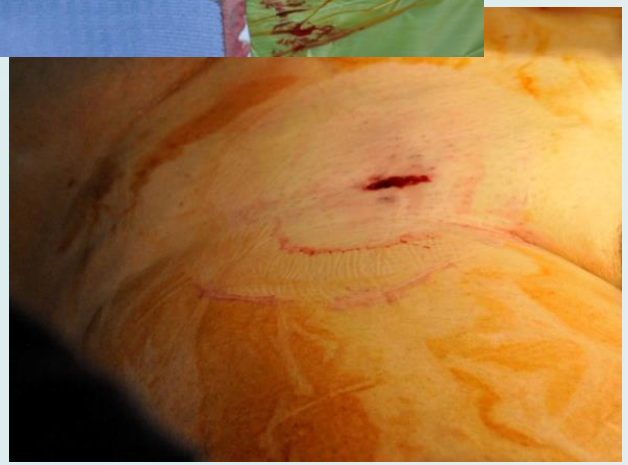
Advantages of low profile endograft

- Less arterial trauma
- Improved flexibility and trackability

- Liberal use of percutaneous access and local anesthesia
- Reduced hospitalization

Minimally invasive procedure





Standard cases: preoperative planning

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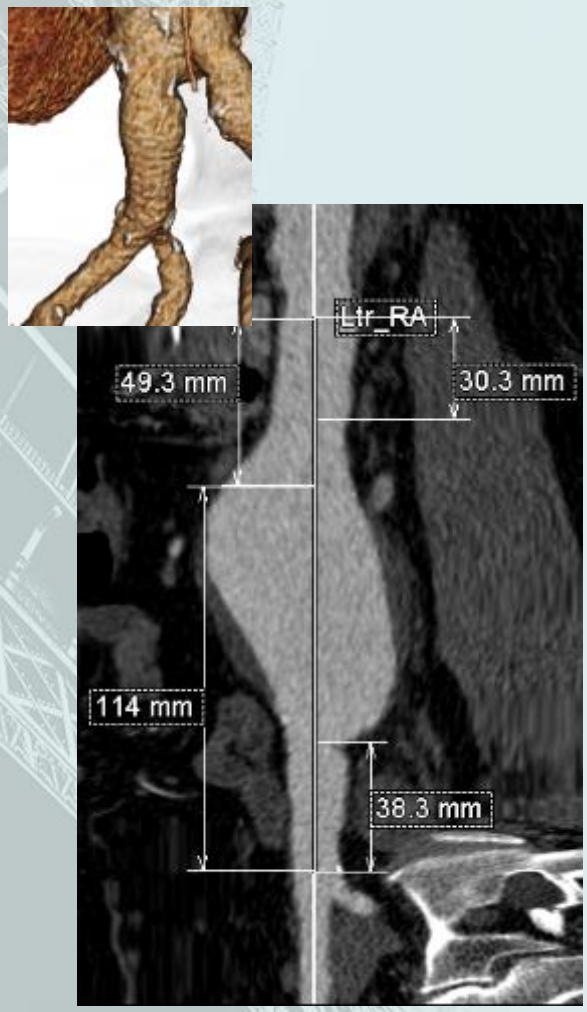
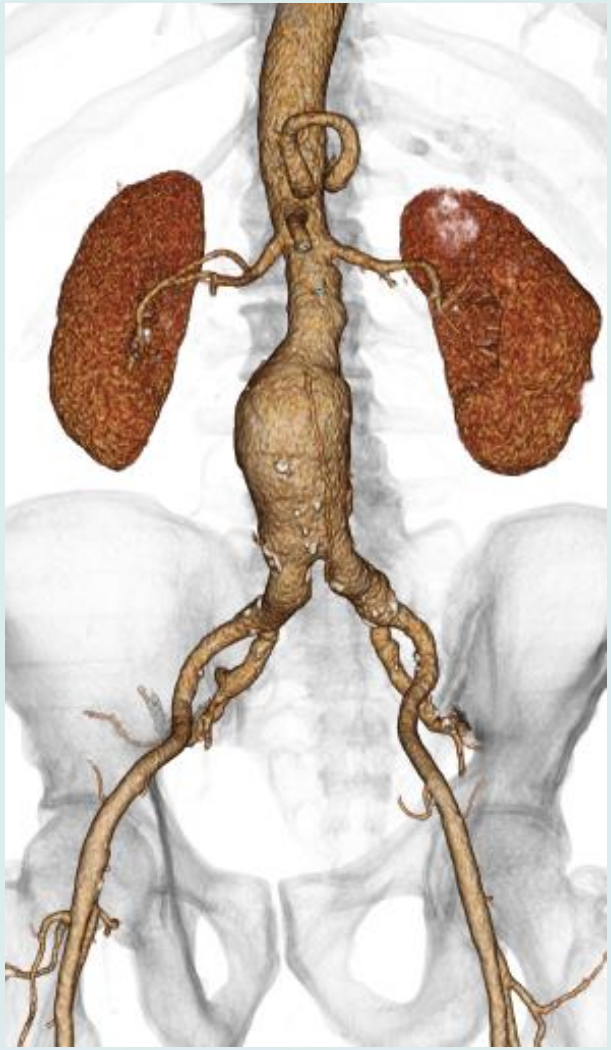
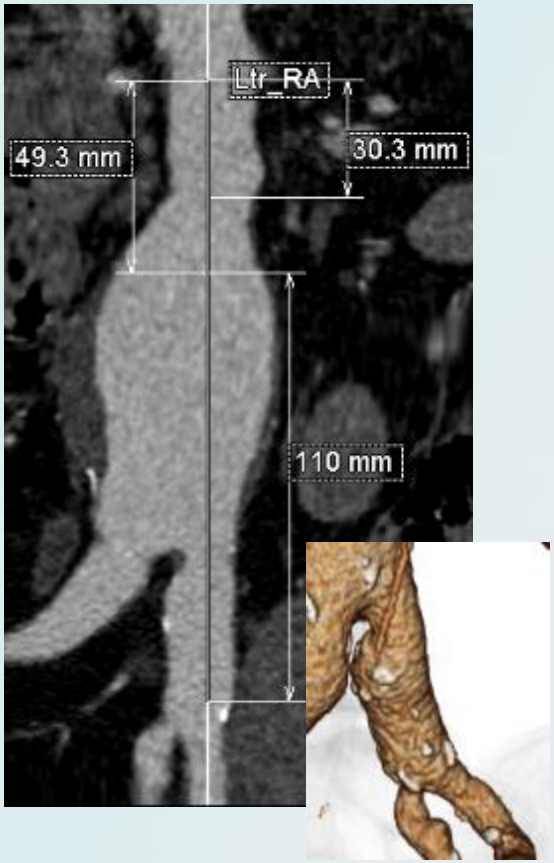
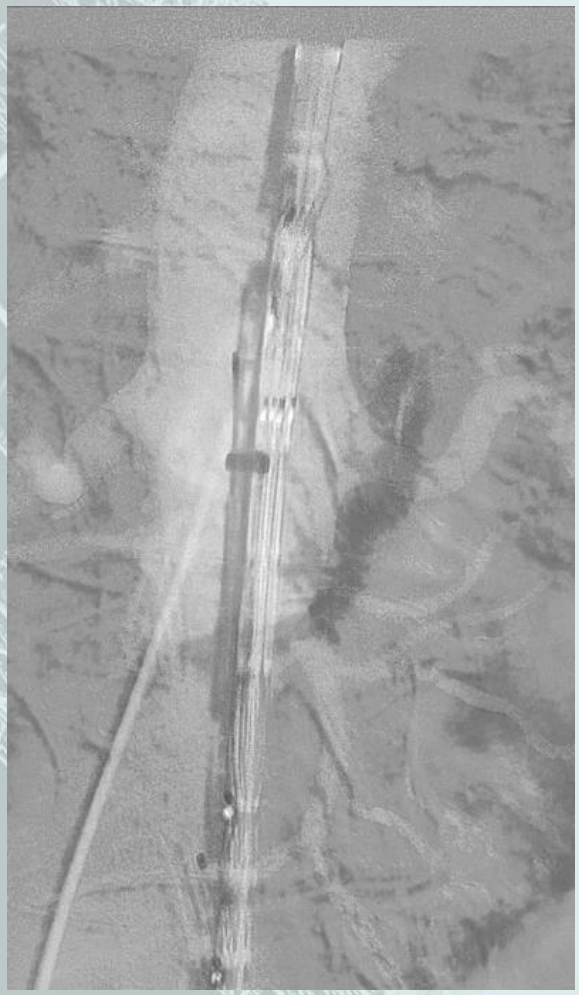
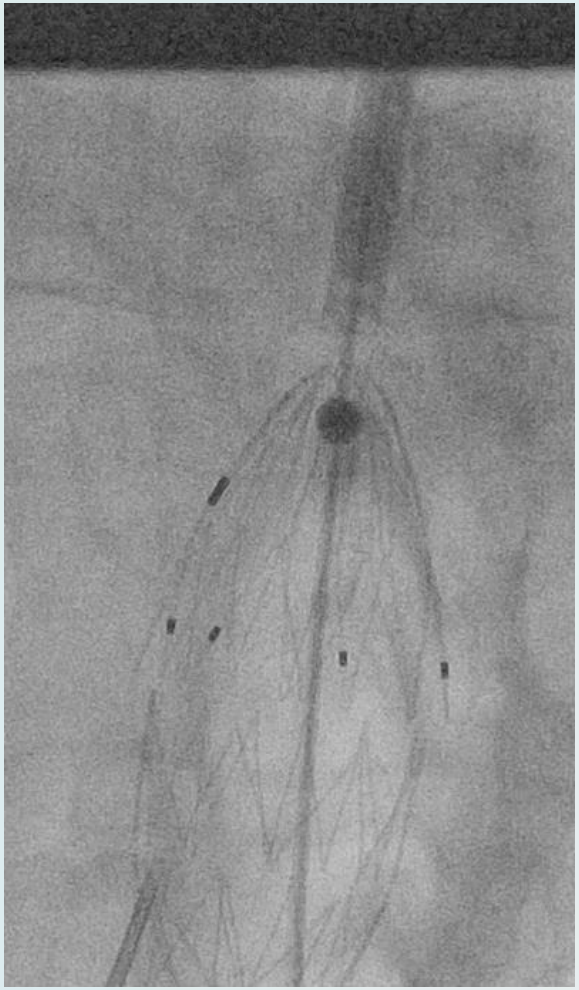




