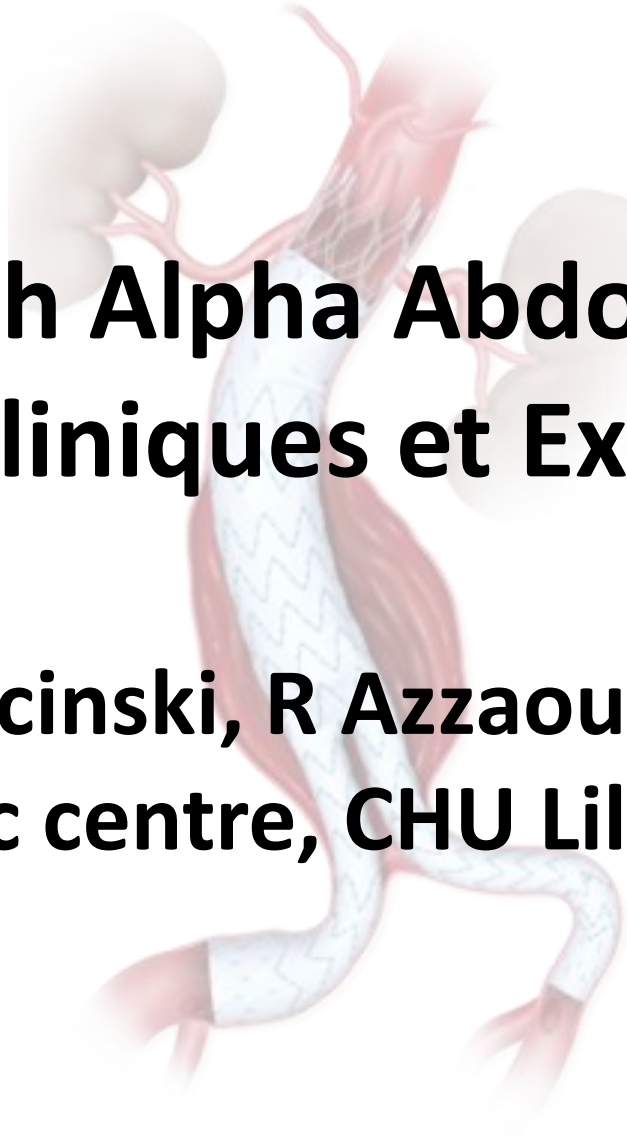

Zenith Alpha Abdominale : Cas Cliniques et Expérience

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FACULTE DE MEDECINE
Centre Hospitalier Régional Universitaire de Lille

EVAR – guidelines

Eur J Vasc Endovasc Surg (2011) 41, S1–S58

ELSEVIER

esvs Journal

Management of Abdominal Aortic Aneurysms Clinical Practice Guidelines of the European Society for Vascular Surgery

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KEYWORDS
Abdominal aortic aneurysms;
Guidelines;
Management;
Clinical practice;
Evidence-based medicine

Introduction

Purpose of these guidelines

The European Society for Vascular Surgery (ESVS) appointed the AAA Guidelines Committee to write the current clinical practice guidelines document for surgeons and physicians who are involved in the care of patients with abdominal aortic aneurysms (AAAs). Guideline development was recommended in 1990 by the Institute of Medicine to improve decision making for specific patients' circumstances and to decrease the variability in appropriate and inappropriate

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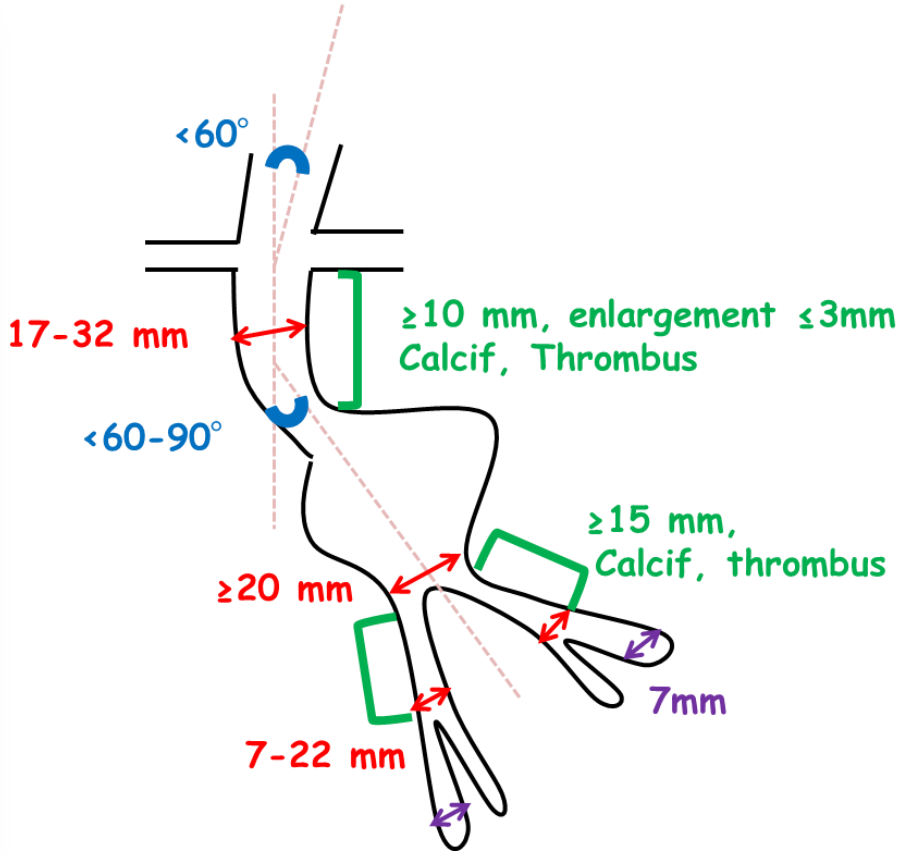

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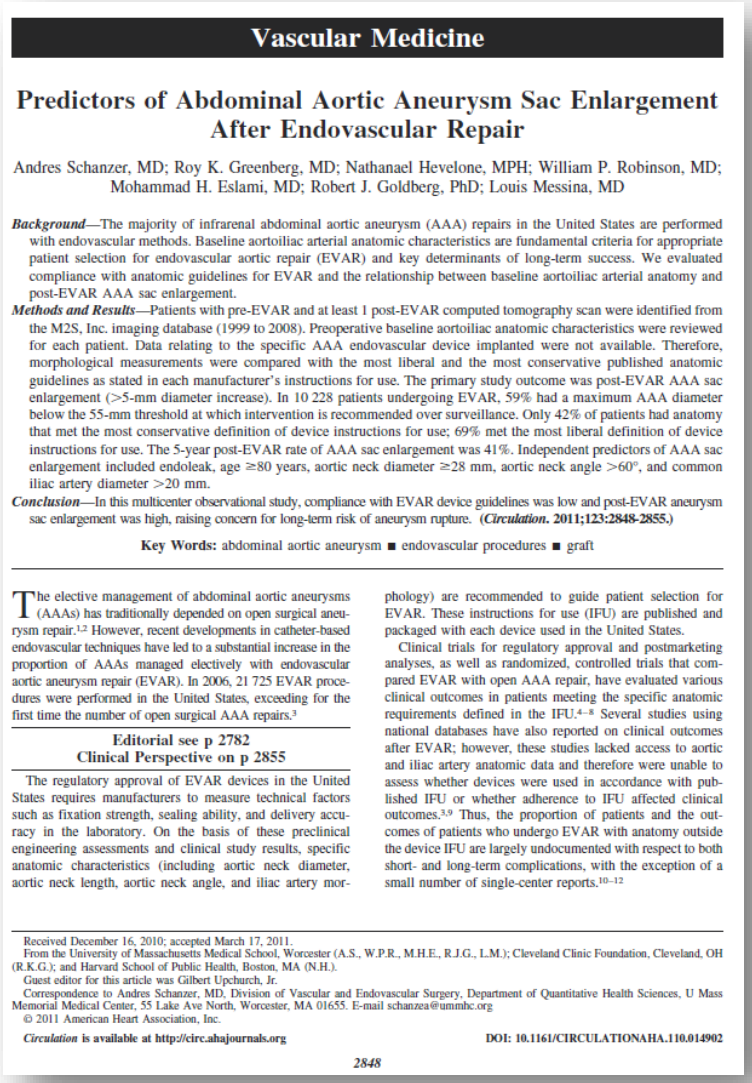

Vascular Medicine

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥80 years, aortic neck diameter ≥28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. **(*Circulation*. 2011;123:2848-2855.)**

Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

The elective management of abdominal aortic aneurysms (AAAs) has traditionally depended on open surgical aneurysm repair.[1,2] However, recent developments in catheter-based endovascular techniques have led to a substantial increase in the proportion of AAAs managed electively with endovascular aortic aneurysm repair (EVAR). In 2006, 21 725 EVAR procedures were performed in the United States, exceeding for the first time the number of open surgical AAA repairs.[3]

Editorial see p 2782
Clinical Perspective on p 2855

The regulatory approval of EVAR devices in the United States requires manufacturers to measure technical factors such as fixation strength, sealing ability, and delivery accuracy in the laboratory. On the basis of these preclinical engineering assessments and clinical study results, specific anatomic characteristics (including aortic neck diameter, aortic neck length, aortic neck angle, and iliac artery morphology) are recommended to guide patient selection for EVAR. These instructions for use (IFU) are published and packaged with each device used in the United States.

Clinical trials for regulatory approval and postmarketing analyses, as well as randomized, controlled trials that compared EVAR with open AAA repair, have evaluated various clinical outcomes in patients meeting the specific anatomic requirements defined in the IFU.[4–8] Several studies using national databases have also reported on clinical outcomes after EVAR; however, these studies lacked access to aortic and iliac artery anatomic data and therefore were unable to assess whether devices were used in accordance with published IFU or whether adherence to IFU affected clinical outcomes.[3,9] Thus, the proportion of patients and the outcomes of patients who undergo EVAR with anatomy outside the device IFU are largely undocumented with respect to both short- and long-term complications, with the exception of a small number of single-center reports.[10–12]

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From the University of Massachusetts Medical School, Worcester (A.S., W.P.R., M.H.E., R.J.G., L.M.); Cleveland Clinic Foundation, Cleveland, OH (R.K.G.); and Harvard School of Public Health, Boston, MA (N.H.).
Guest editor for this article was Gilbert Upchurch, Jr.
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Disrespect of IFU's 1st to 3rd generation devices =

Main cause of EVAR failure,
with sac expansion

EVAR - New devices = What for?

- **To treat more patients with challenging anatomies**
- Would increase up to 60% patients eligible for EVAR with LP stentgrafts

Kristmundsson T et al. Vascular 2014

Outcomes with LP Stentgrafts

J Vasc Surg. 2015 Oct;62(4):841-7. doi: 10.1016/j.jvs.2015.04.452. Epub 2015 Aug 1.

Evaluation of the Zenith low-profile abdominal aortic aneurysm stent graft.

Sobocinski J[1], Briffa F[2], Holt PJ[3], Martin Gonzalez T[2], Spear R[2], Azzaoui R[2], Maurel B[2], Haulon S[2].

Author information

Abstract

BACKGROUND: Low-profile (LP) stent grafts are now commercially available in Europe for endovascular aortic aneurysm repair (EVAR). In this study the midterm outcomes and characteristics of patients treated with this last generation of stent grafts were compared with a cohort of patients treated with "standard-profile" (SP) stent grafts.

METHODS: The current study enrolled all patients treated for elective EVAR by the SP Zenith Flex stent graft (Cook Medical, Bloomington, Ind) between March 2010 and November 2011 and patients treated for elective EVAR by the Zenith LP stent graft (Cook Medical) between November 2011 and March 2013. All patients had a follow-up >18 months. Preoperative computed tomography angiograms were analyzed on a dedicated three-dimensional workstation. All data were prospectively collected in an electronic database and retrospectively analyzed. A comparative study was conducted.

RESULTS: The present study included 208 patients (107 SP and 101 LP). Patients' physiologic characteristics were similar in both groups. The iliac anatomy was considered "more challenging" in LP patients: respectively, 7% and 22% (P = .002) of SP and LP patients had bilateral external iliac diameter <7 mm; and 16% and 34% (P = .005) had a combination of an external iliac diameter <7 mm and an iliac tortuosity ratio index >1.5. No 30-day deaths were documented. The 24-month freedom from reintervention and overall survival rates after SP and LP were, respectively, 88% and 91% (P = .450) and 92% and 96% (P = .153). The 24-month rates for freedom from sac expansion and from limb occlusion were 96.4% and 98.7% (P = .320) and 92% and 95% (P = .293), respectively. One patient in each group presented with a type I endoleak during follow-up, and two LP patients presented with a type III endoleak (P = .235).

CONCLUSIONS: This study demonstrates that the last-generation LP stent grafts have favorable midterm outcomes similar to SP stent grafts despite being used to treat more patients with unfavorable iliac anatomy.

Preoperative iliac morphology			SP (107)	LP(102)	
Iliac artery	tortuosity index ratio (median, IQR)	Left	1.3 [1.2-1.4]	1.4 [1.2-1.5]	0.332
		Right	1.3 [1.2-1.4]	1.3 [1.2-1.5]	0.341
	External Iliac artery diameter (median, IQR)	Left	8 [7-9]	8 [6-9]	0.026
		Right	8 [7-9]	8 [6-9]	0.046
	External Iliac diameter <7mm of both iliac sides (left and right)		6.5% (7)	21.8% (22)	0.002
	Iliac tortuosity ratio index>1.5 of both iliac sides (left and right)		8.4% (9)	11.9% (12)	0.492
	Hostile external iliac arteries of both iliac sides (left and right)		6.9% (7)	11.9% (12)	0.231
	External Iliac diameter<7mm OR iliac tortuosity ratio index>1.5 of both iliac sides (left and right)		15.8% (16)	30.8% (33)	0.003
	External Iliac diameter<7mm OR hostile External Iliac of both iliac sides (left and right)		8.4% (9)	21.8% (22)	0.011
	Iliac tortuosity ratio index>1.5 OR hostile External Iliac of both iliac sides (left and right)		15.0% (16)	23.8% (24)	0.116
	External Iliac diameter<7mm OR iliac tortuosity ratio index>1.5 OR hostile External Iliac of both iliac sides (left and right)		16.8% (18)	30.8% (33)	0.026