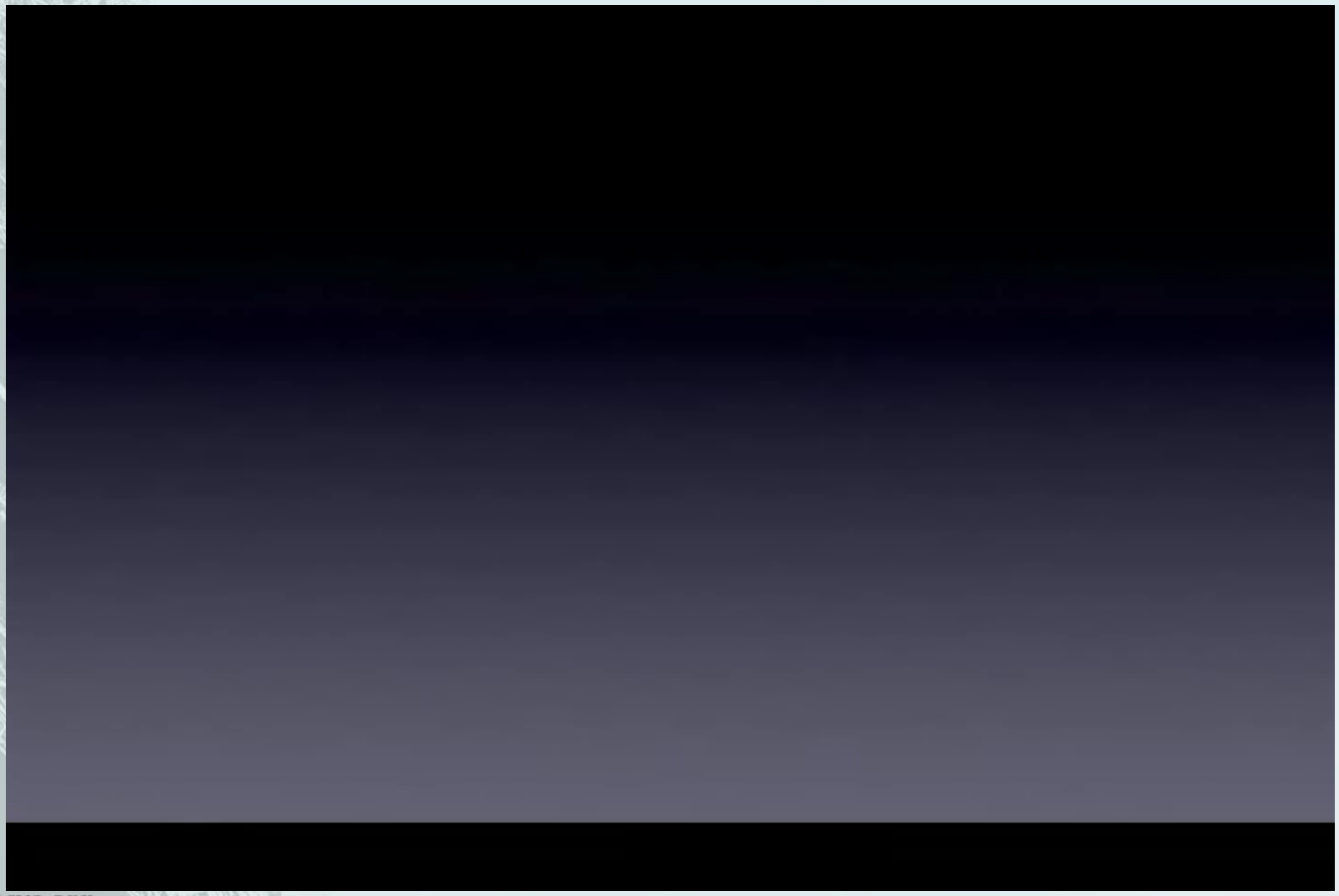


Advantages: proximal precision

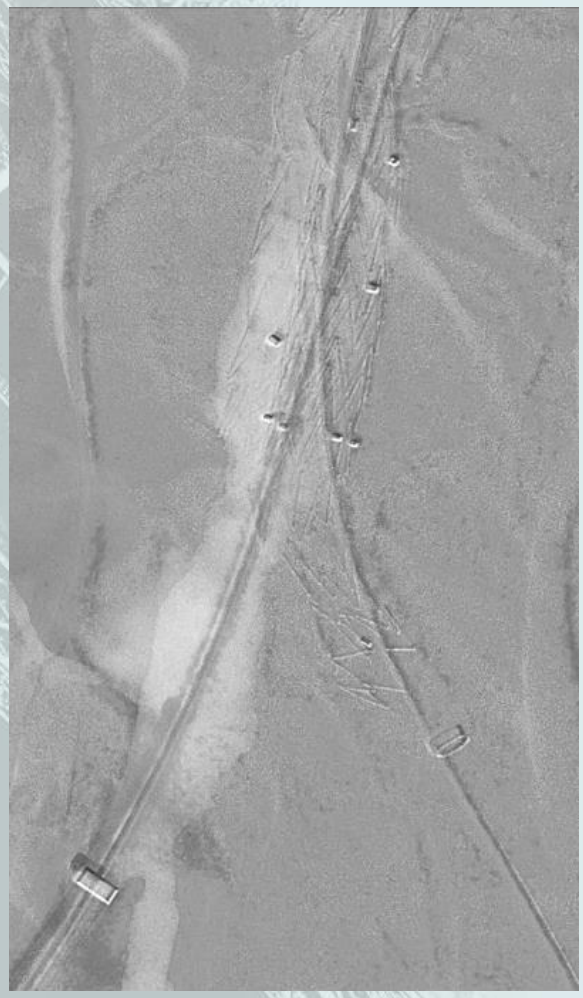


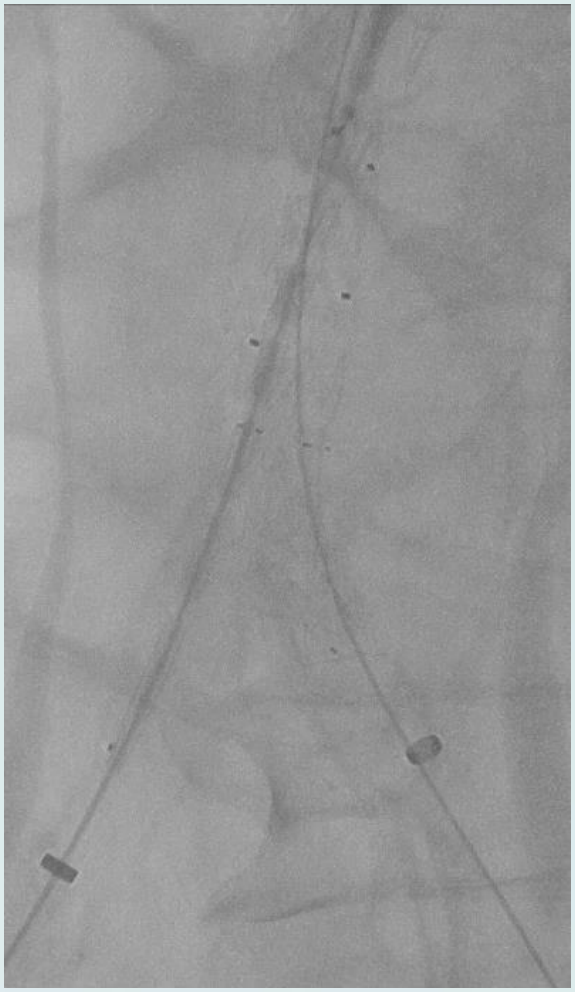


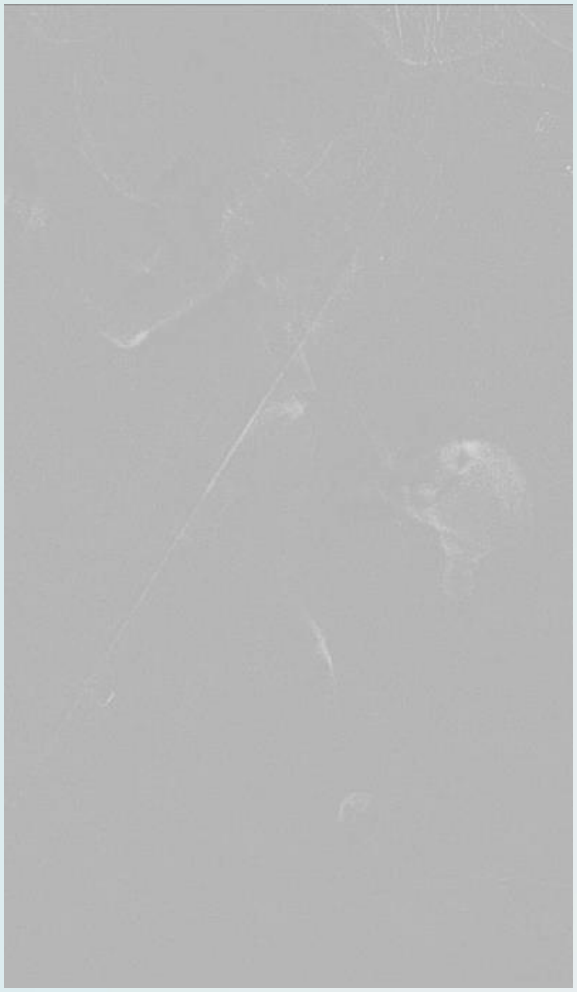
INCRAFT:
aortic main body



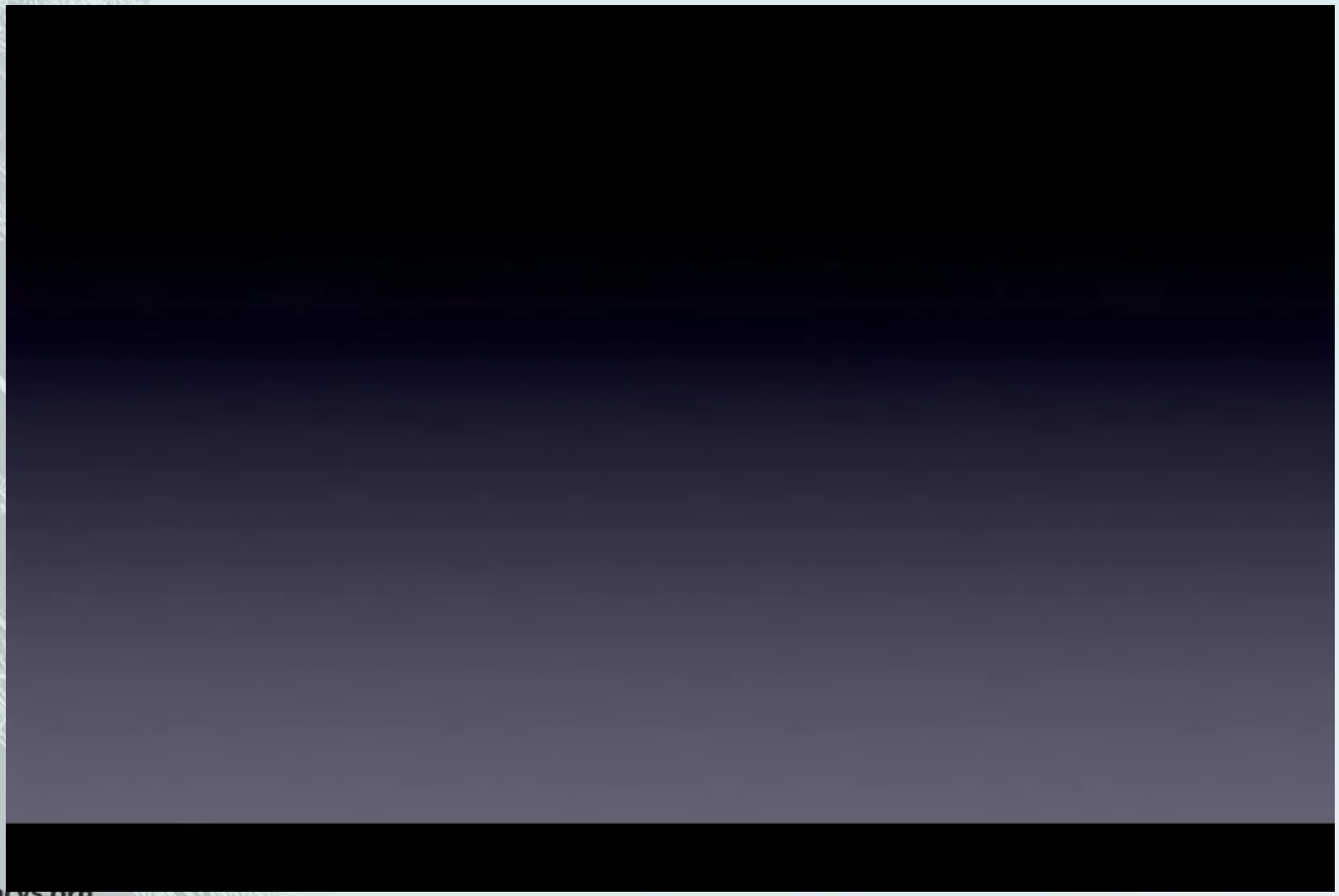
Advantages: in situ sizing



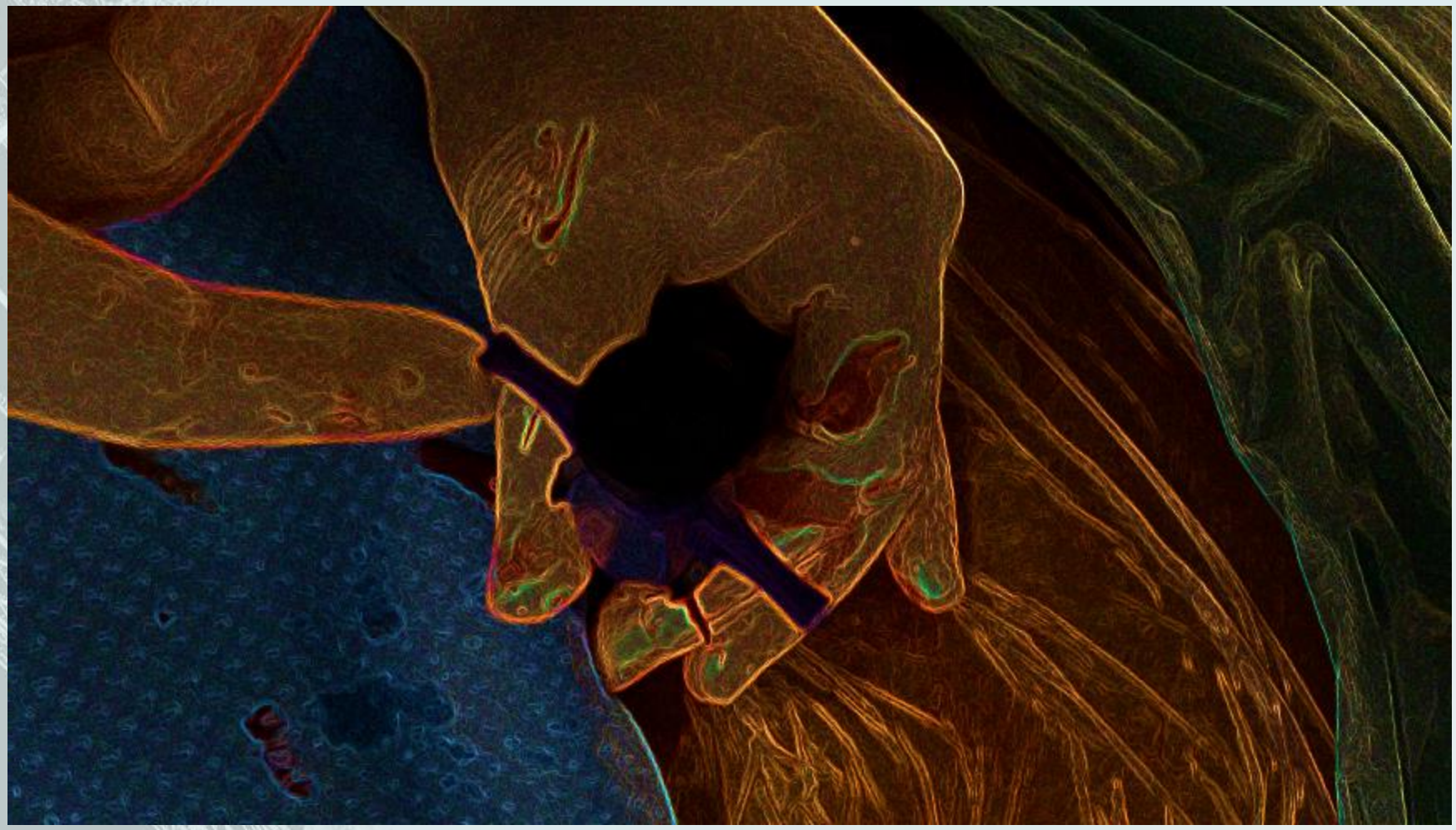




INCRAFT: iliac limbs



Standard cases: which advantages?



Advantages: increased pEVAR applicability

- Main body (14F OD) and contralateral limb access (12F OD) can be closed with 1 Proglide
- Contralateral limb goes through the 11F Terumo sheath

1 Proglide up to 14F

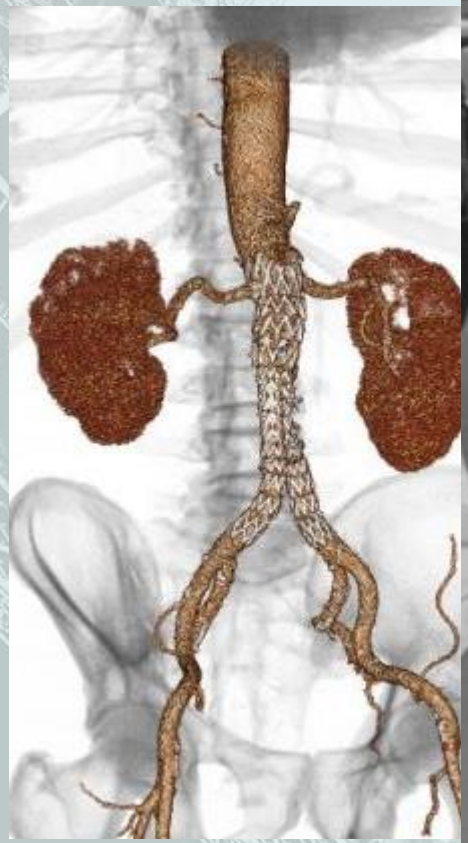
pEVAR: cost reduction

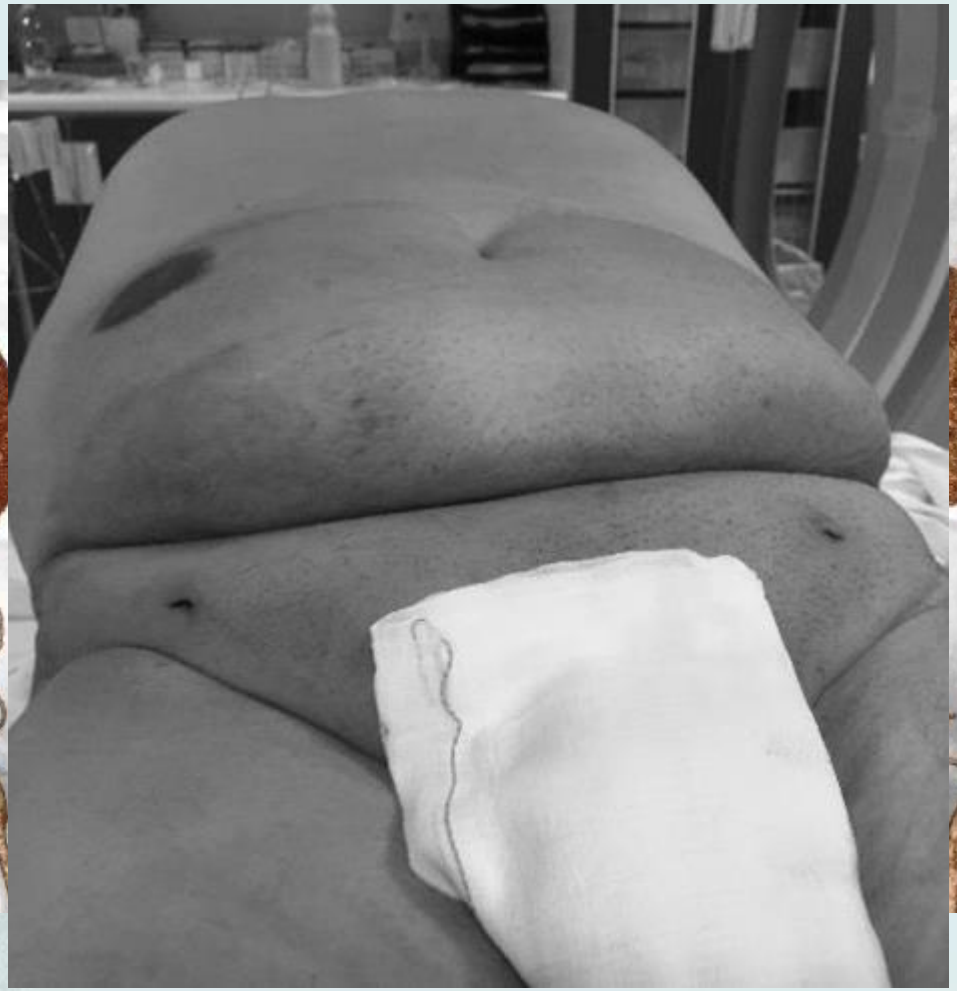
- Total value (cost-savings) due to ProGlide:
  - When 1 ProGlide device is used:
    $992.42 - $295 = $697.42
  - When 2 ProGlide devices are used:
    $992.42 - $590 = $402.42

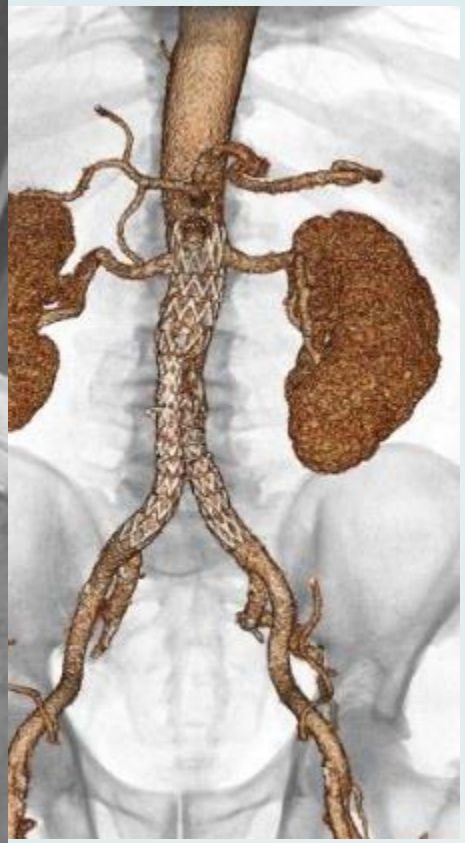
Rome, Italy:
1 Proglide €165

Economic Assessment of Vascular Closure for EVAR and TEVAR – FINAL REPORT
Data on file from Abbott based on PEVAR Trial

Standard cases: expanding pEVAR in obese patient







Italian Percutaneous EVAR (IPER) Registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft

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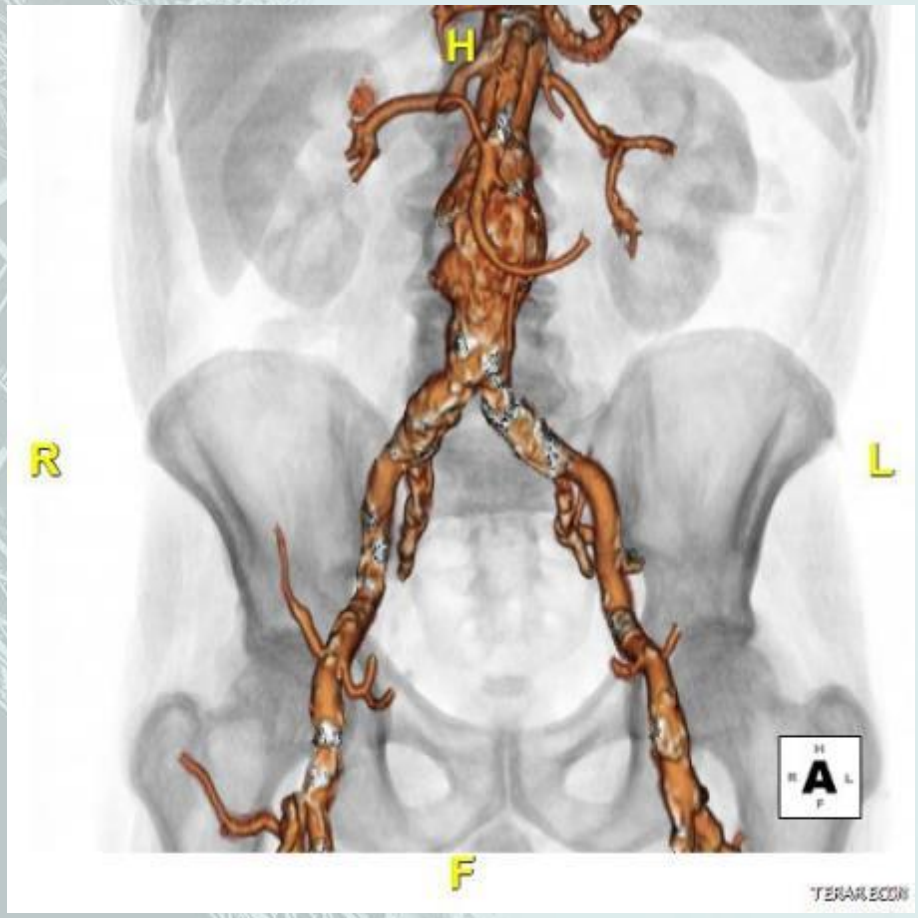
2381 femoral access: January 2010 – December 2014

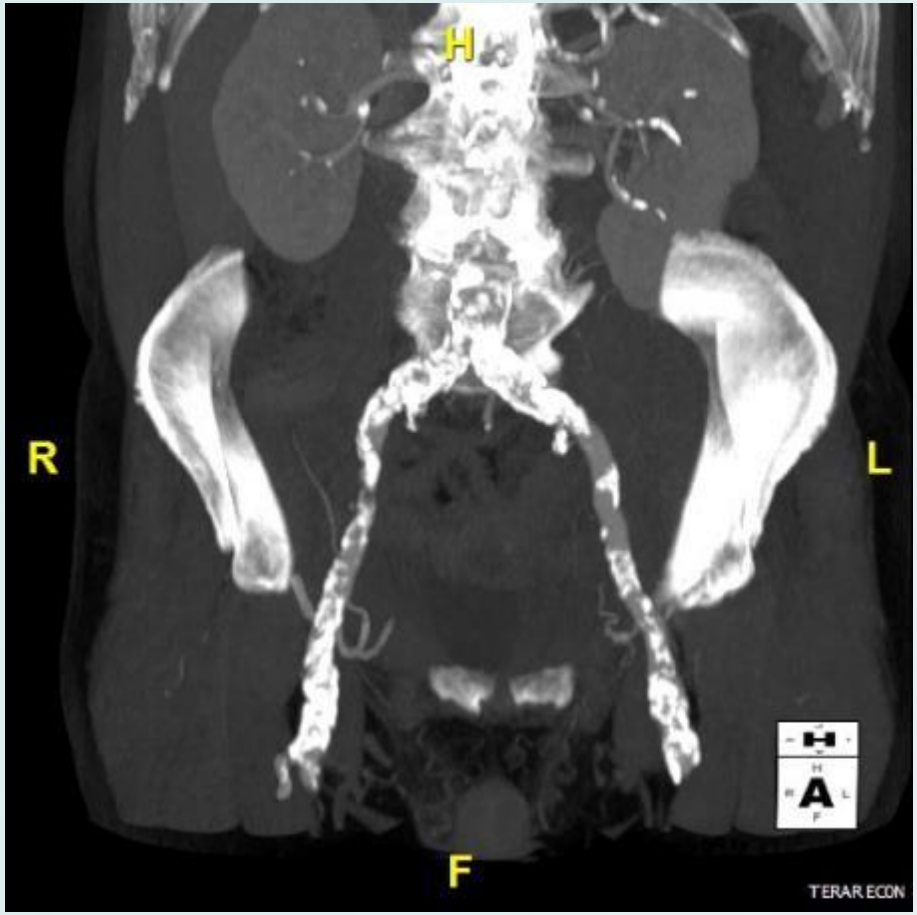
Conversion	OR	IC 95%	*p*
CFA calcifications	1.65	1.01 – 2.68	< .05
Iliac tortuosity	1.62	.99– 2.65	.052
> 18 Fr	1.16	.69 – 1.97	.57
High CFA bifurcation	.94	.22– 3.91	.93
Obesity	.94	.50 – 1.76	.85