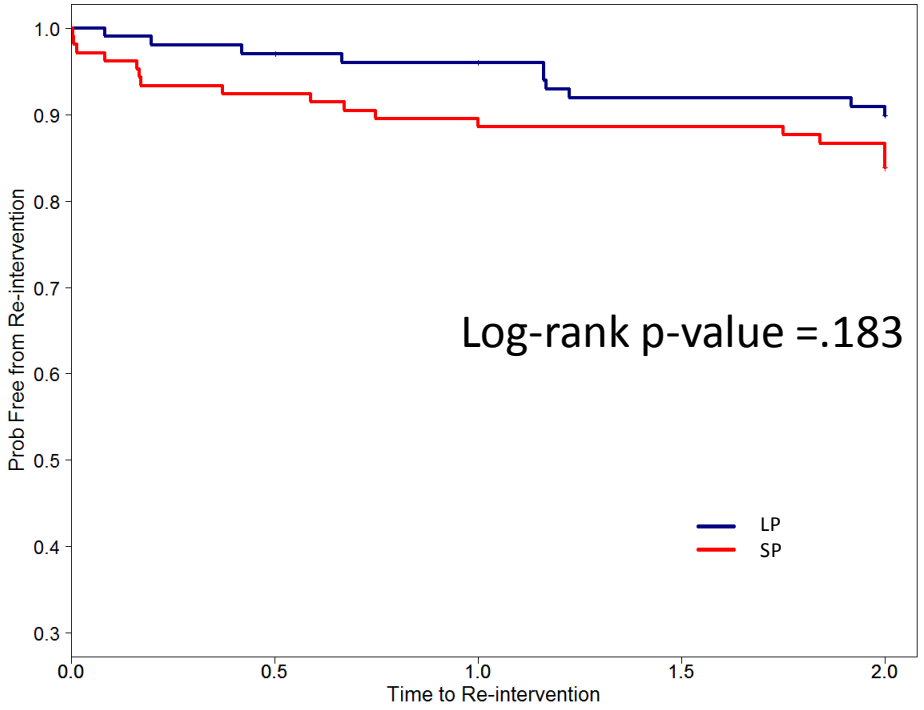
Prox: Proximal; Ao: Aorta; diam: diameter; IQR: Interquartile range

More hostile preop iliac morphologies in LP group

Sobocinski J et al. JVS 2015

Results

Follow-up / Reintervention



	time (year)	n.risk	n.event	survival	95% CI	
	0	105	0	1	1	1
SP group	1	94	12	0.886	0.827	0.949
	2	91	5	0.838	0.771	0.912
	0	101	0	1	1	1
LP group	1	96	4	0.96	0.923	0.999
	2	89	6	0.899	0.842	0.96

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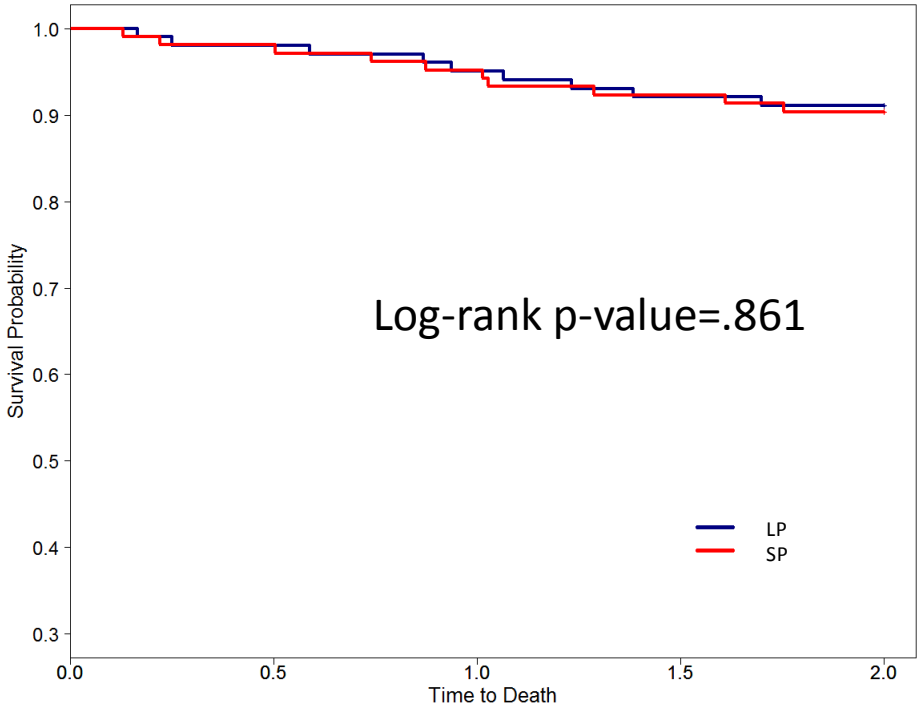
Results

Follow-up / death



	time (year)	n.risk	n.event	survival	95% CI	
	0	104	0	1	1	1
SP group	1	99	5	0.952	0.912	0.994
	2	94	5	0.904	0.849	0.962
	0	101	0	1	1	1
LP group	1	96	5	0.95	0.909	0.994
	2	92	4	0.911	0.857	0.968

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Updated data in Lille, december 2016

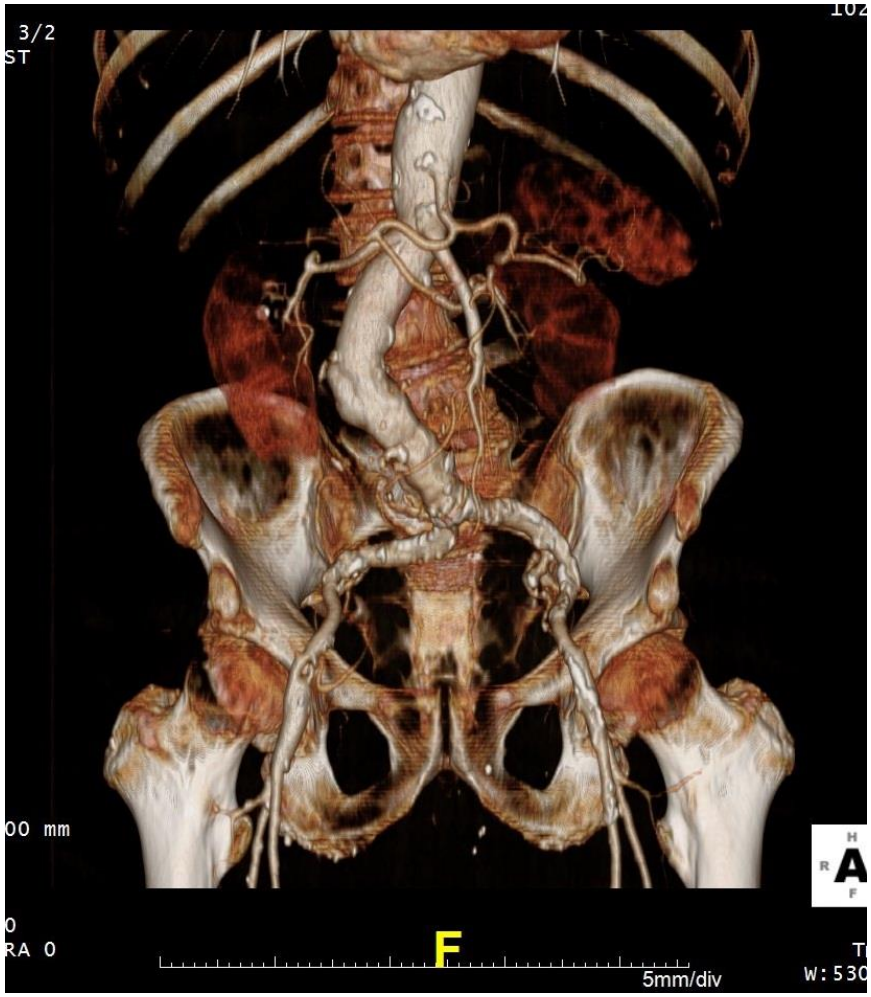
- **From jan 2012 to nov 2016:**

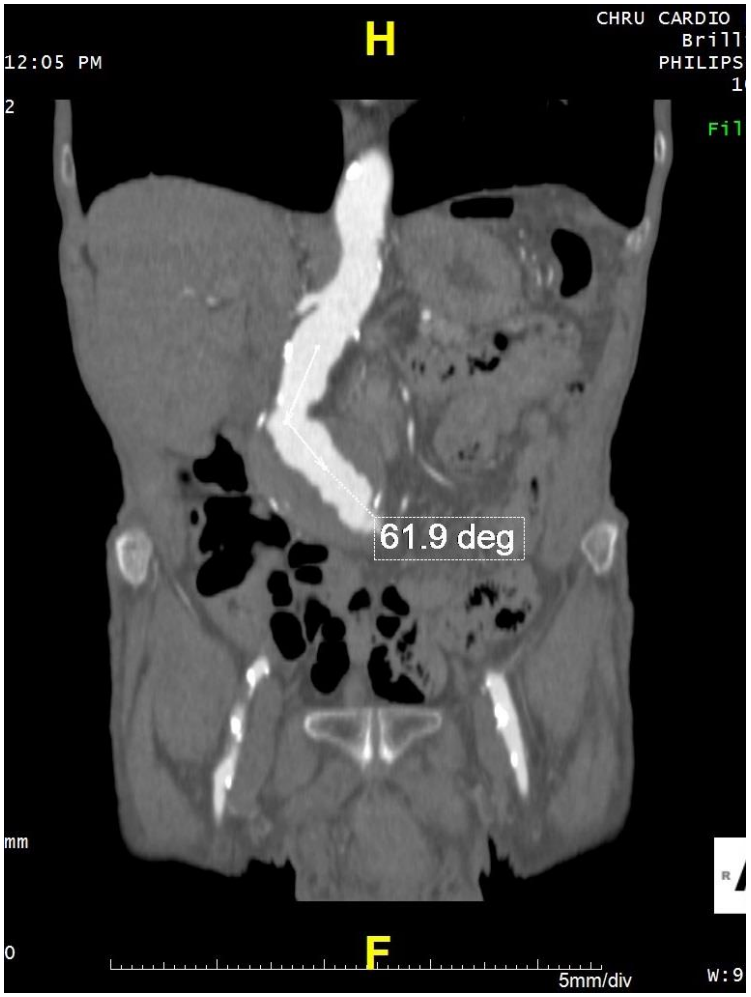
480 EVAR

295 patients with either combination of LP+ZSLE or Alpha (ZIMB + ZISL)

Standard grafts with large aortic diameter (>32mm)