Pratesi G et al., J Cardiovasc Surg 2015

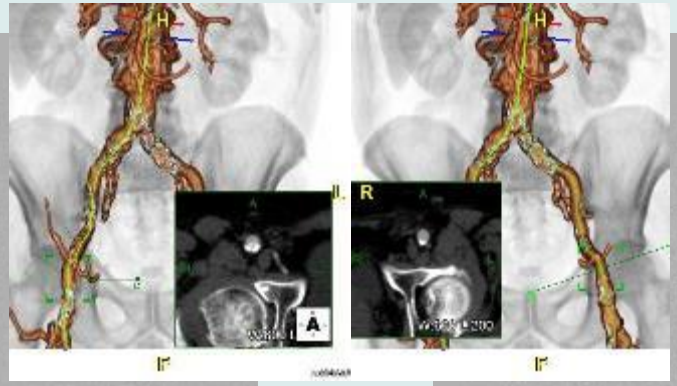
CLUB DEL PERCUTANEO

Standard cases: expanding pEVAR in calcified CFA

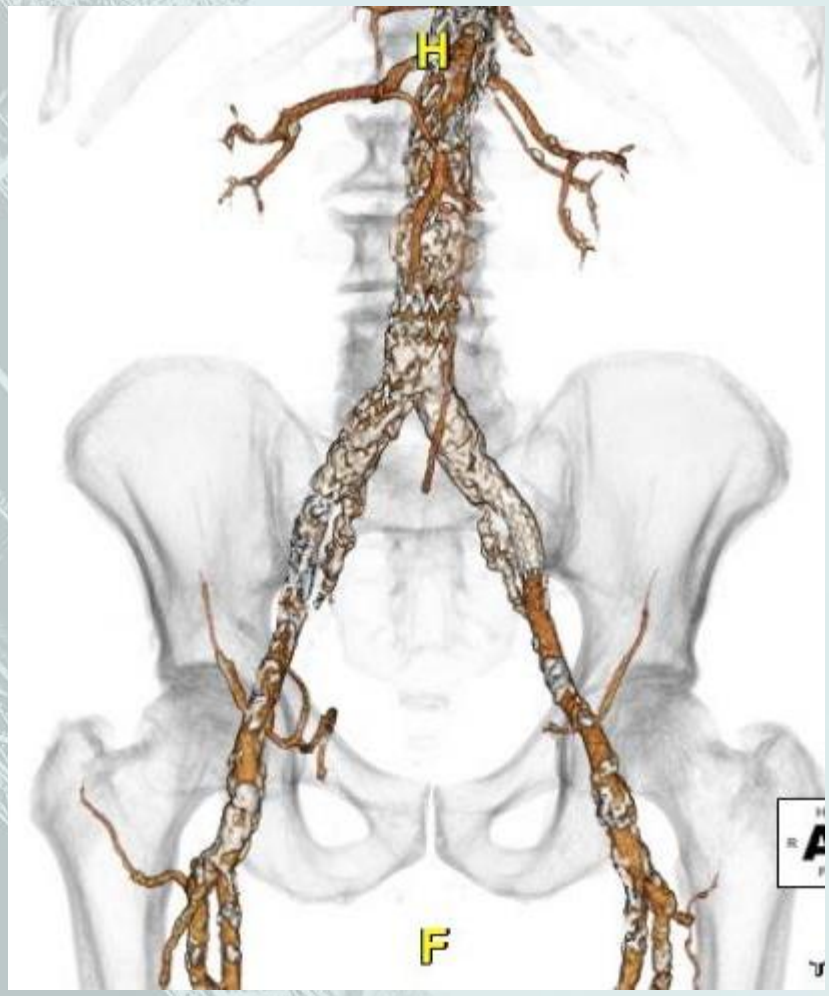


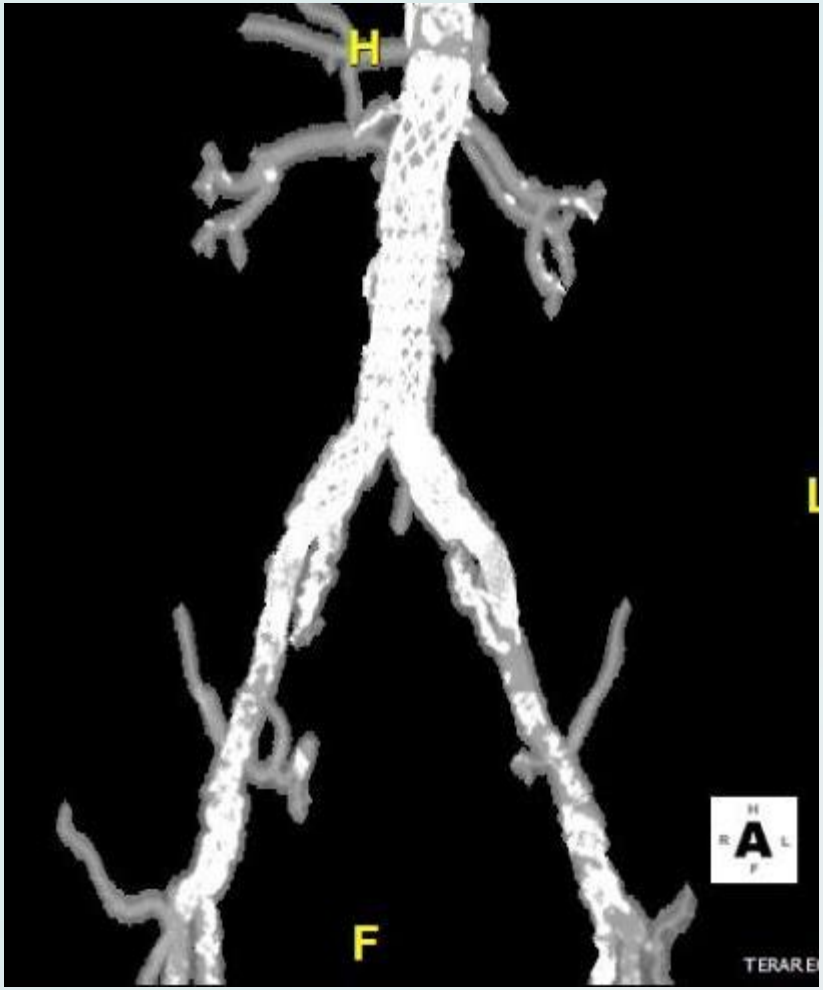


Standard cases: expanding pEVAR in calcified CFA



Standard cases: expanding pEVAR in calcified CFA





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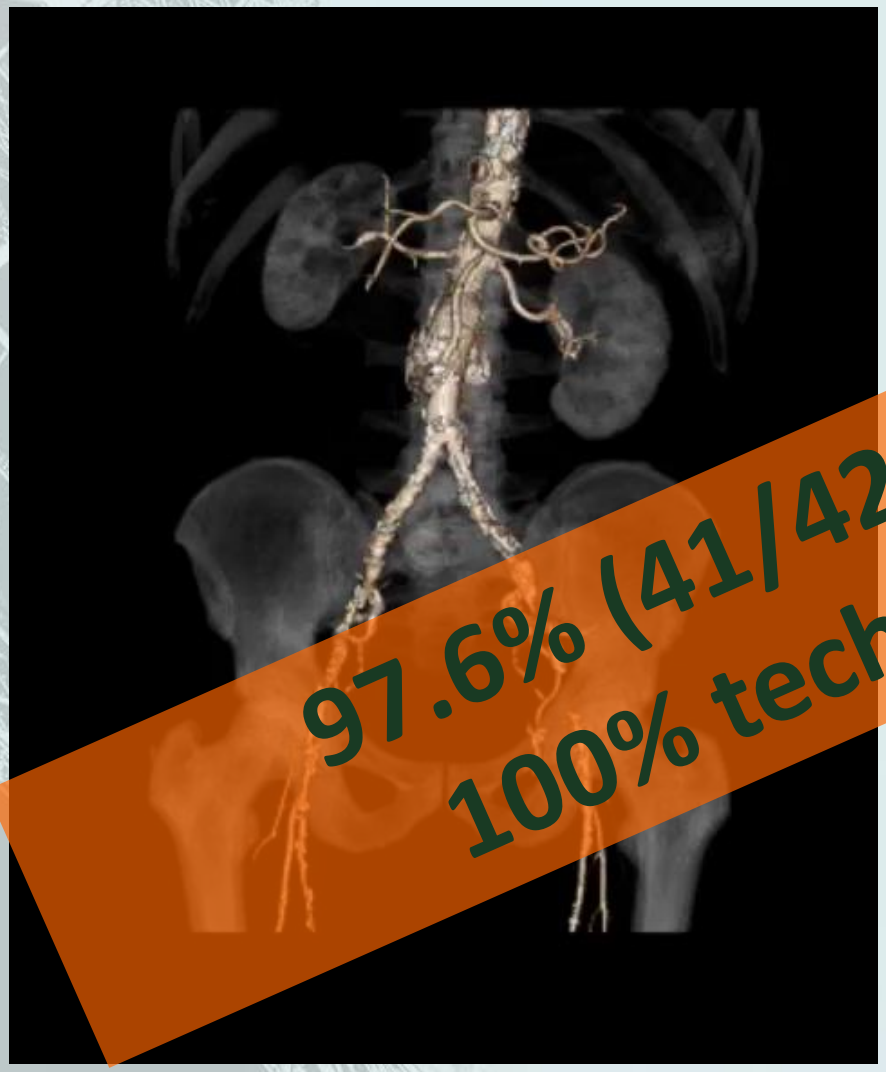
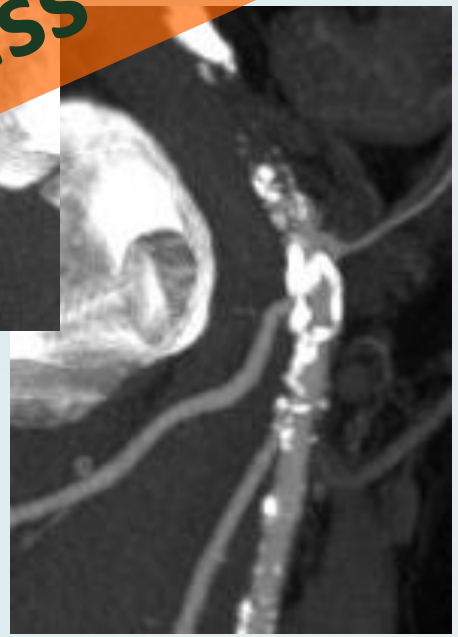
pEVAR with INCRAFT® experience

(September 2014 – December 2016)





97.6% (41/42) applicability

100% technical success

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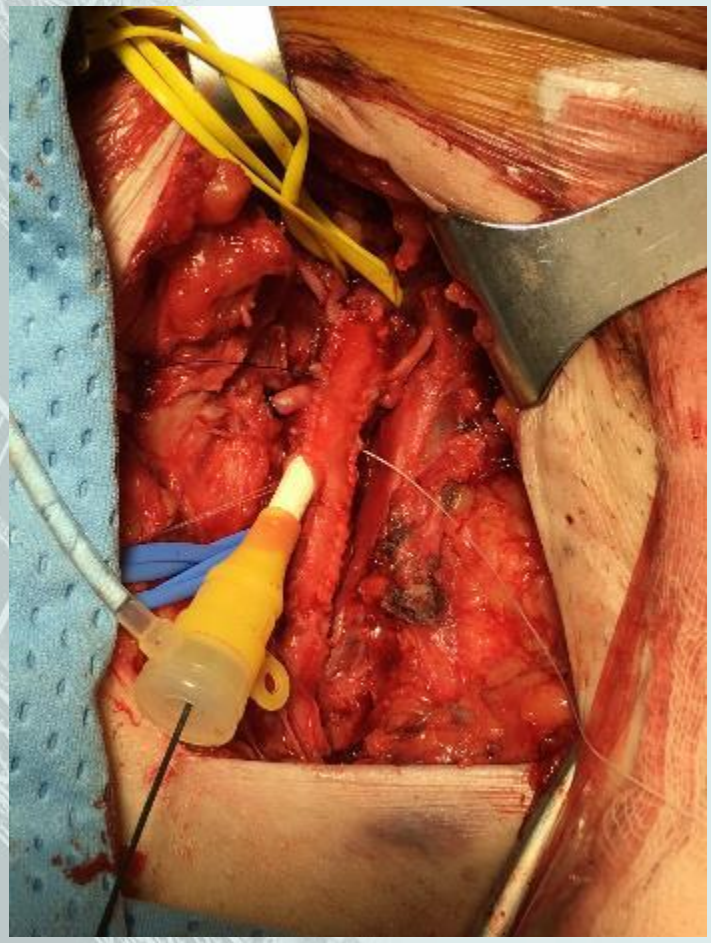
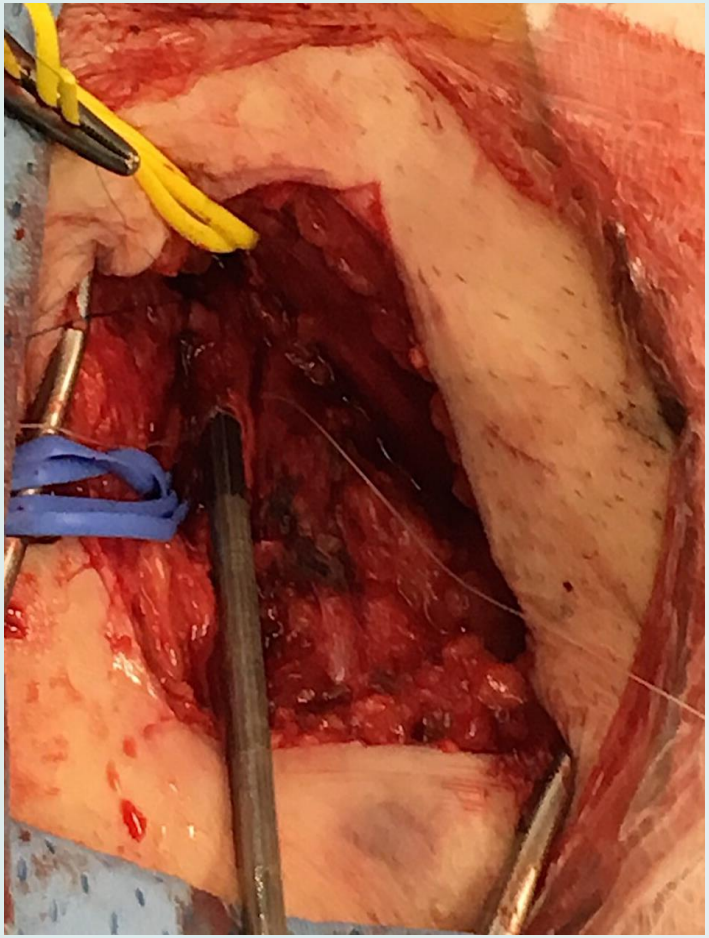
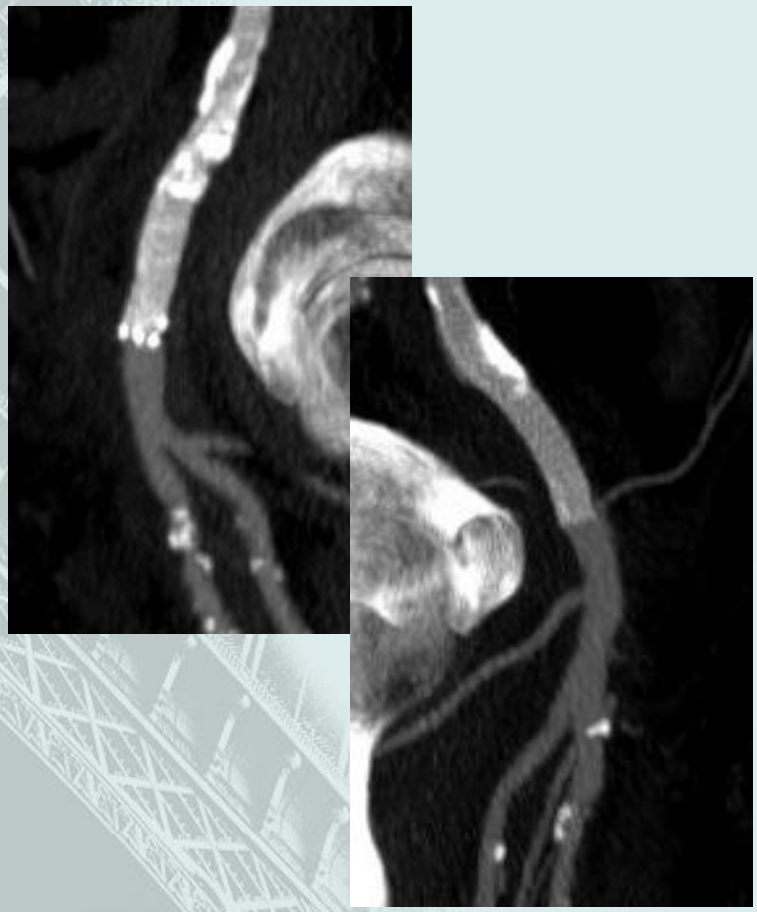
(September 2014 – December 2016)

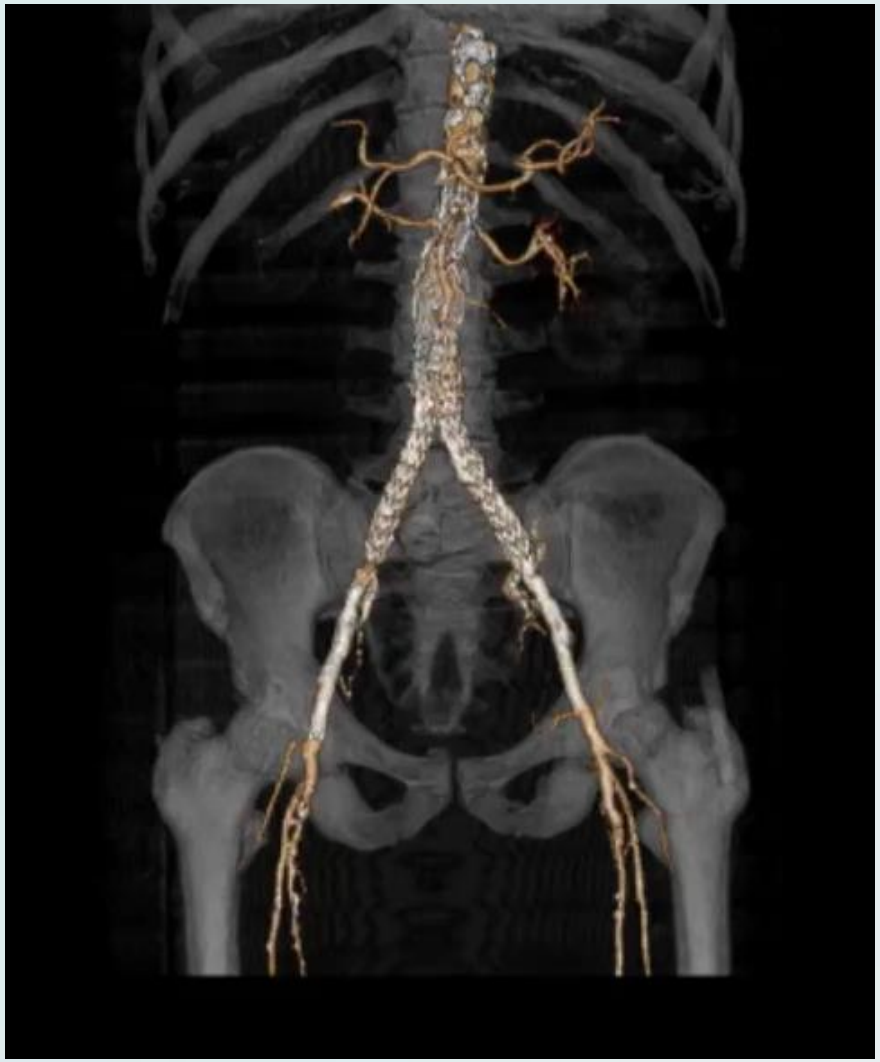




pEVAR with INCRAFT® experience

(September 2014 – December 2016)





Expanding EVAR applicability in complex access vessels

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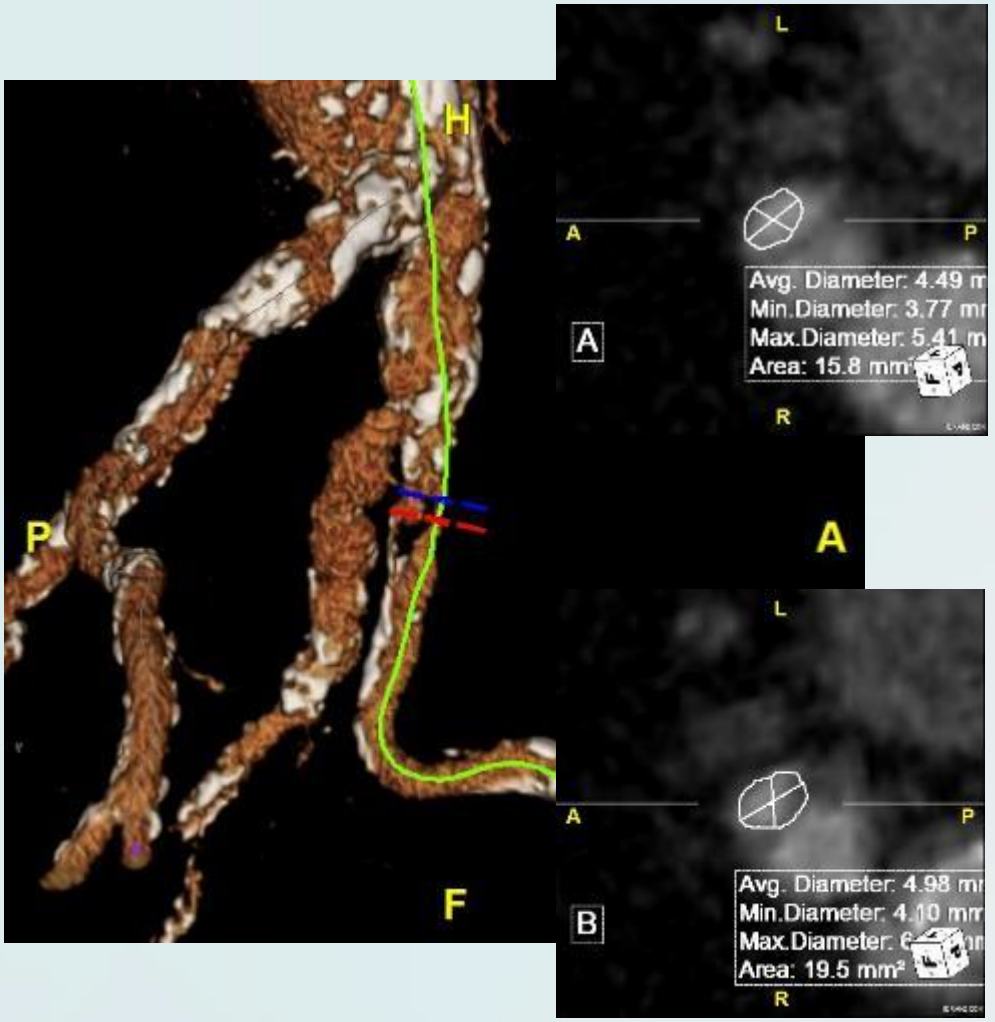
- Tortuous, calcified, narrow vessels
- Small aortic bifurcation (< 15 mm)
- *Occluded access vessels*