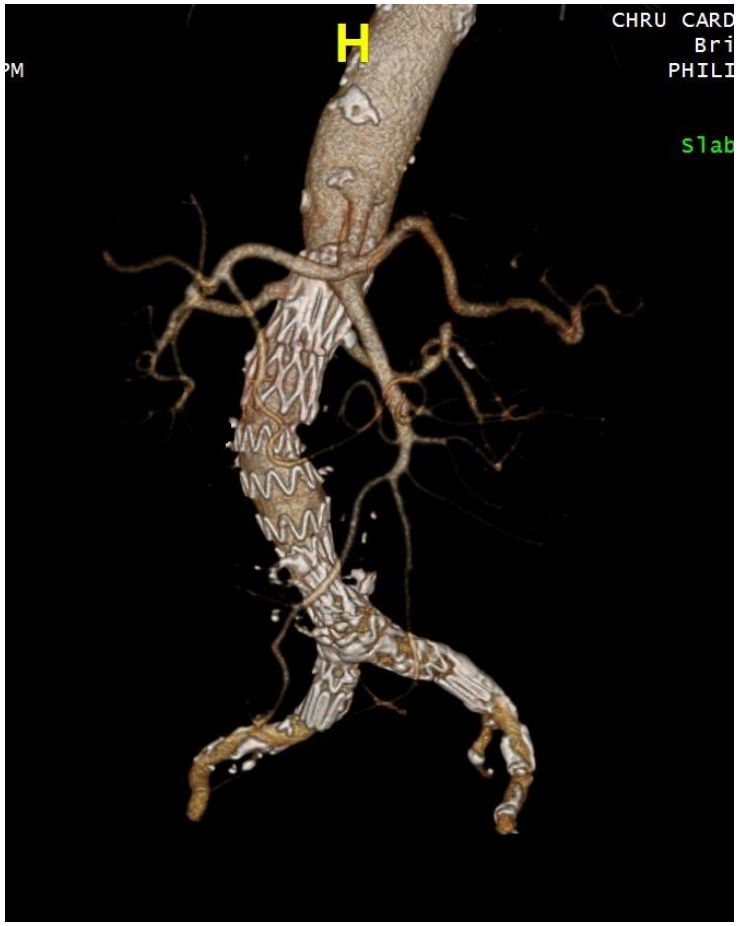
AAA - Case #1

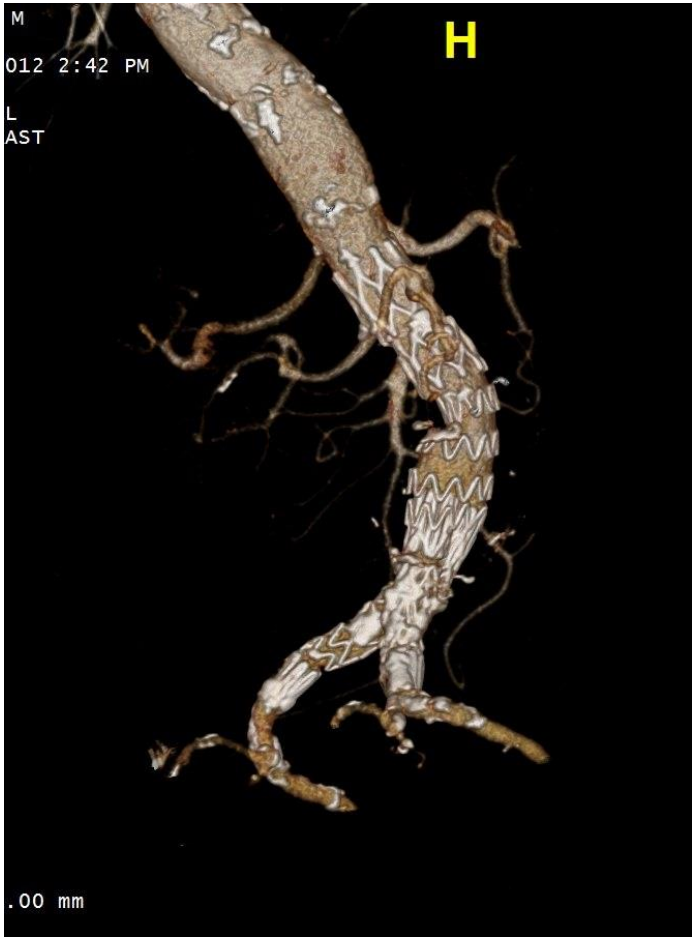




Major aortic and iliac angulations

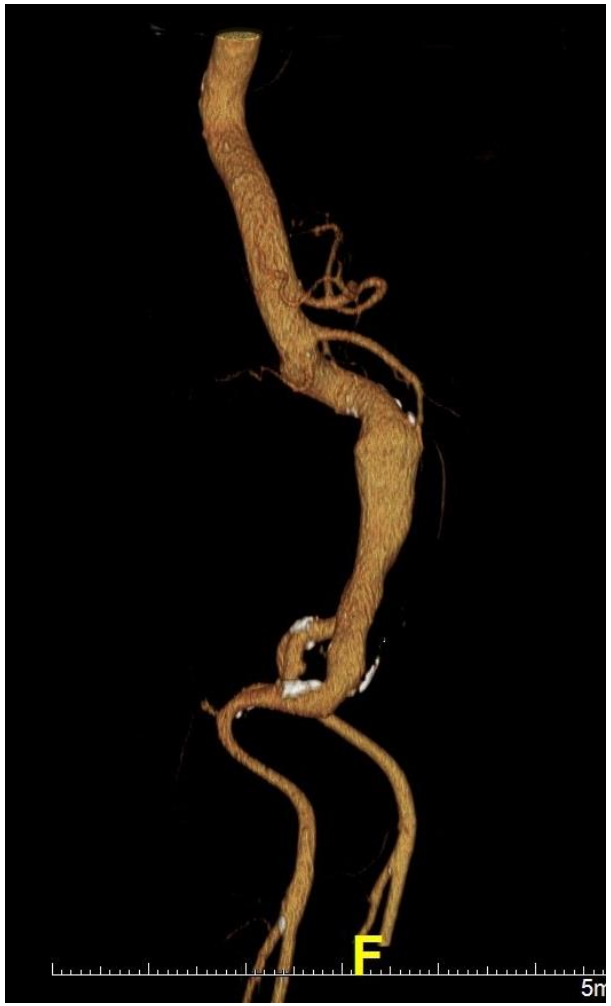
AAA - Case #1

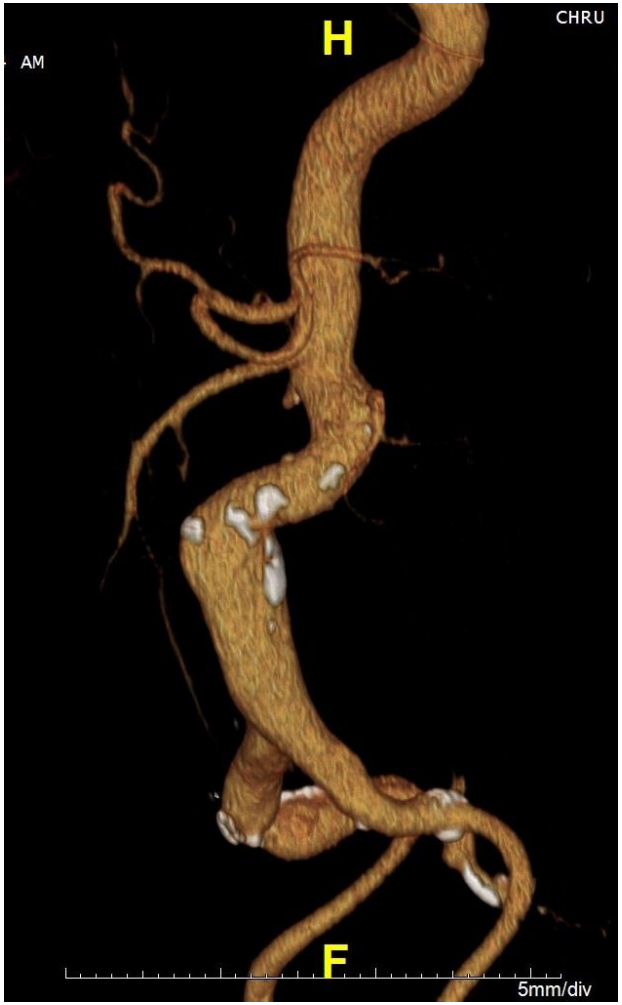




Excellent conformability

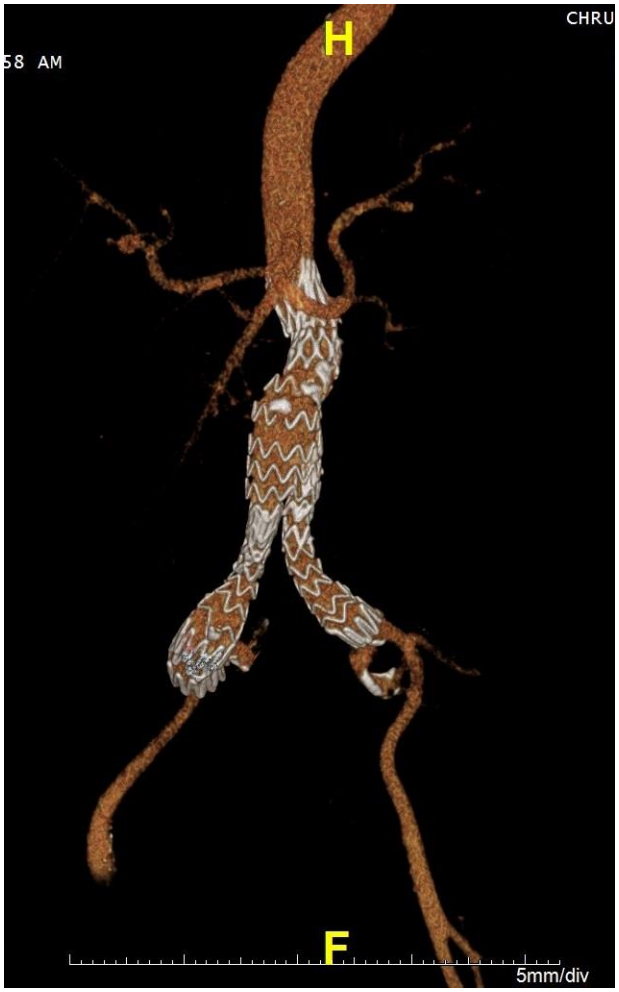
AAA Case #2

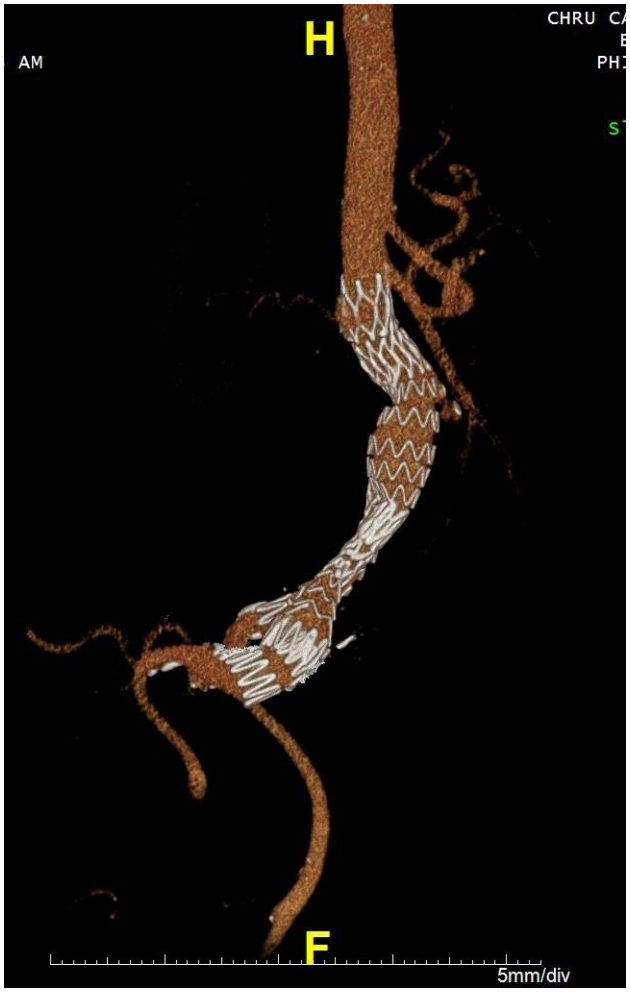




Small & tortous access / major aortic angulation

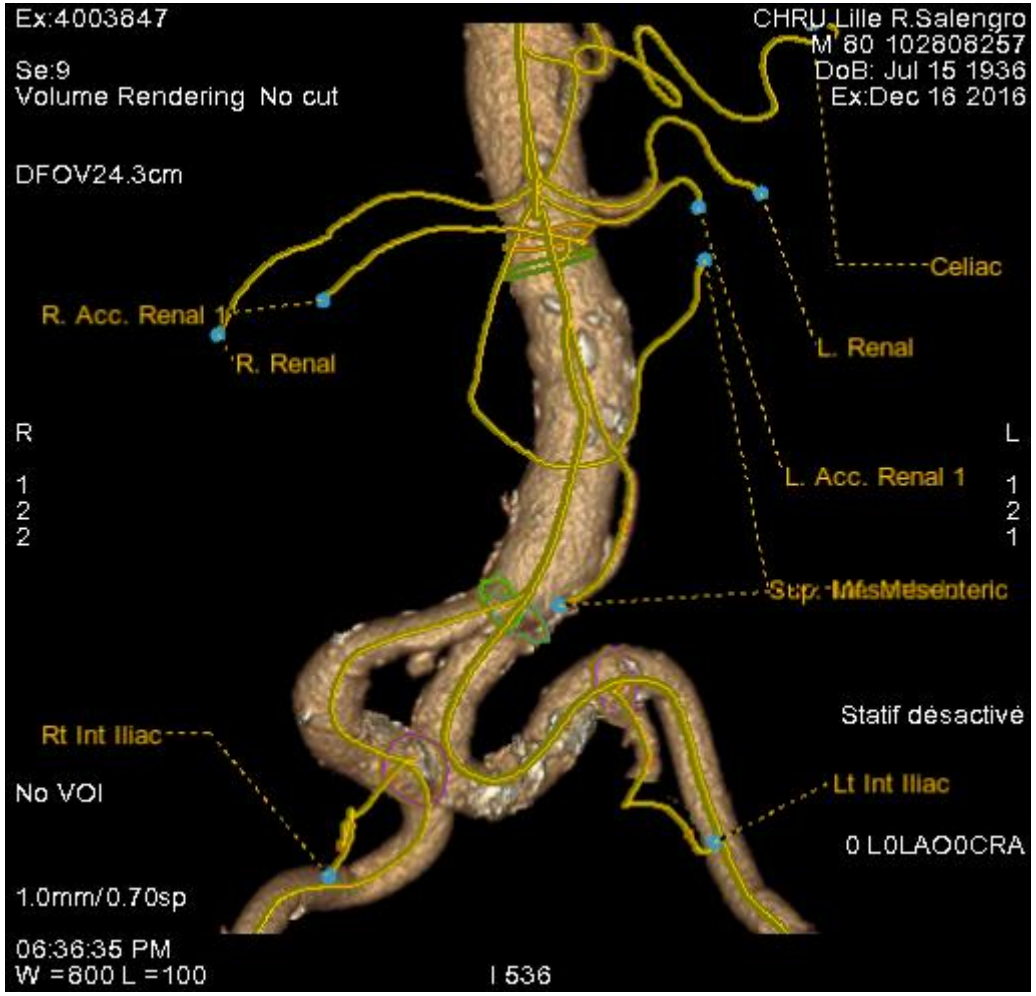
AAA Case #2





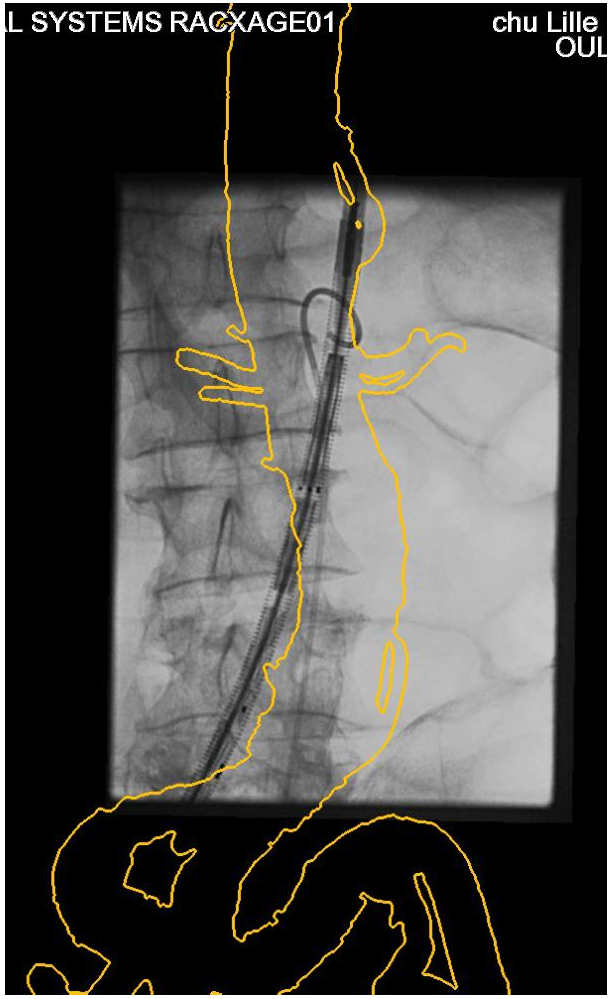
Excellent conformability

AAA - Case #3



Tortous access

AAA - Case #3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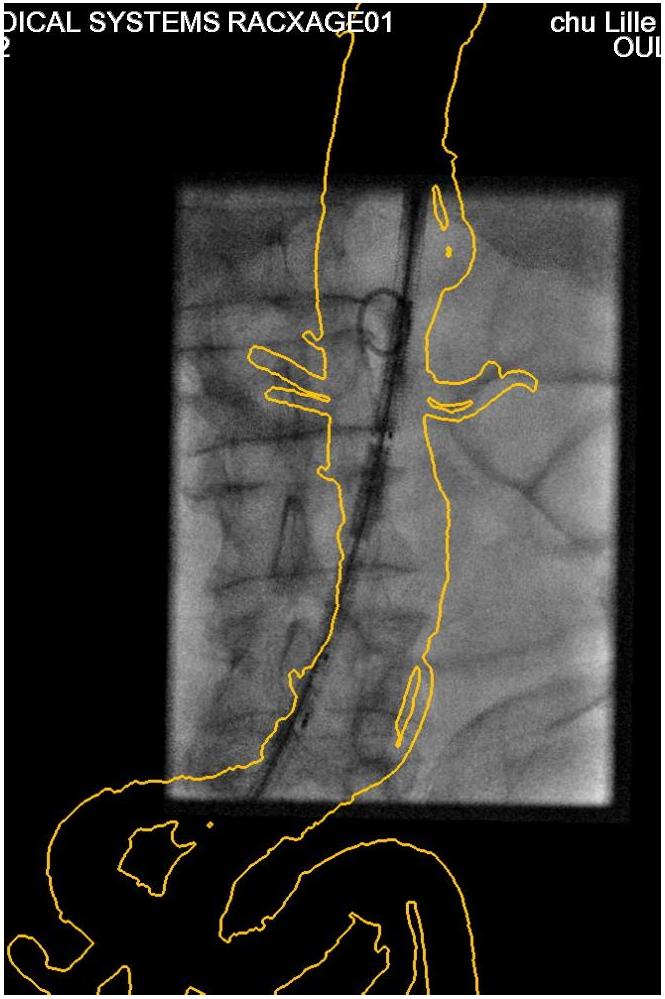