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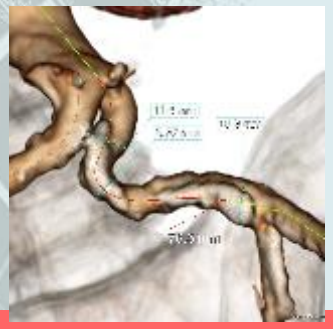
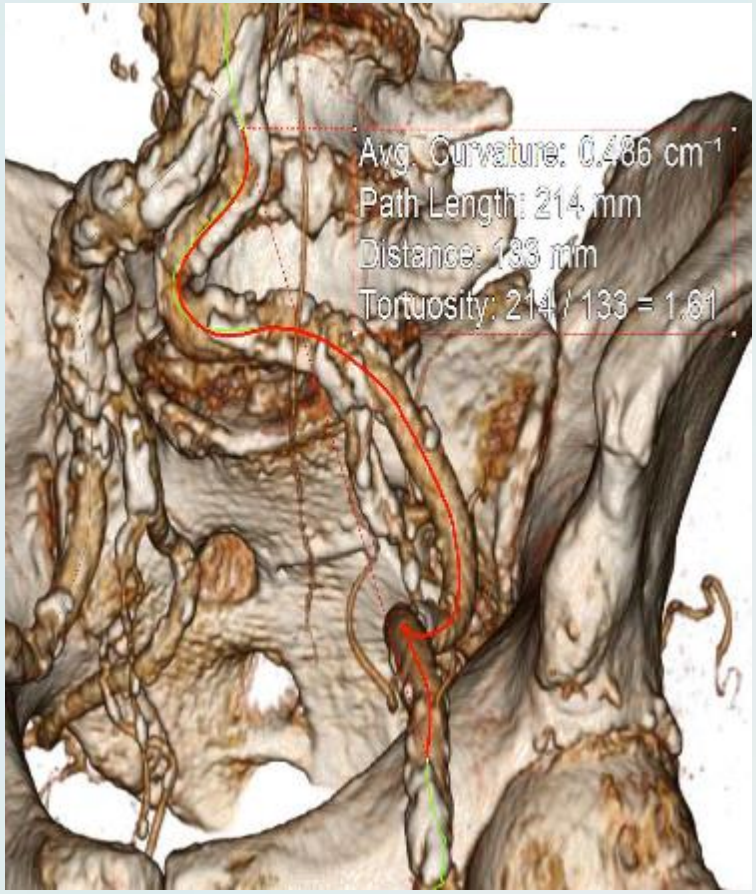
Incraft® experience: challenging access vessels

(September 2014 – December 2016)





Tortuosity index (τ)

Rt side1.53 ± 0.19 ; Lt side 1.45 ± 0.18

Access vessels diameter

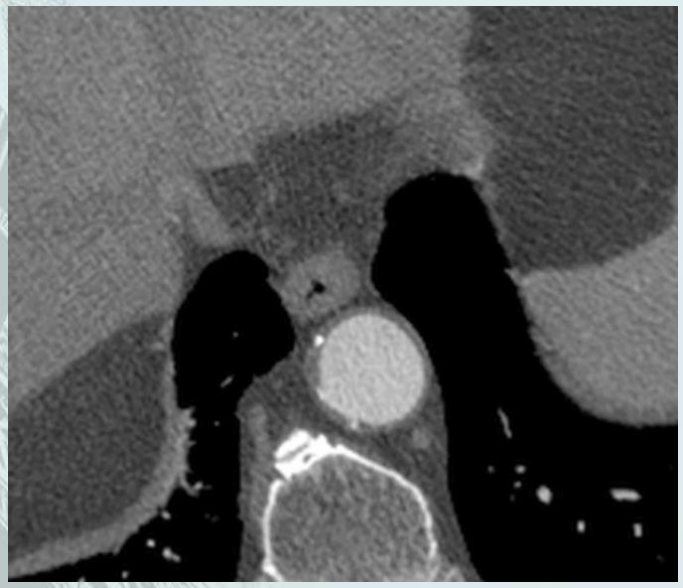
6.42 ± 1.8 mm

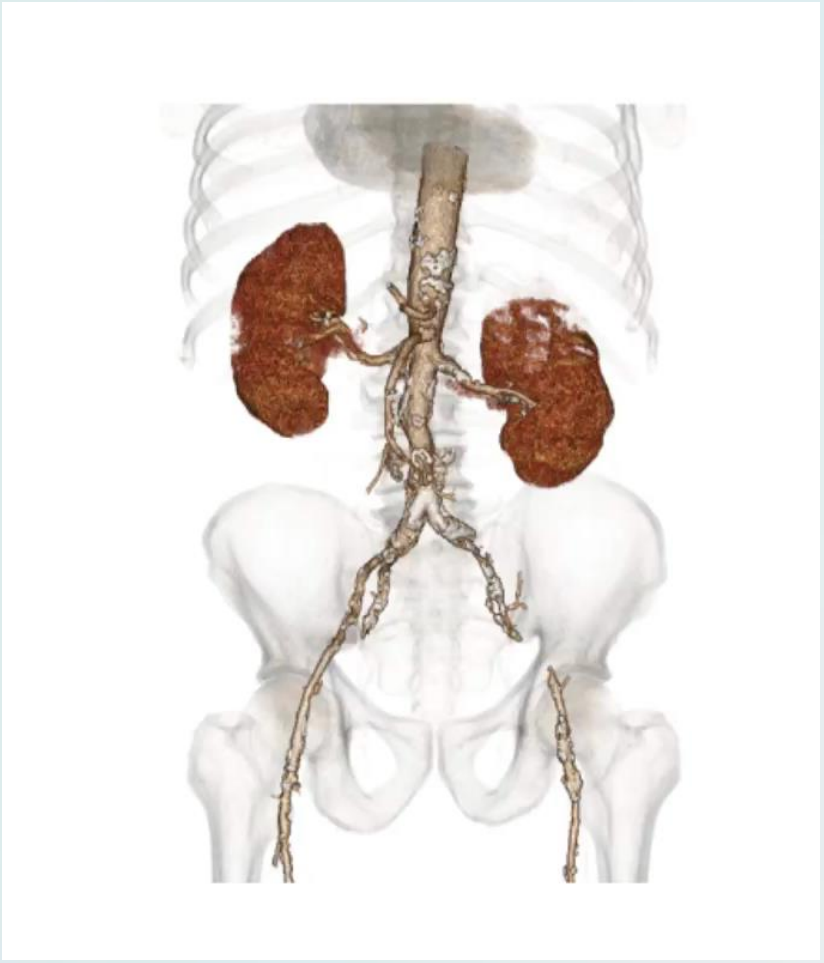
Iliac axis occlusion

5/42(11.9%)

Complex cases: challenging access vessels

- Male, 75 y/o
- AAA 55mm, small aortic bifurcation (15 mm), left symptomatic EIA occlusion, right EIA severe stenosis





Complex access vessels:

small calcified aortic bifurcation and EIA occlusion

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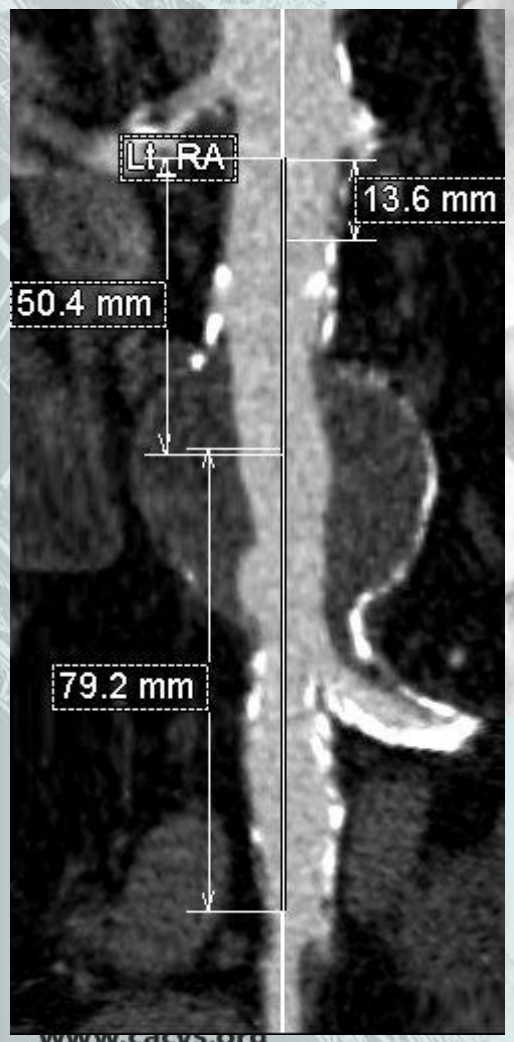

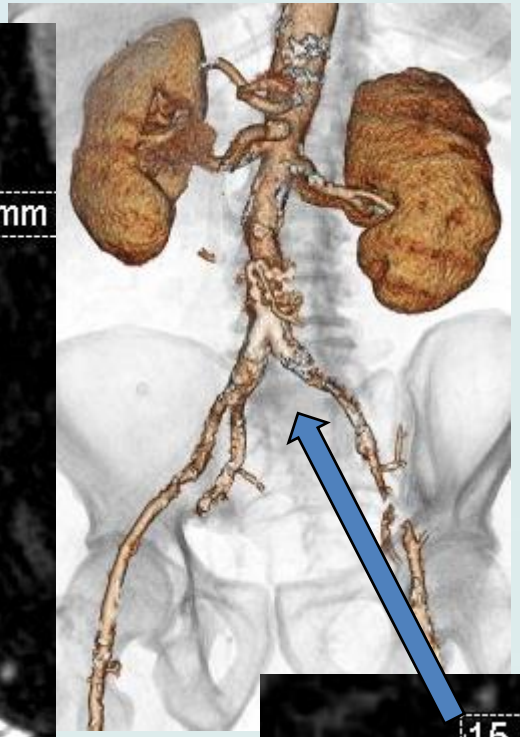

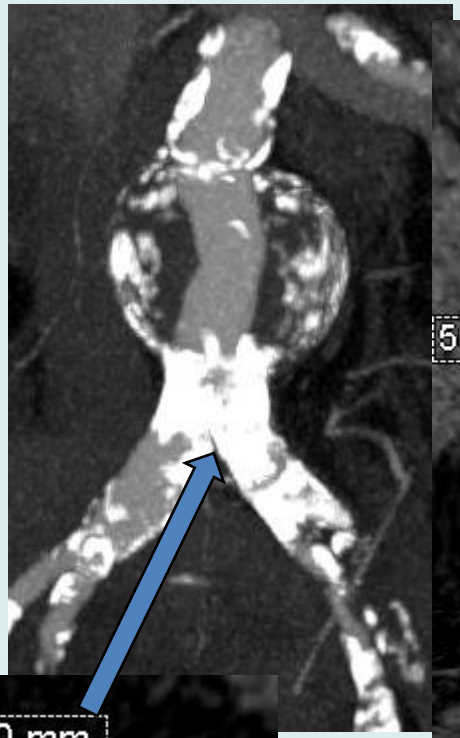

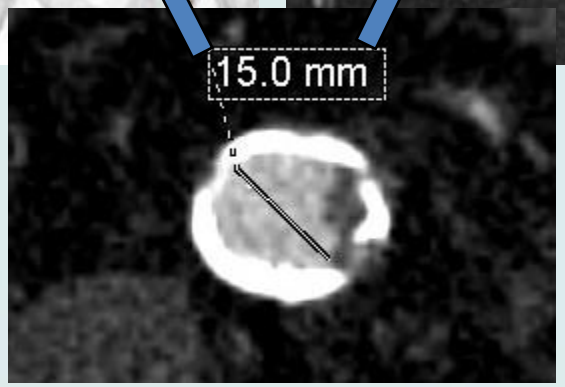

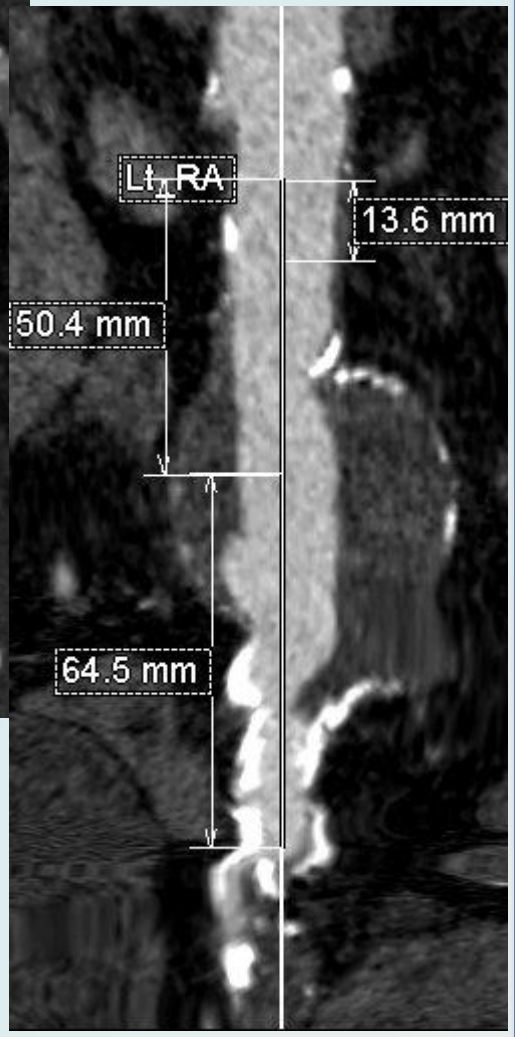

Complex access vessels:

small calcified aortic bifurcation and EIA occlusion

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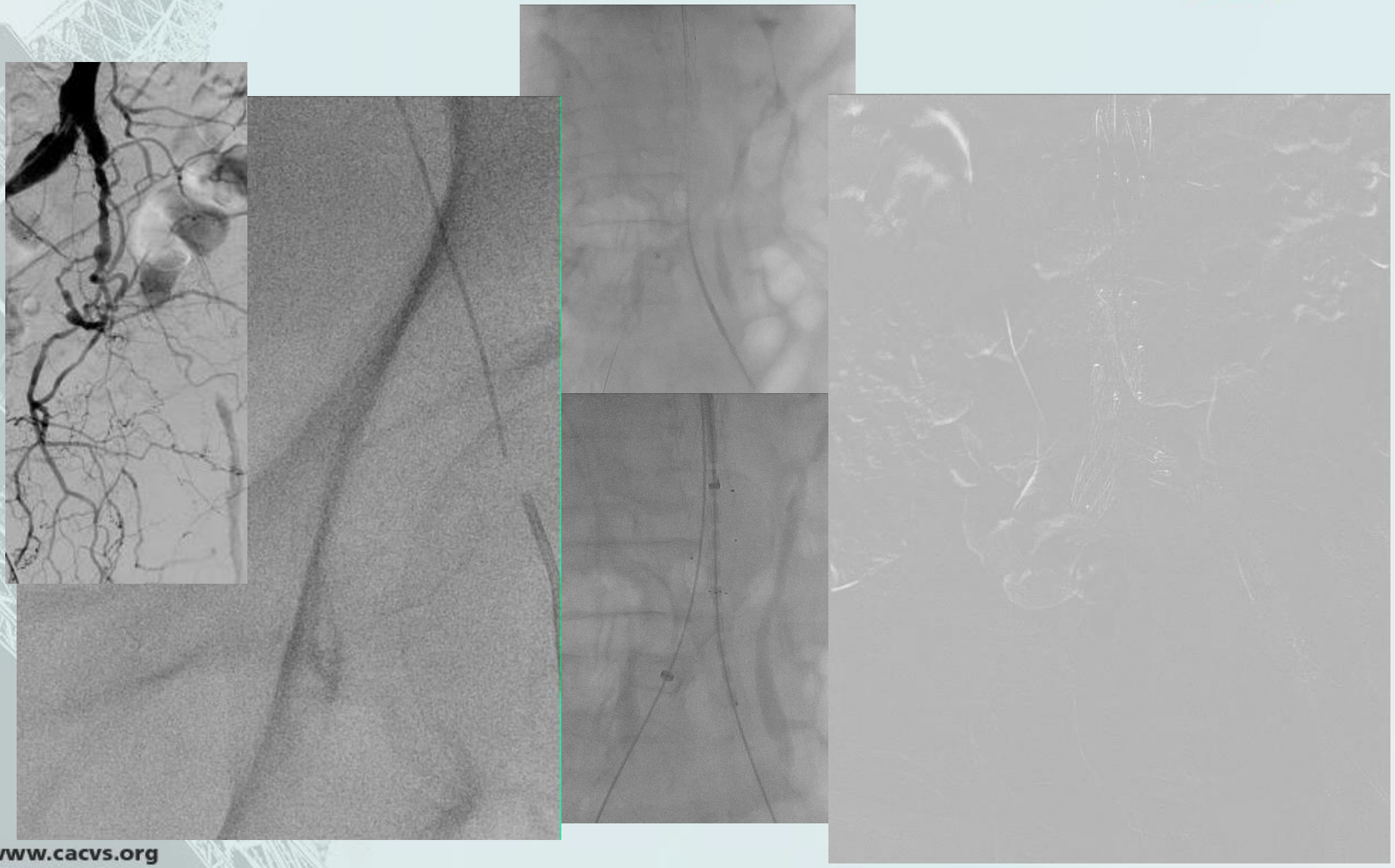