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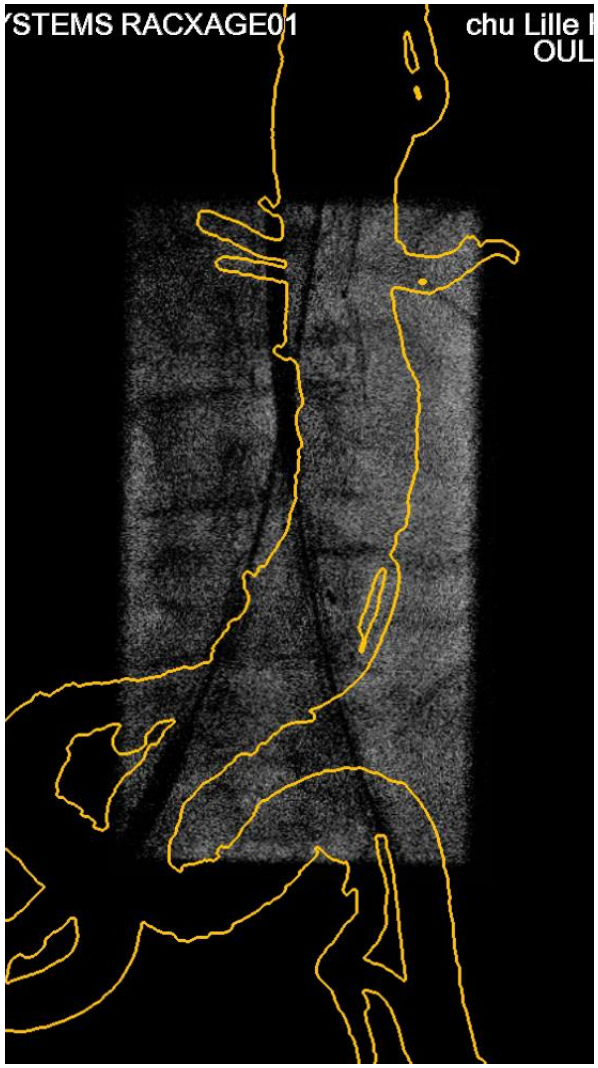
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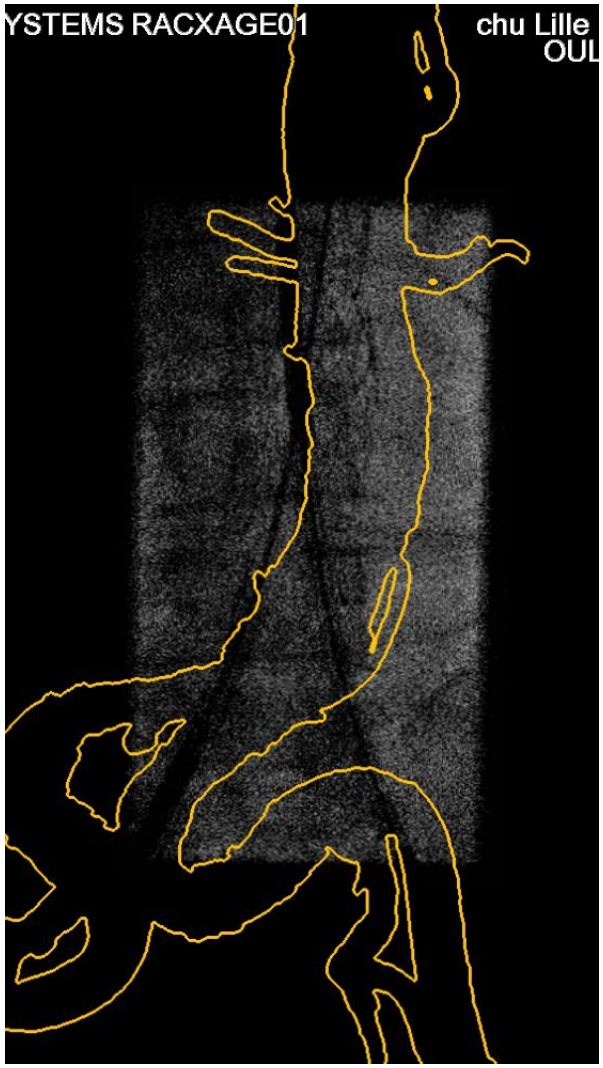
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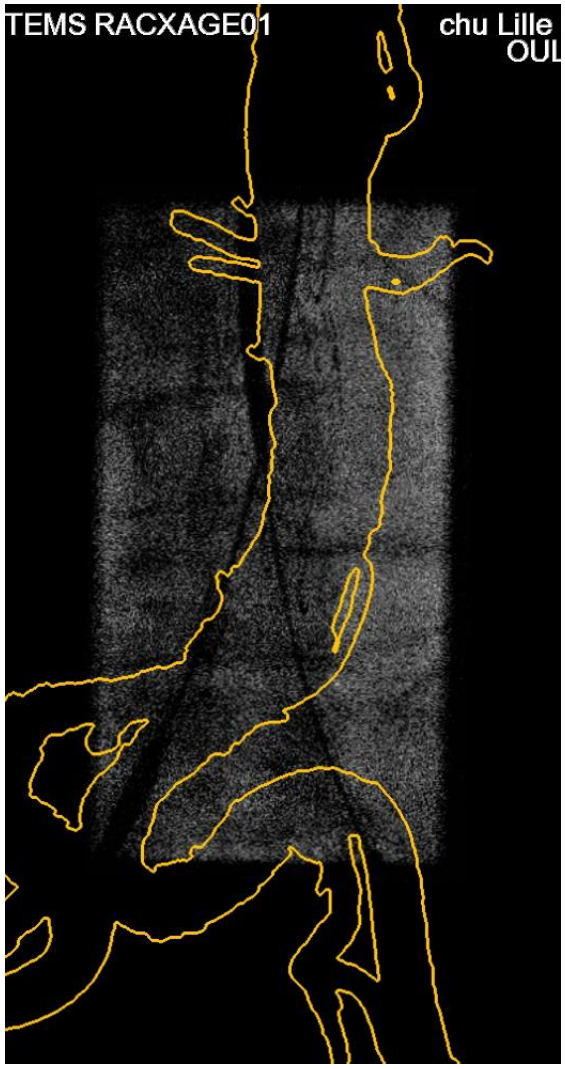
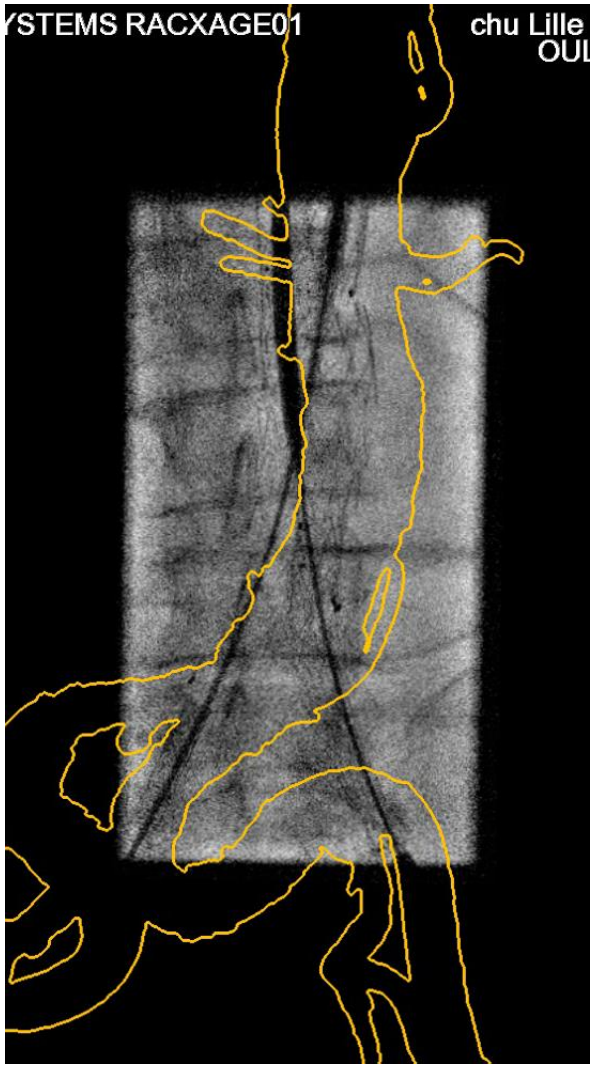
AAA - Case #3