INCRAFT
in complex access vessels

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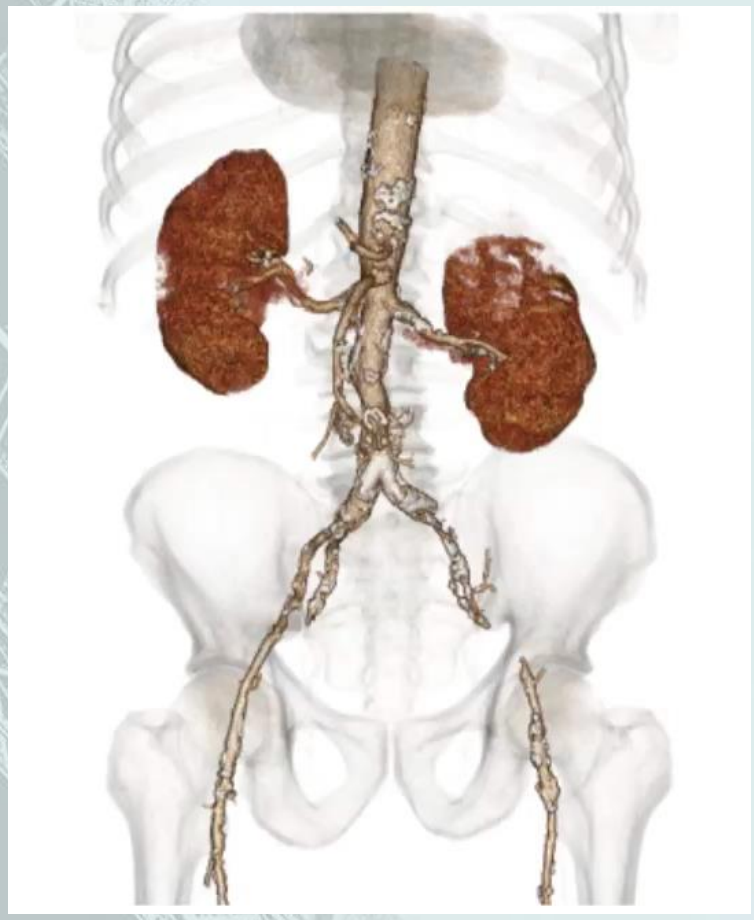
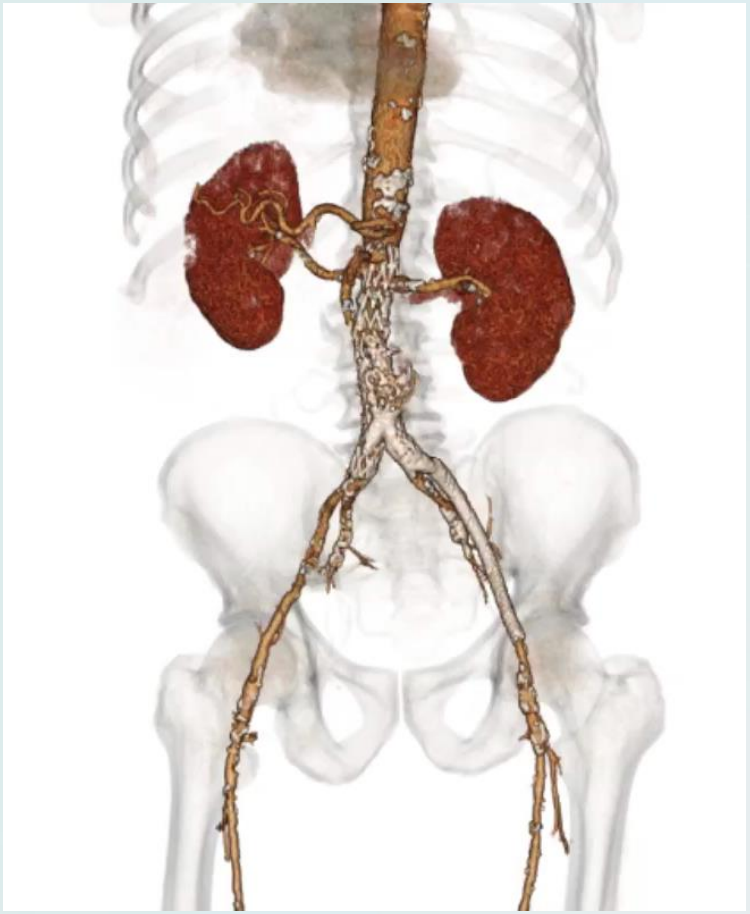
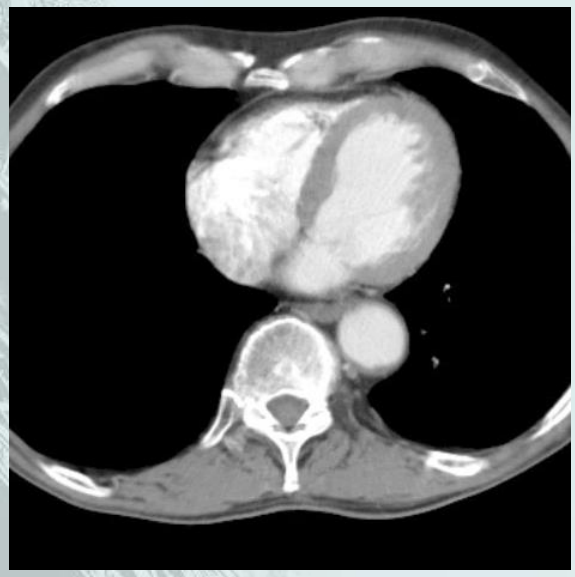
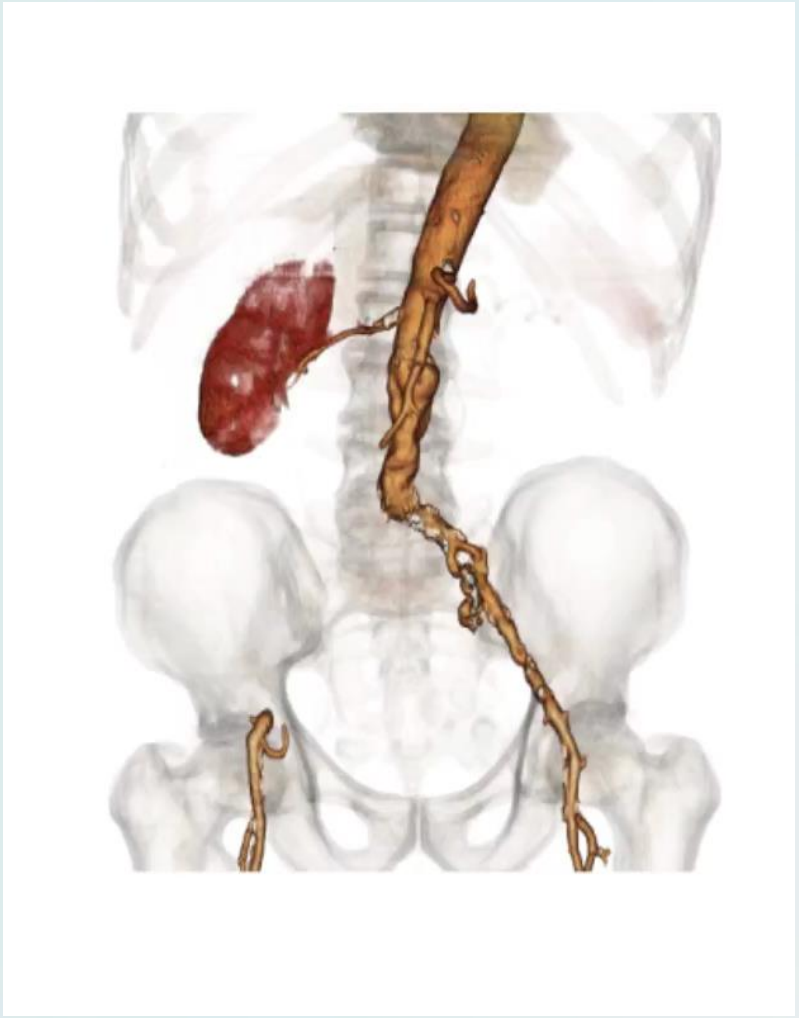




Complex cases: challenging access vessels

- Male, 74 y/o
- Hypertension, CAD, CVD, CRI (creat 2,1 mg/dL)
- AAA 58mm, Rt symptomatic CIA-EIA occlusion





Complex access vessels:

Common and external iliac artery occlusion

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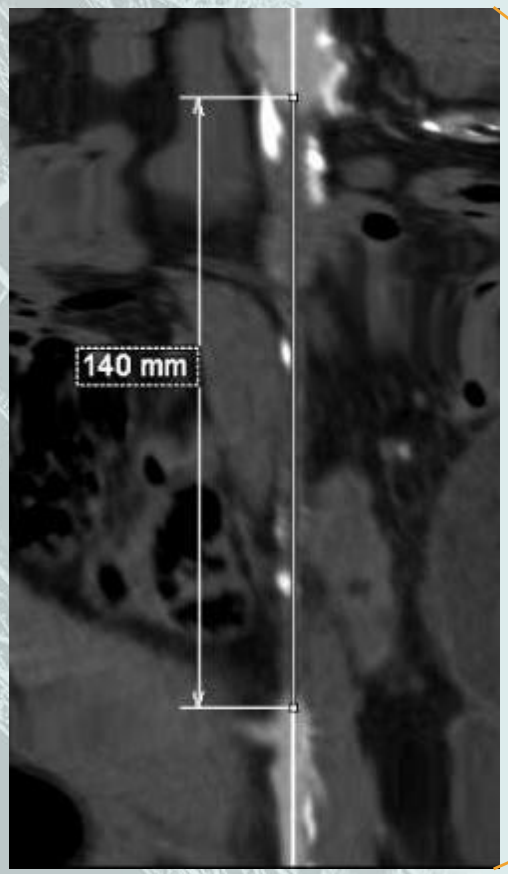
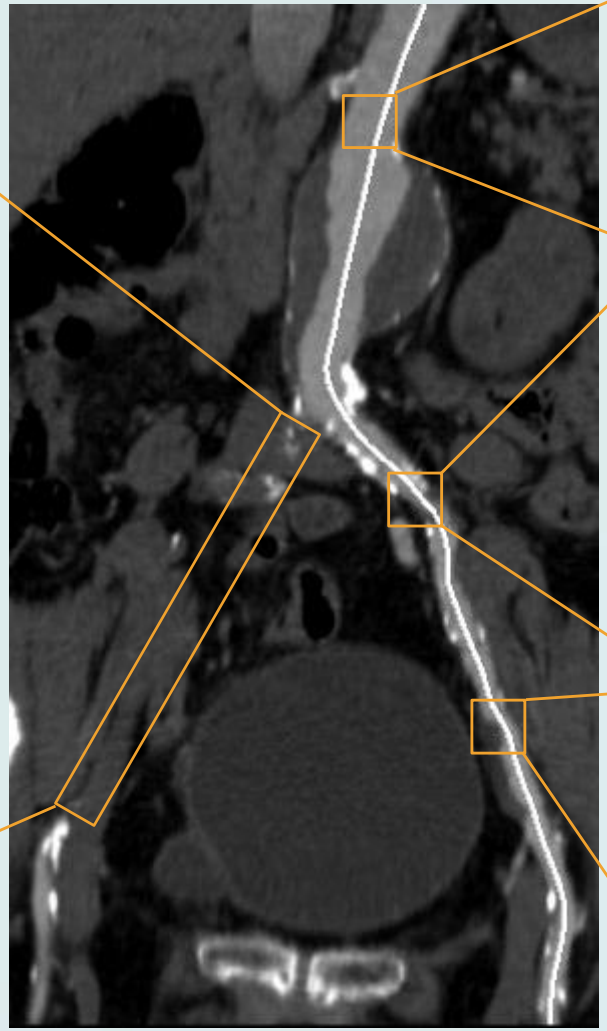
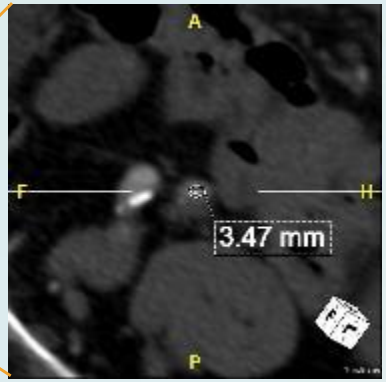
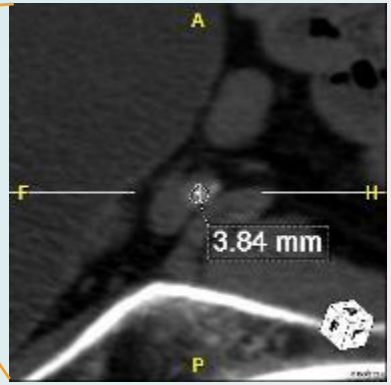
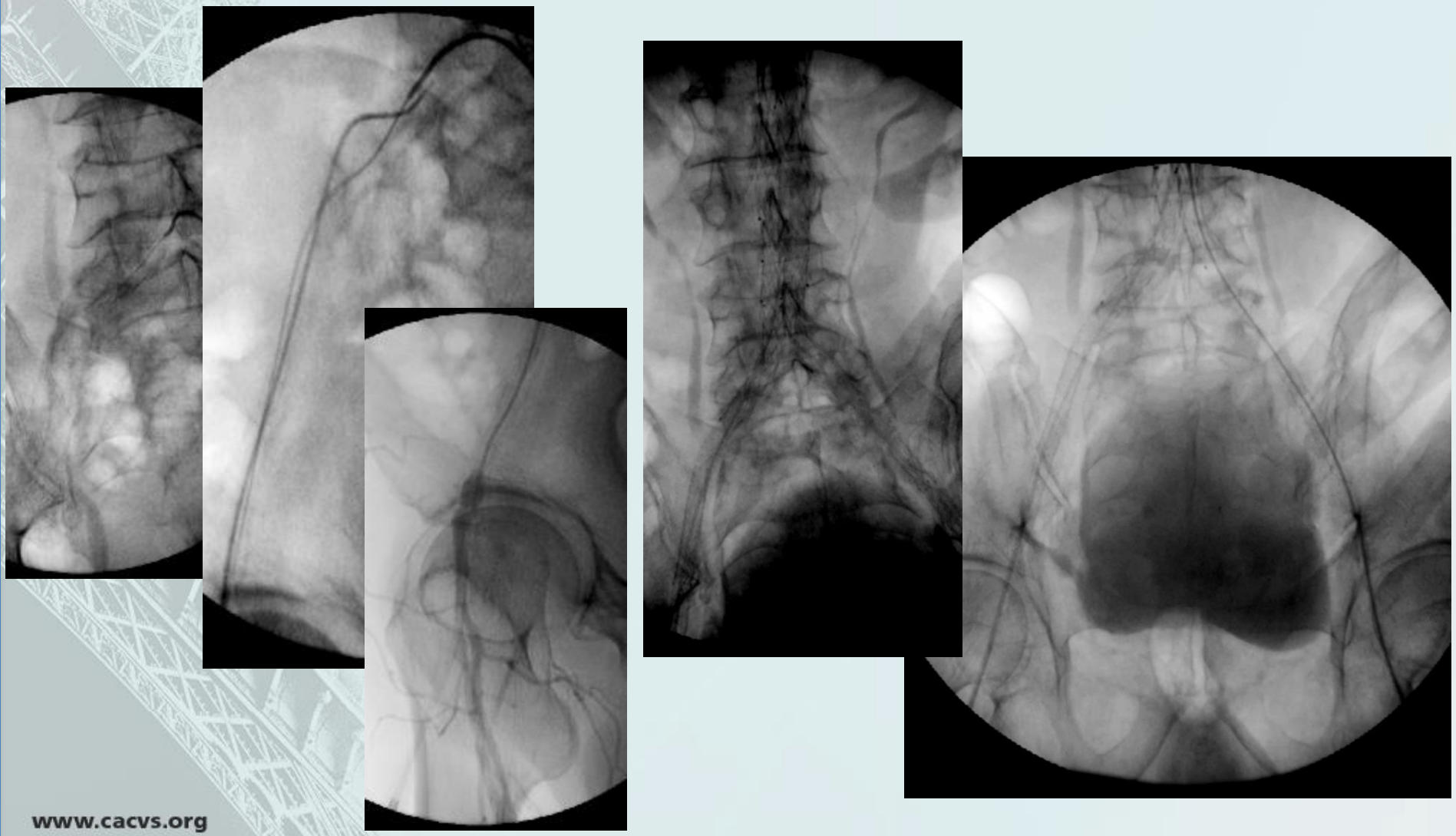




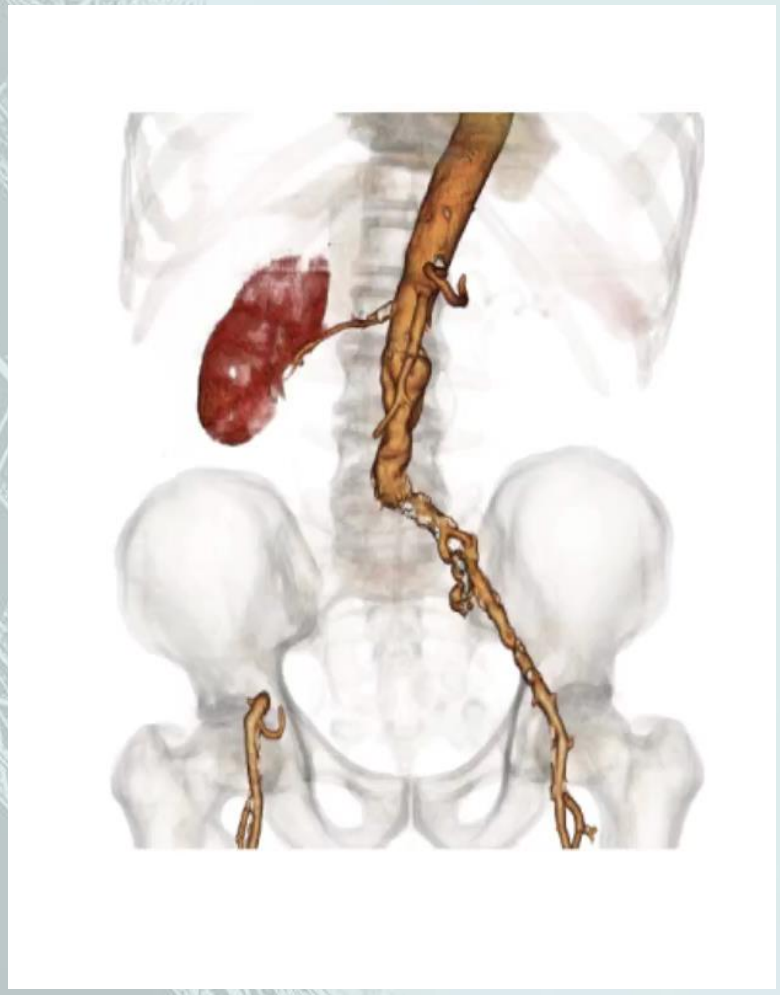


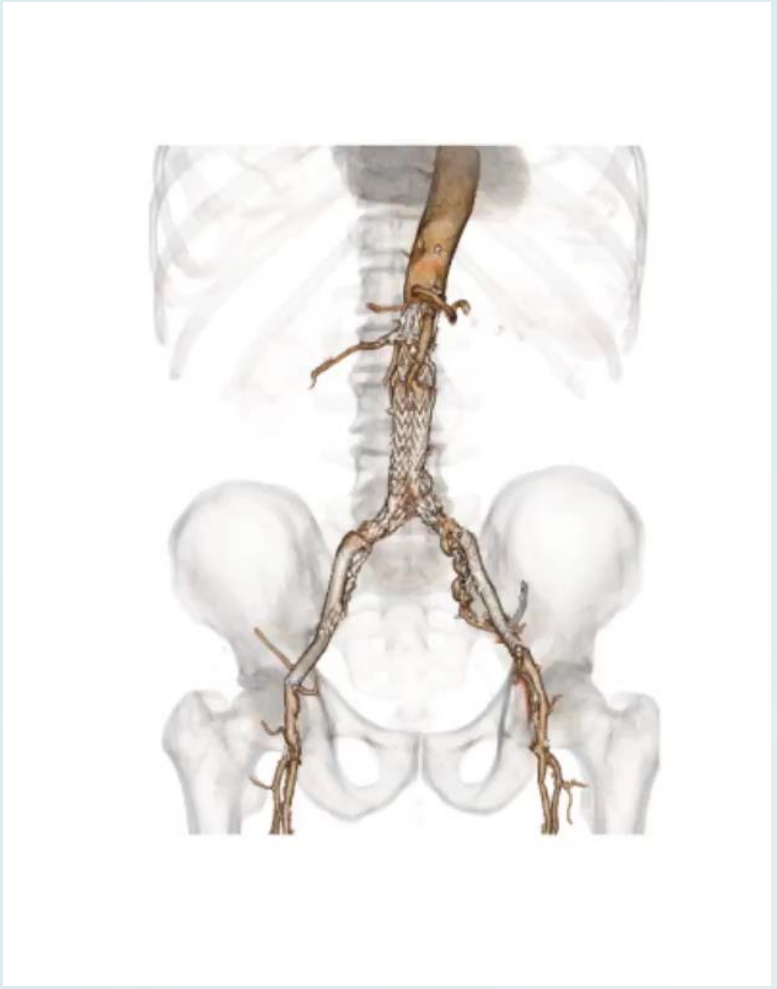


Complex access vessels: Common and external iliac artery occlusion



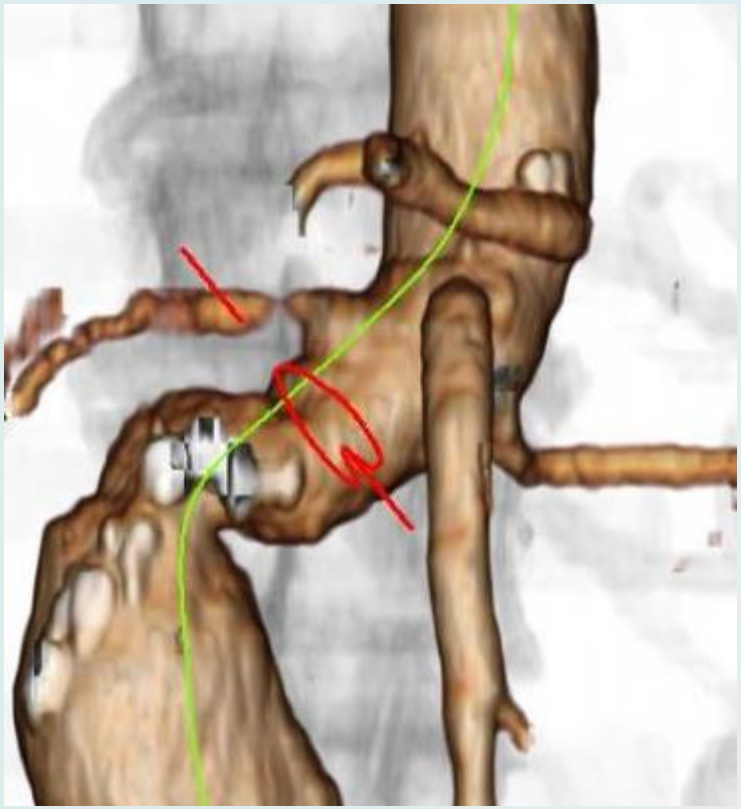
INCRAFT
in complex access vessels



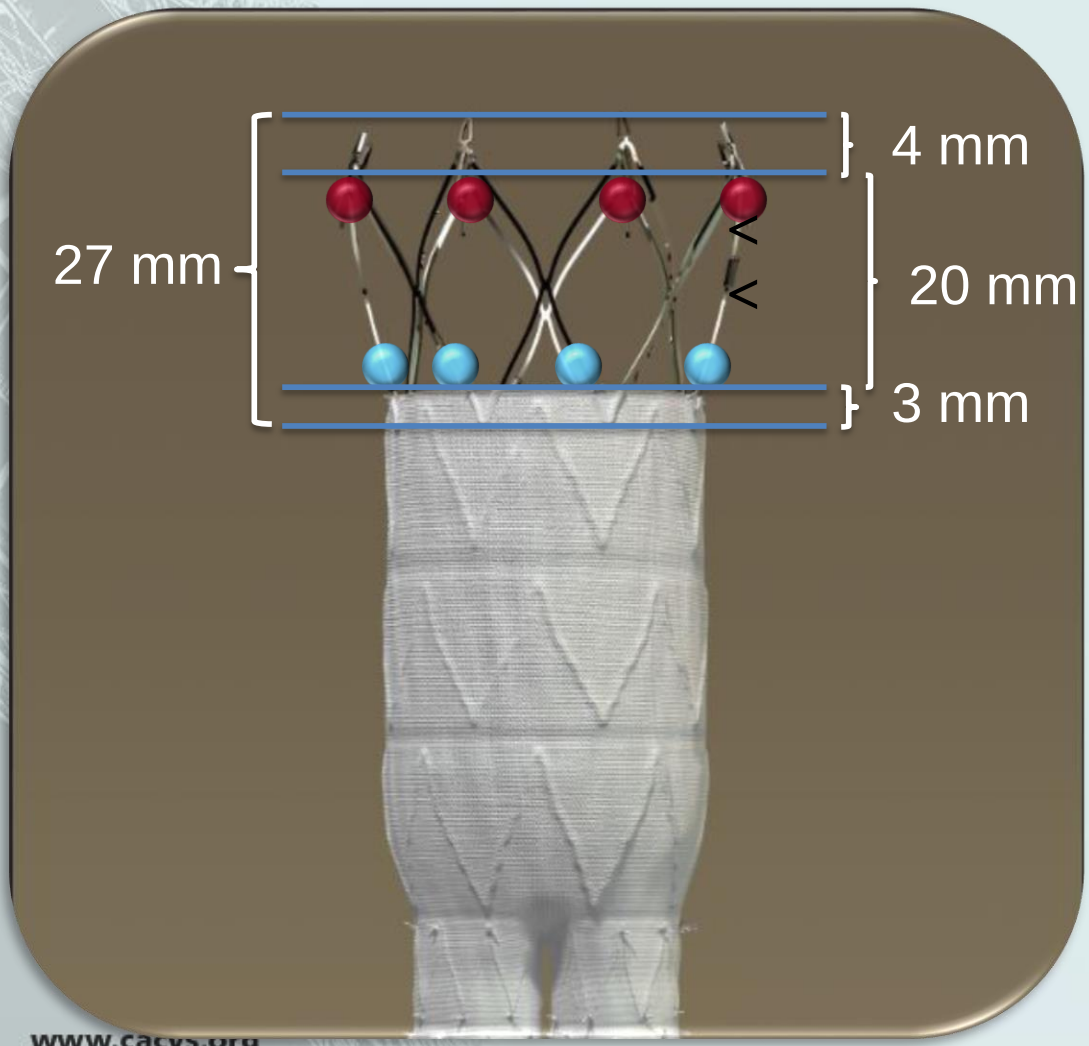


Expanding EVAR applicability in complex proximal aortic neck

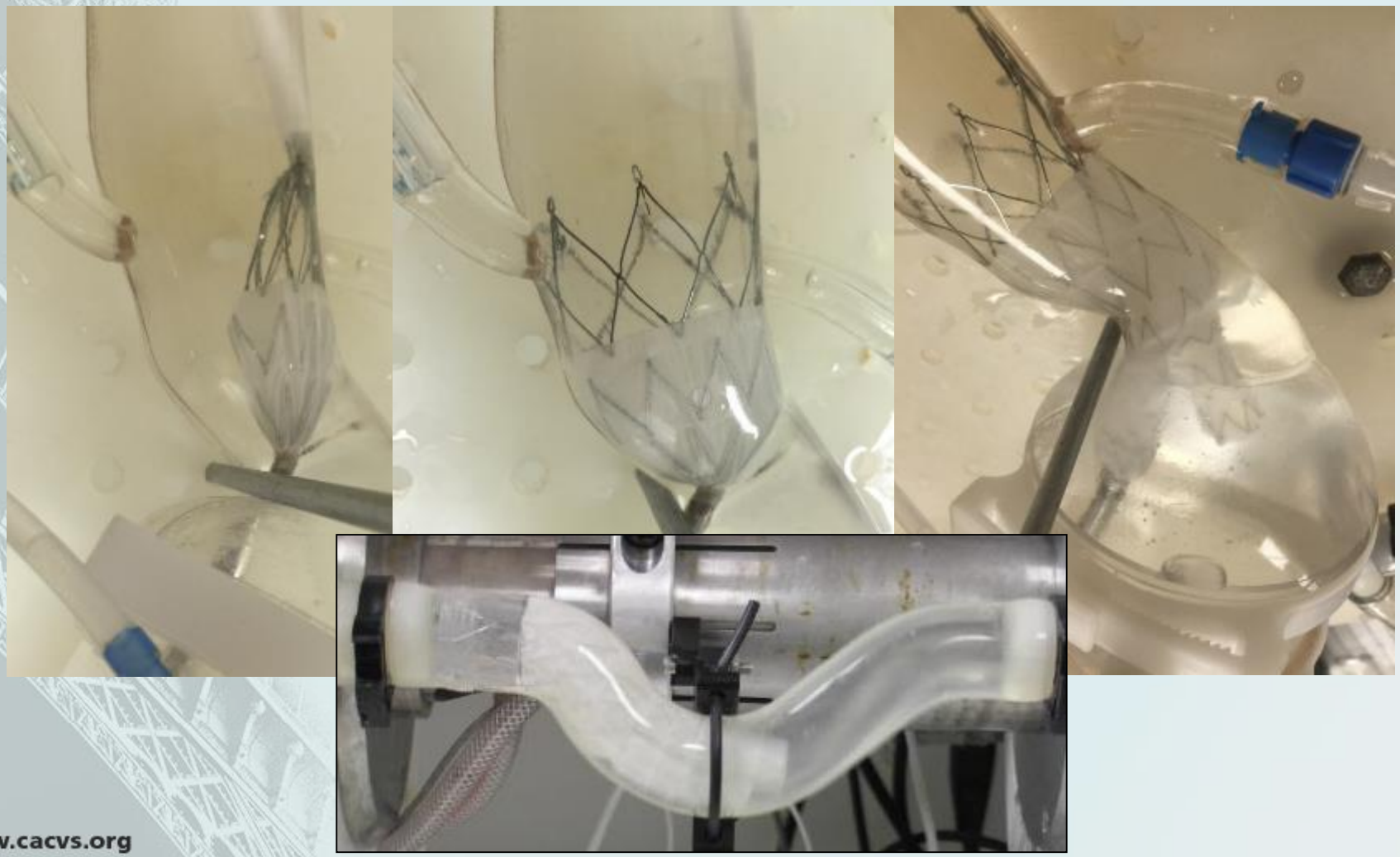
- Precise deployment with ability to be repositioned
- Proximal sealing zone design
- Proven neck compliance w/o neck enlargment



INCRAFT®: proximal design



INCRAFT®: proximal conformability



Complex cases: challenging proximal aortic neck

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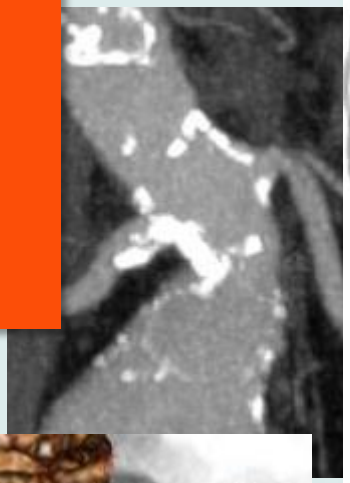
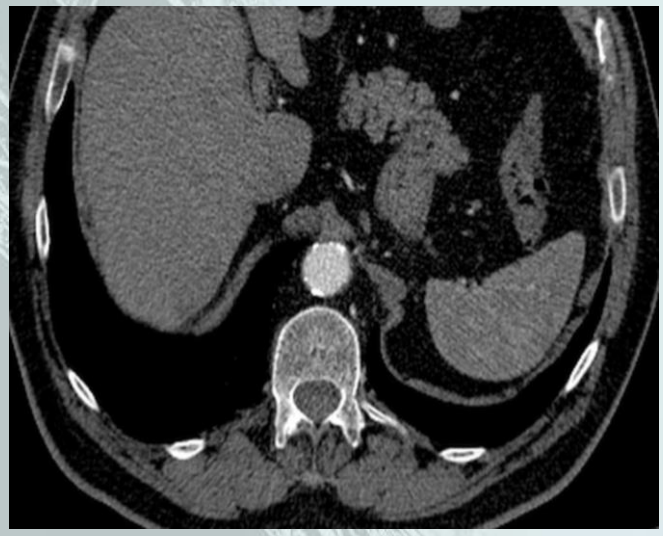
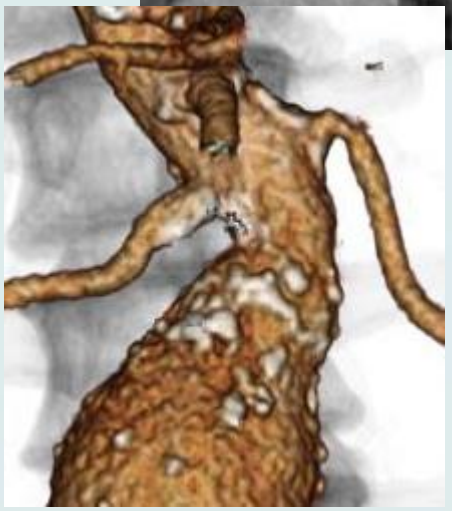
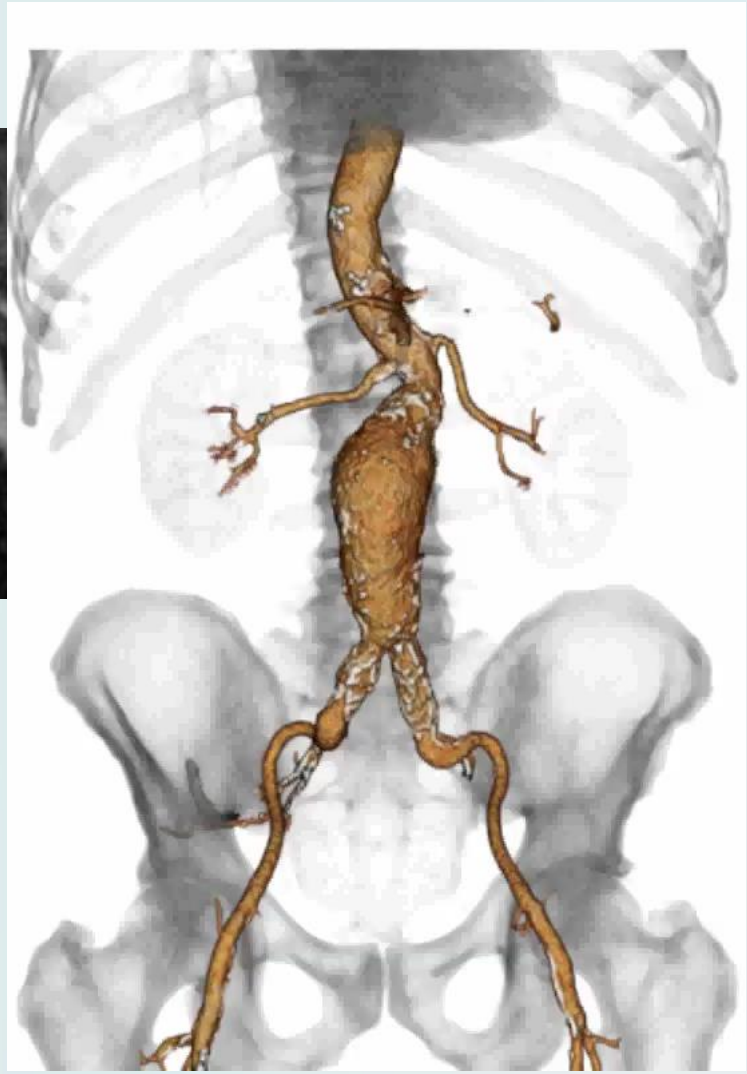
- *Male, 68 y/o*
- *AAA 56 mm*
- *7 mm proximal aortic neck with calcification*
- *Infrarenal angulation 90°*









Complex proximal aortic neck: short, angulated, calcified

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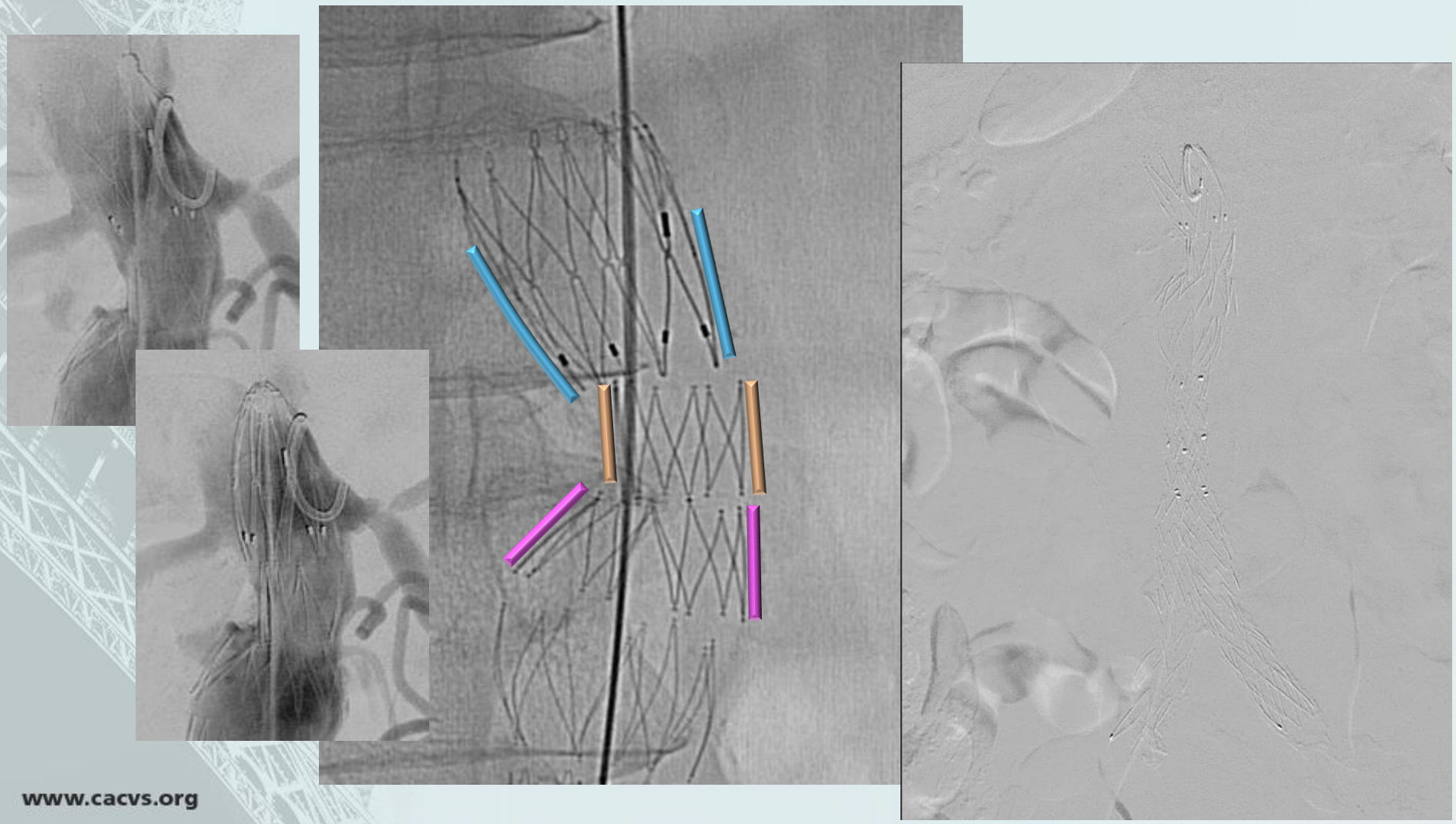

INCRAFT
in complex proximal aortic neck

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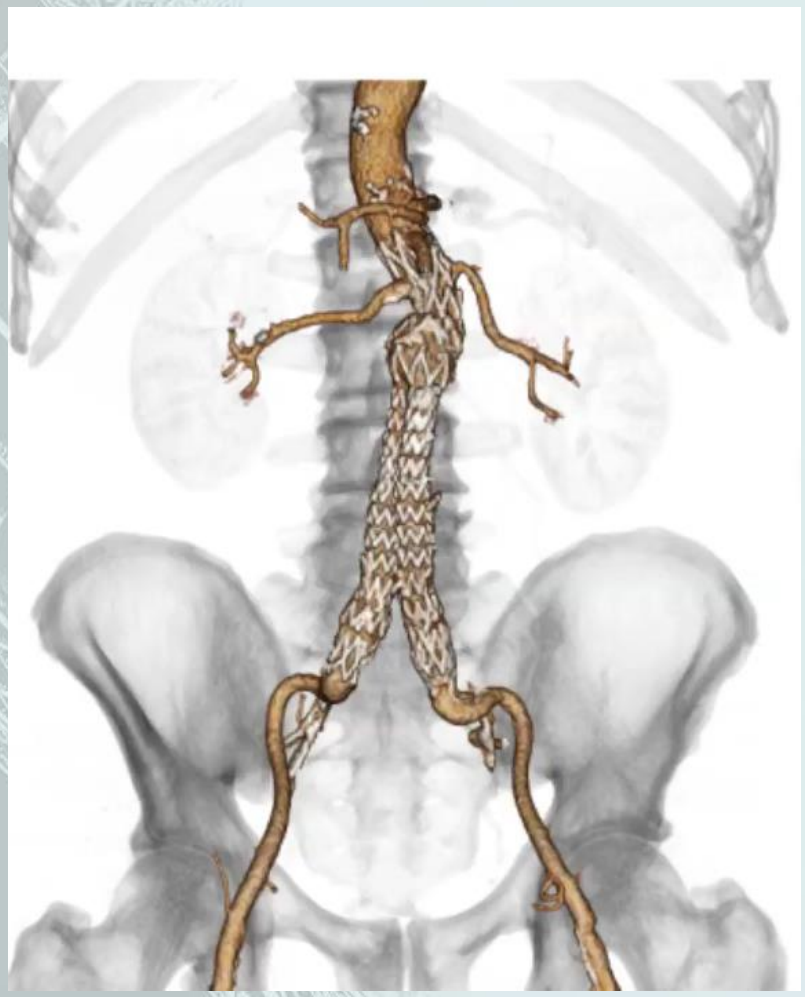

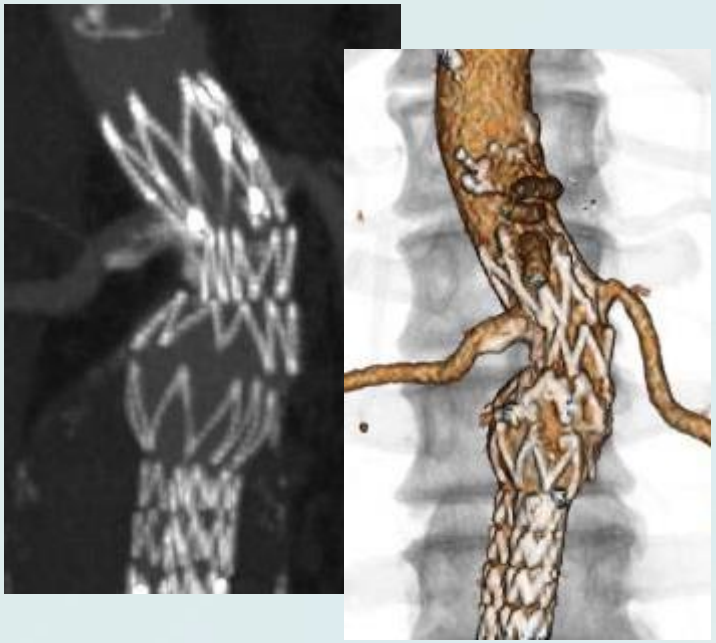

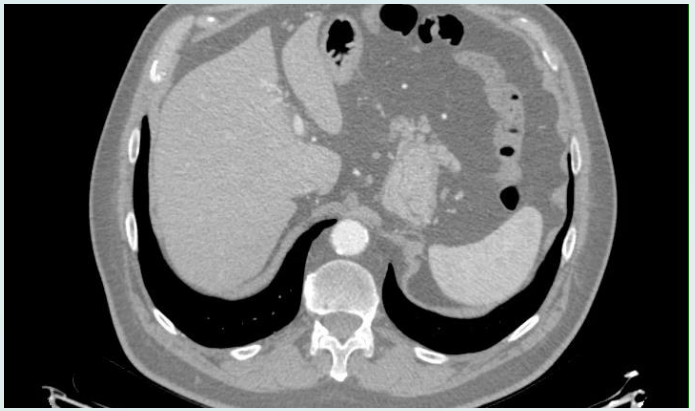

Complex cases: challenging proximal aortic neck

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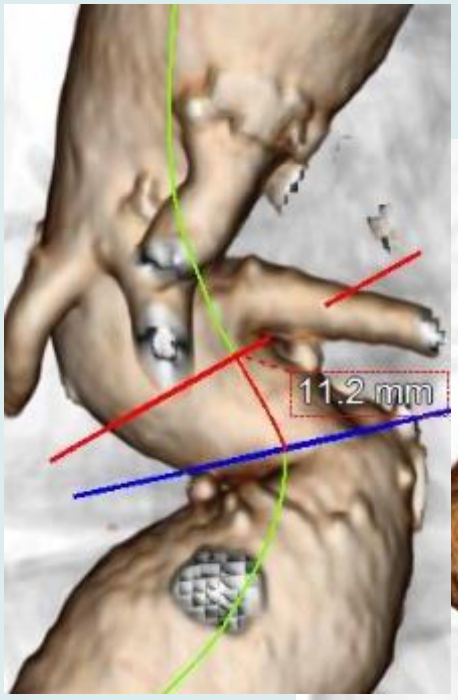
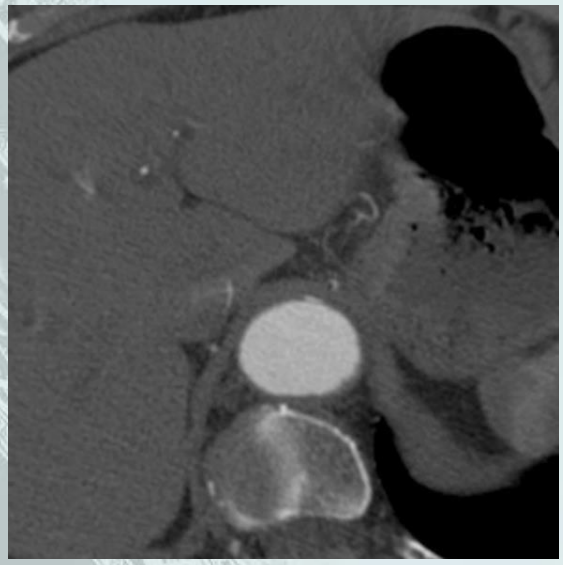
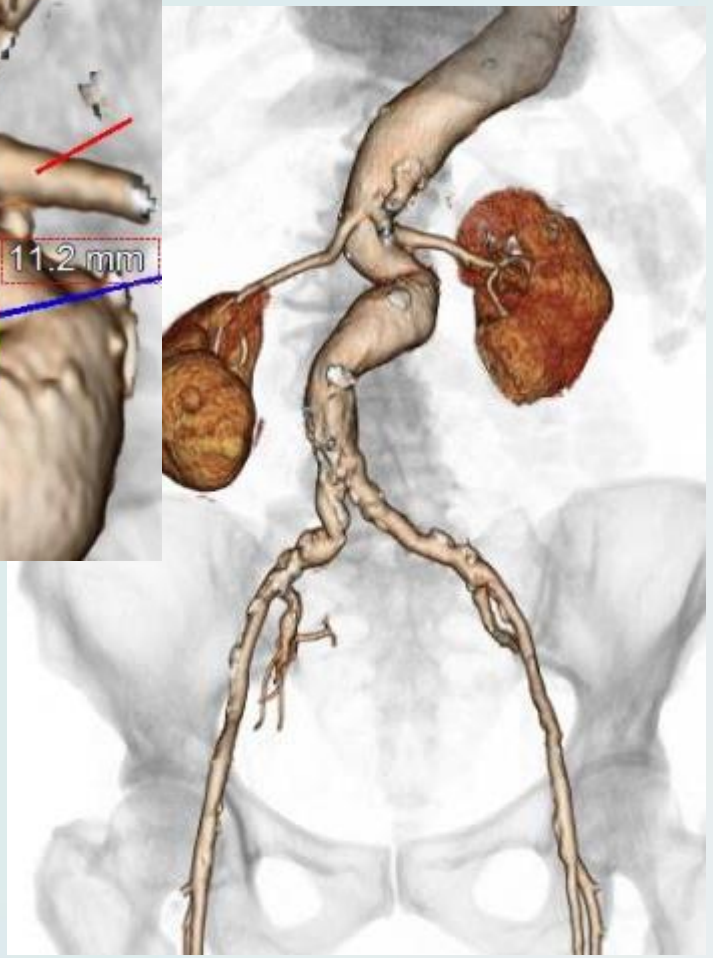
- Female, 75 y/o
- Saccular AAA 45 mm
- 11 mm proximal aortic neck with supra and infrarenal angulation (75 and 90°)







Complex proximal aortic neck:
short with supra and infra-renal angulation

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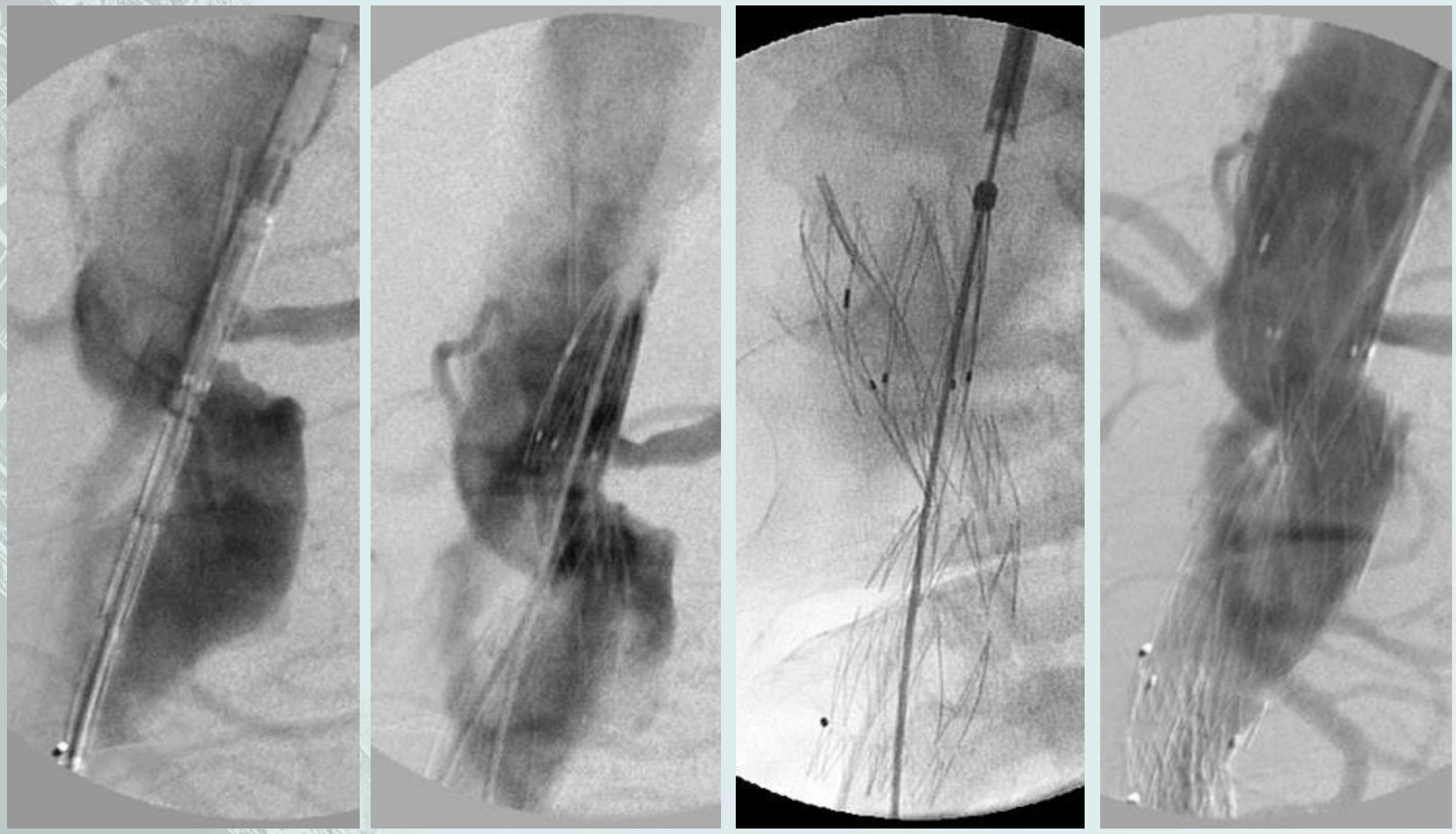

INCRAFT
in complex proximal aortic neck

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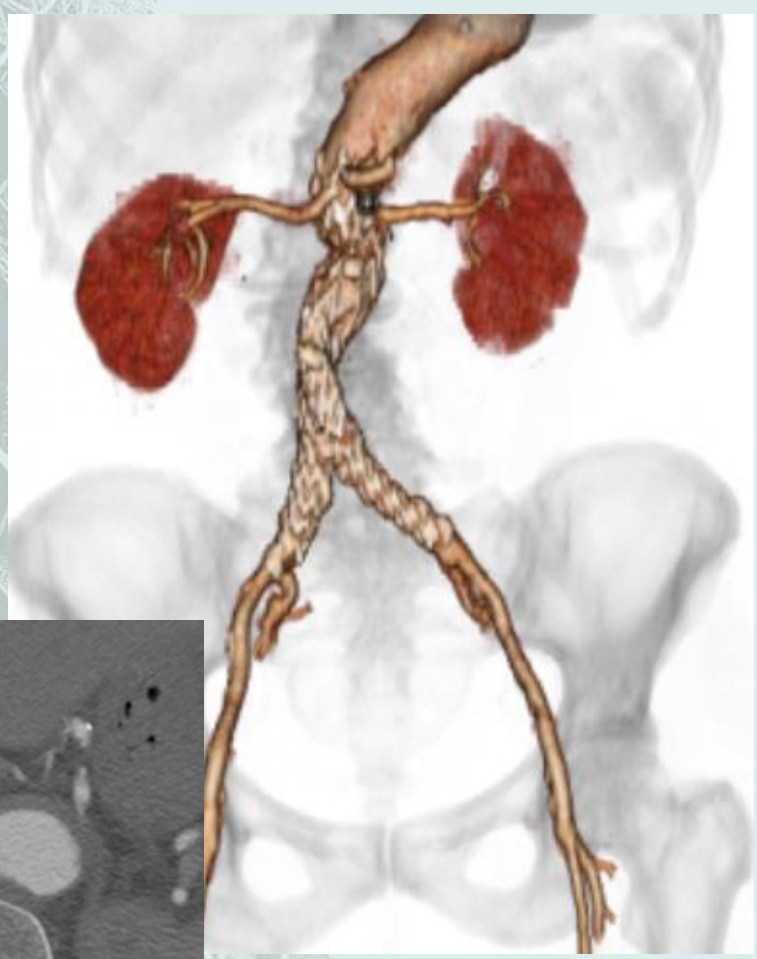

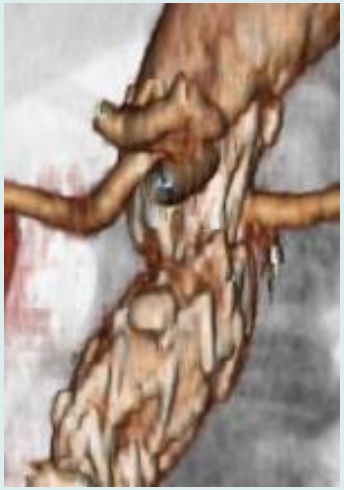

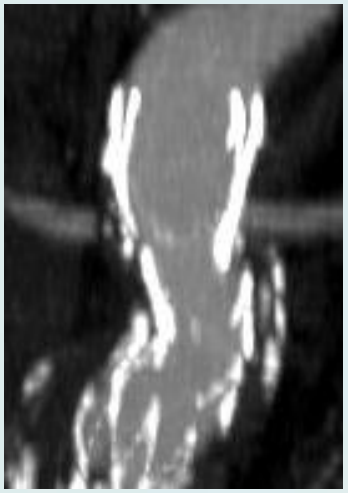

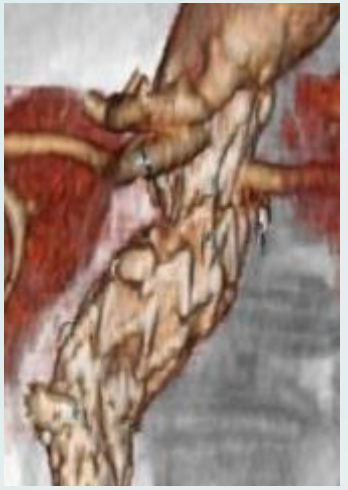

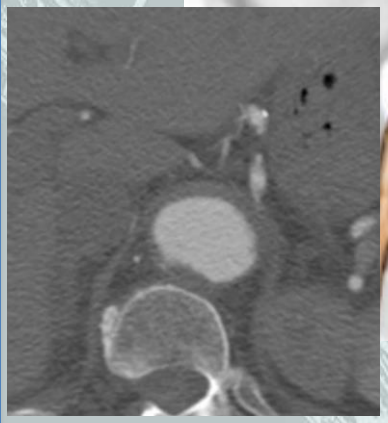

Complex cases: challenging proximal aortic neck

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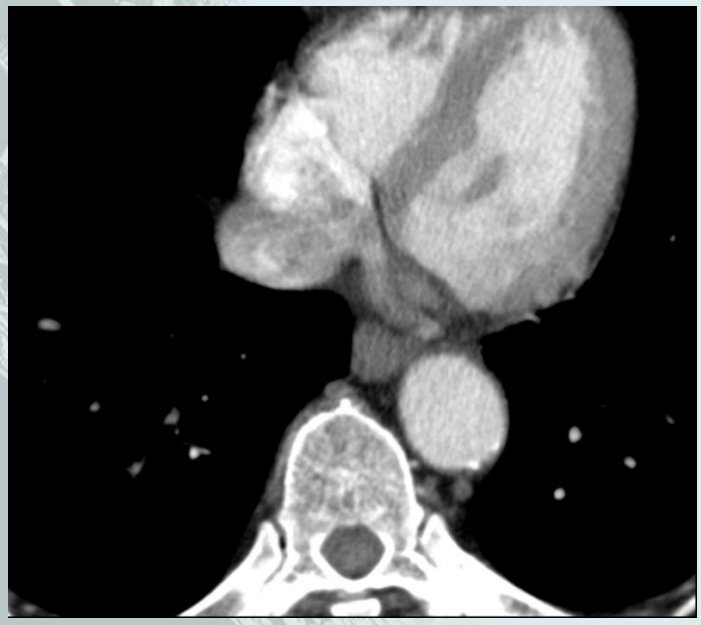
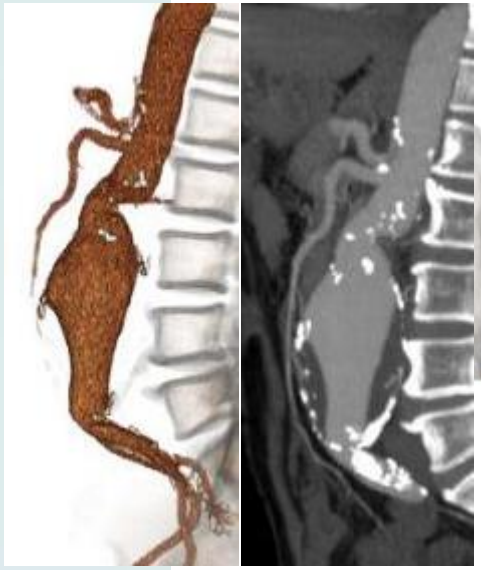
- Male, 70 y/o
- Symptomatic AAA 62 mm
- 10 mm proximal aortic neck
- Hourglass configuration





Complex proximal aortic neck: short with hourglass configuration

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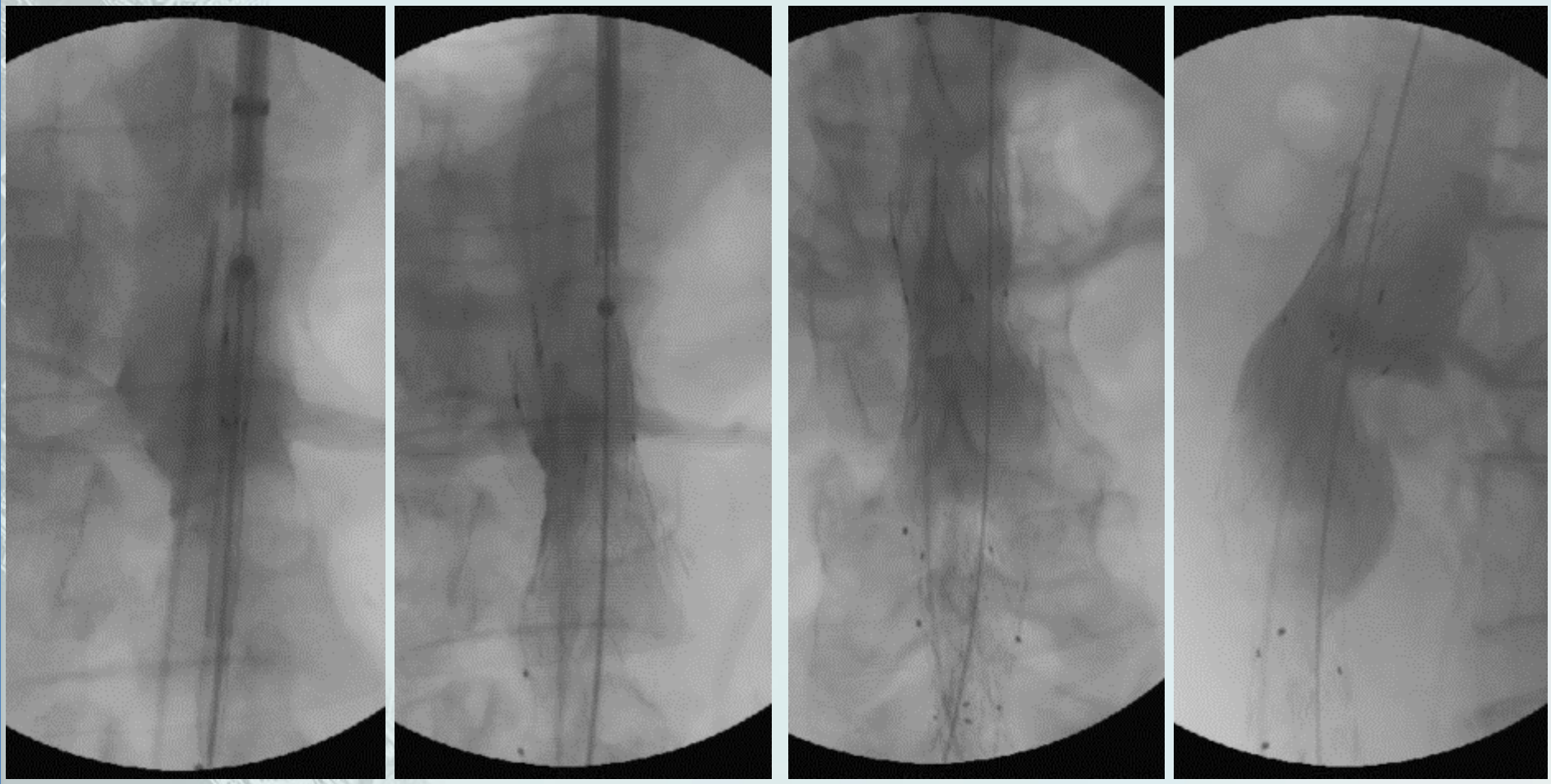

INCRAFT
in complex proximal aortic neck

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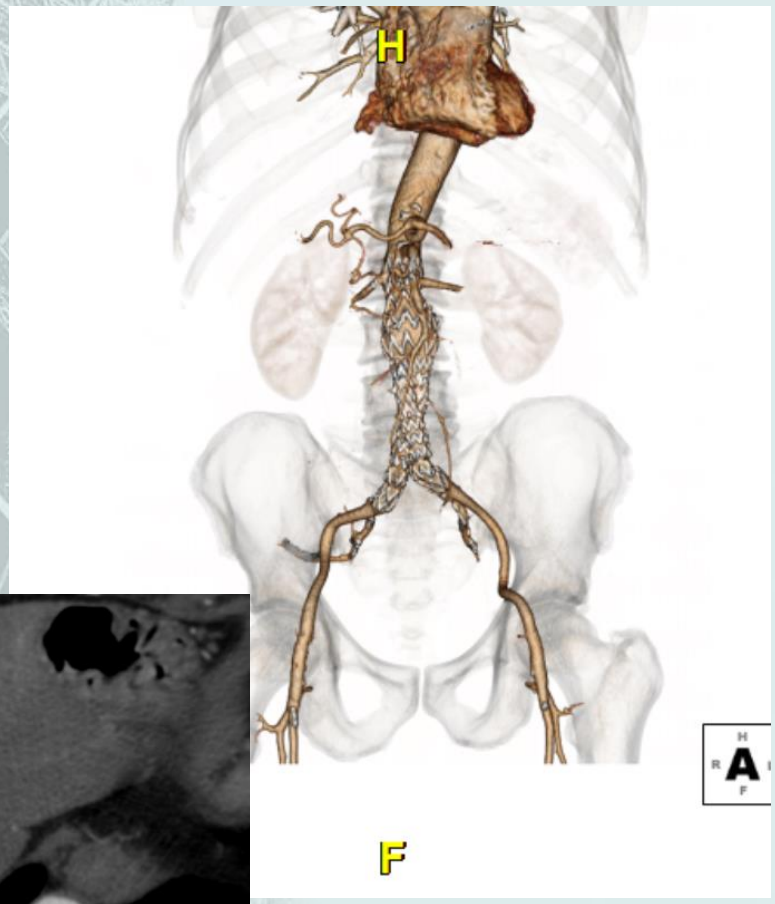

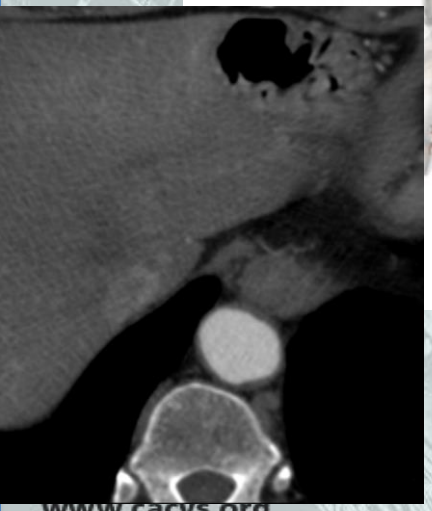

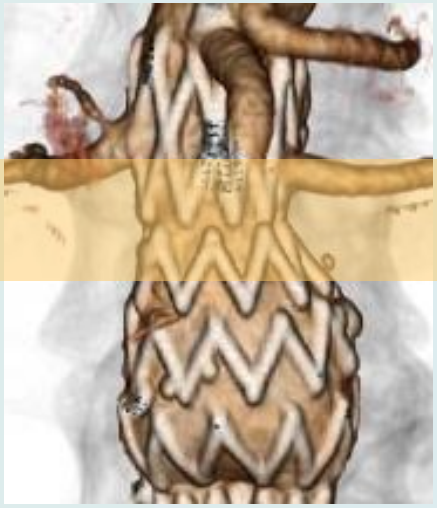

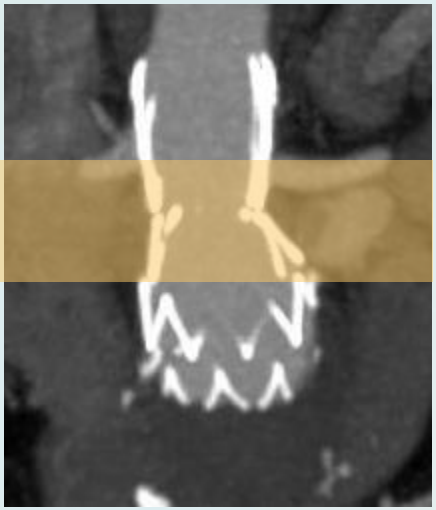

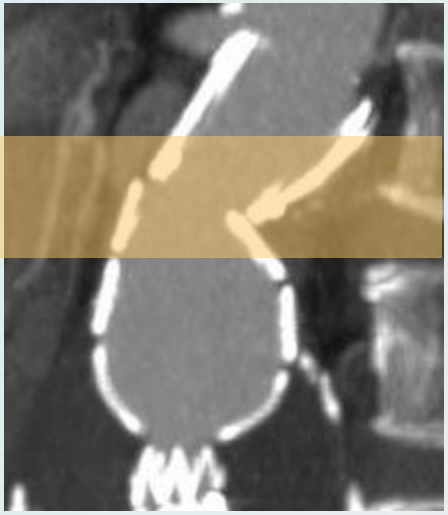

INCRAFT
in complex proximal aortic neck

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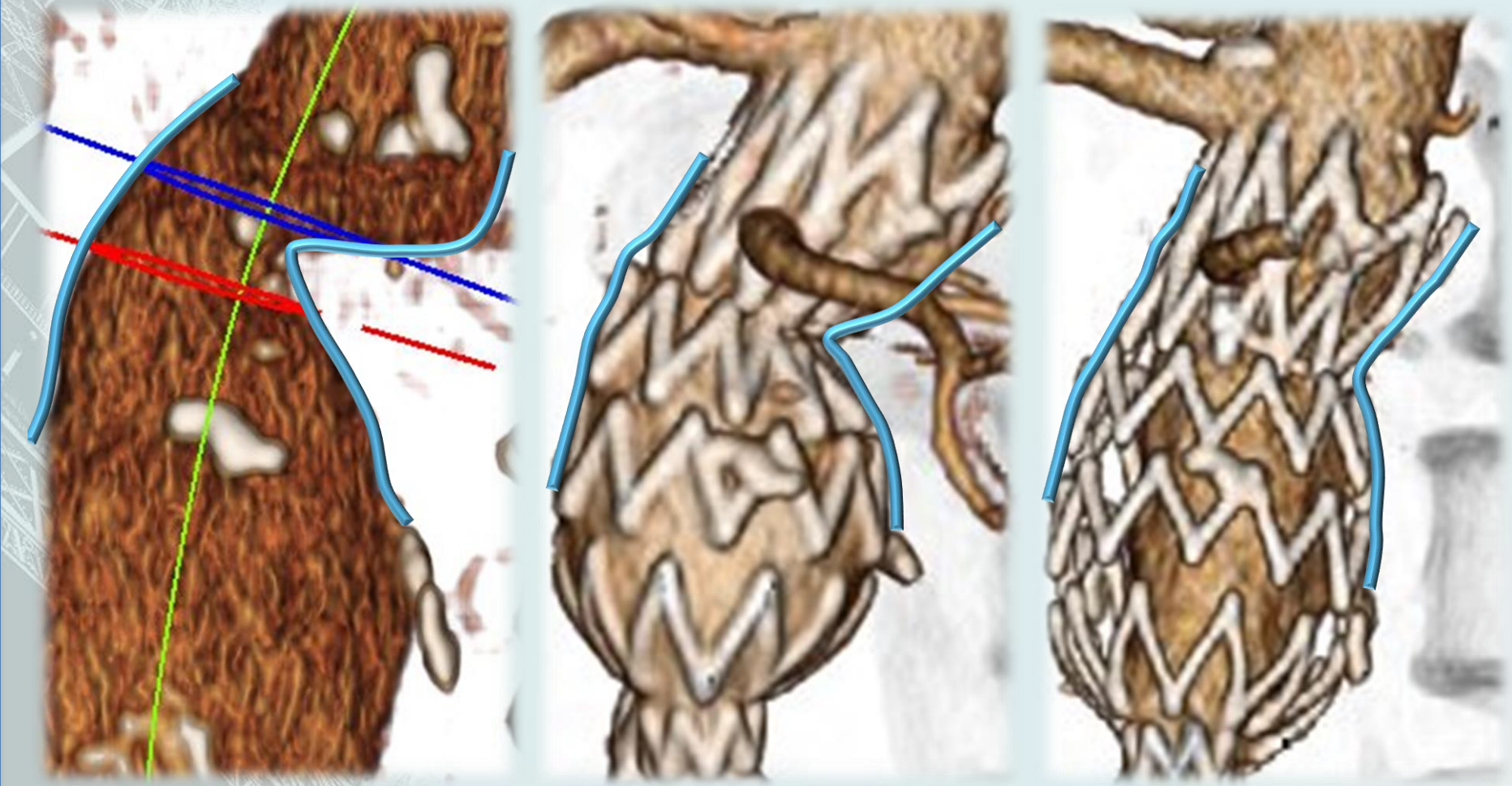
Preop CTA **CTA @ 1 M** **CTA @ 1 Y**



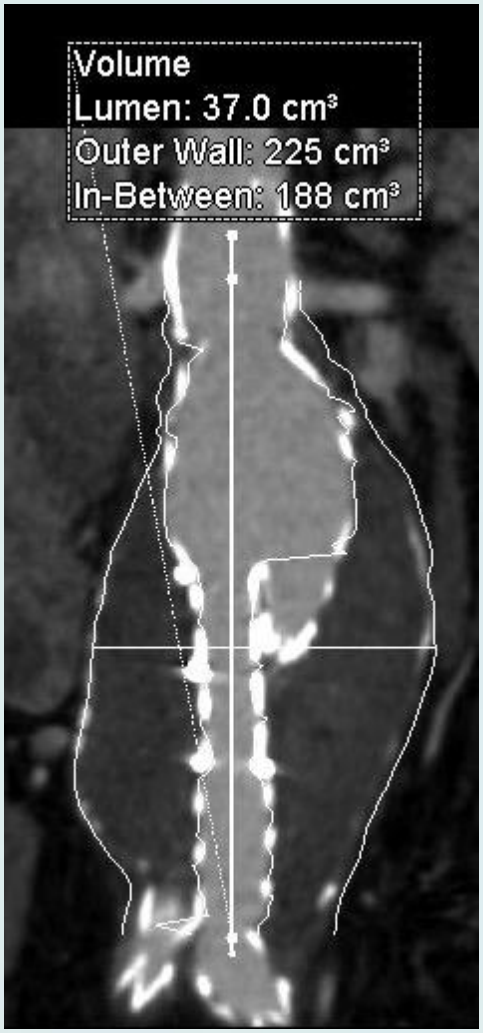
INCRAFT
in complex proximal aortic neck

- Preop diameter: 62mm
- Preop volume: 225 cm^3

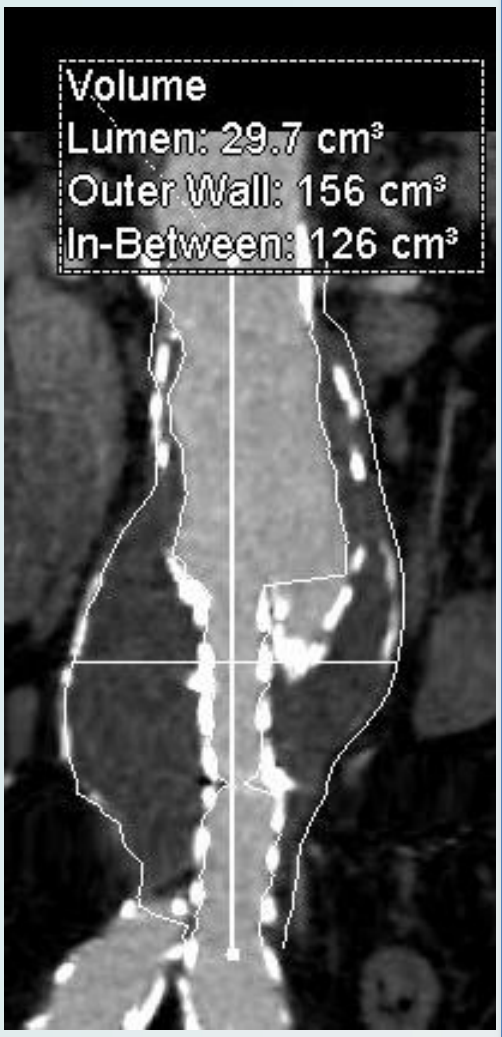
- Postop 1 Y diameter: 51mm
- Postop volume: 156 cm^3

Shrinkage @ 1 Y:
69 cm^3 30.5%

CTA @ 1 M



CTA @ 1 Y



Vascular Surgery – University of Rome "Tor Vergata"

42 INCRAFT procedures

(September 2014 – December 2016)

20 patients with complex anatomy
proximal aortic neck or challenging access vessels

Proximal aortic neck diameter	22.9 ± 2.5 mm (18-28)
Proximal aortic neck length	15.3 ± 6.8 mm (4-30)
Proximal aortic neck angulation	29.7 ± 22.9 ° (5-90)
Left external iliac artery diameter	6.3 ± 2.1 mm (4-12)
Right external iliac artery diameter	6.2 ± 1.9 (4.7-11)
Iliac access tortuosity	11/42 (35%)
Iliac access occluded	5/42 (11.9%)

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Incraft in standard vs complex anatomy

(September 2014 – December 2016)

median age 75.5 ± 7.5 ys (range 65-85)

	Standard group (n=22)	Complex group (n=20)	p
Technical success	22/22 (100%)	20/20 (100%)	-
30-day mortality	-	1/20 (5%)	.27
Limb occlusion	-	1/20 (5%)	.27
Reintervention	1/22 (4.5%)	1/20(5%)	.52
Type II Endoleak	5/22 (22.7%)	2/20 (10%)	.20
Type I/III endoleak	-	-	

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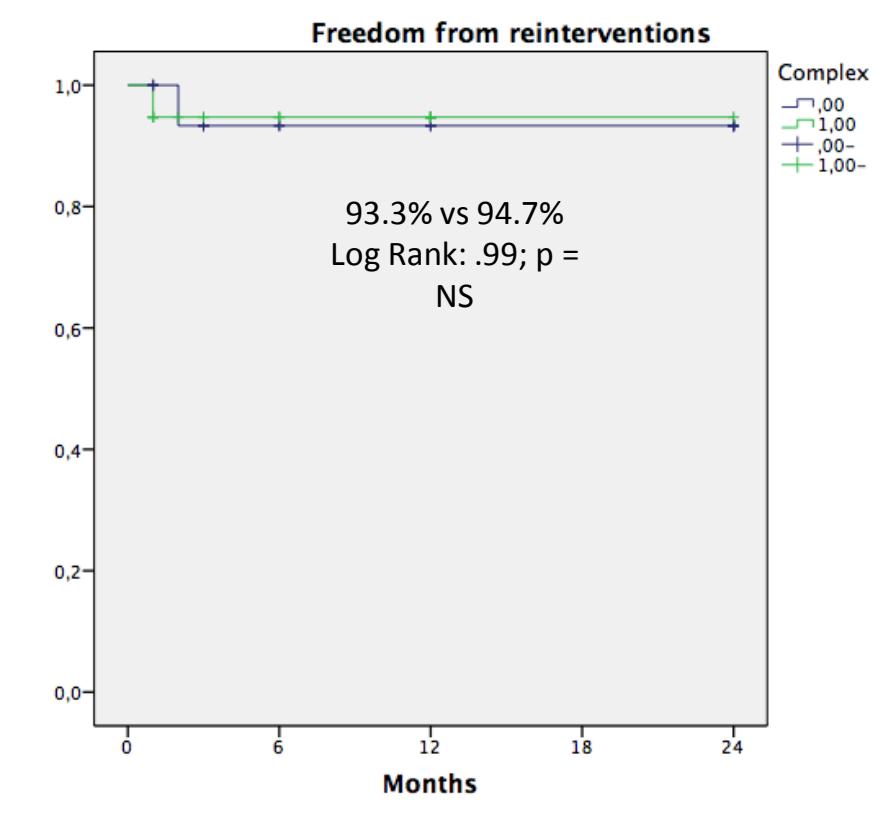

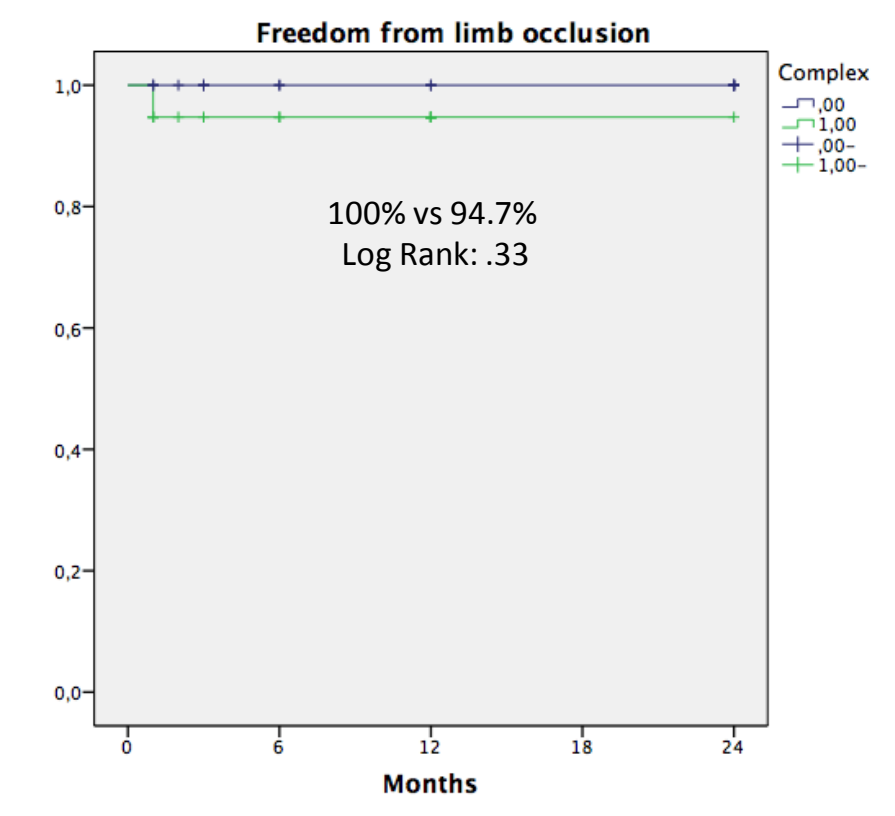

Conclusions

- Low profile endograft can expand EVAR feasibility in standard and complex cases
- INcraft® showed excellent trackability, accuracy of placement and conformability in challenging proximal and distal anatomies
- Clinical data confirm durability of INCRAFT® in the mid-term follow-up