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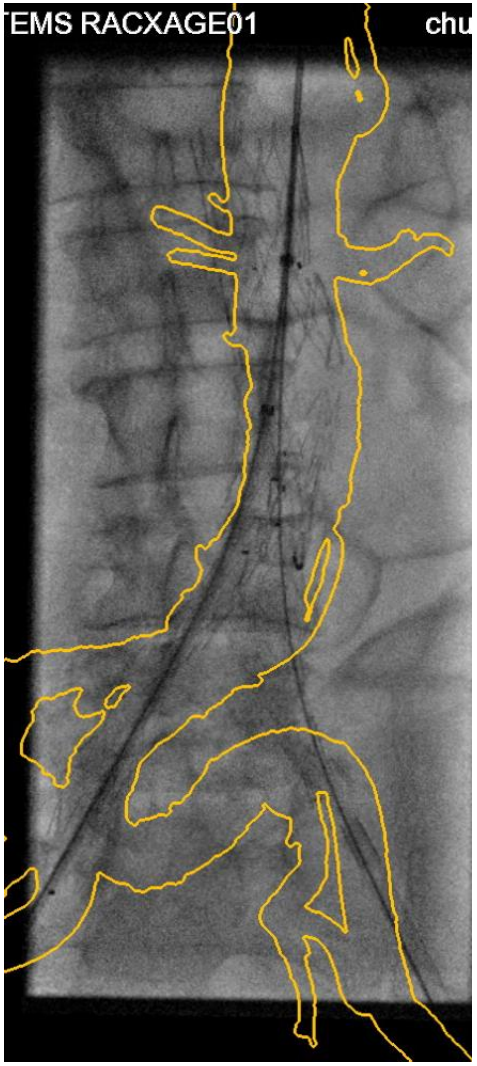

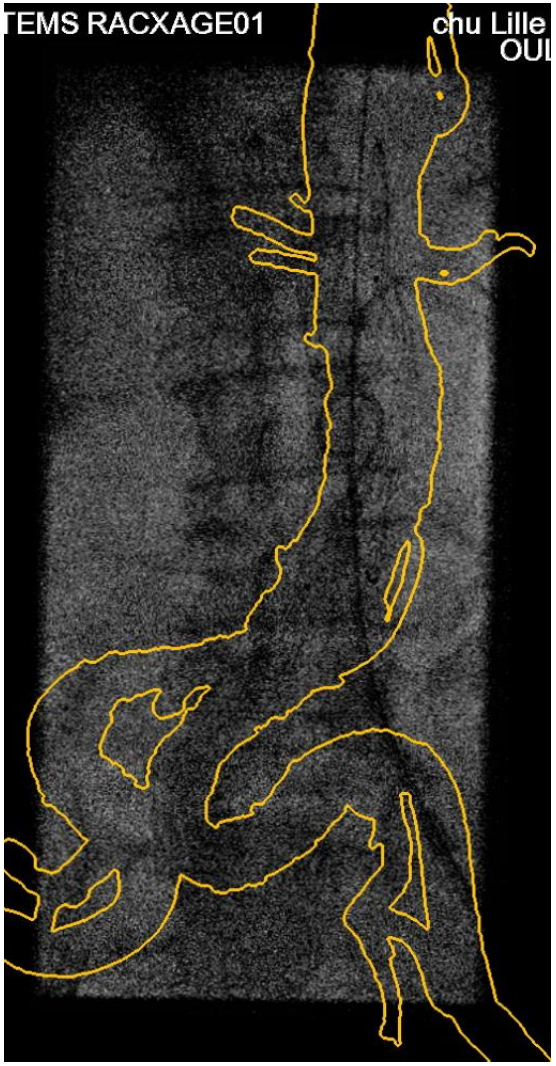

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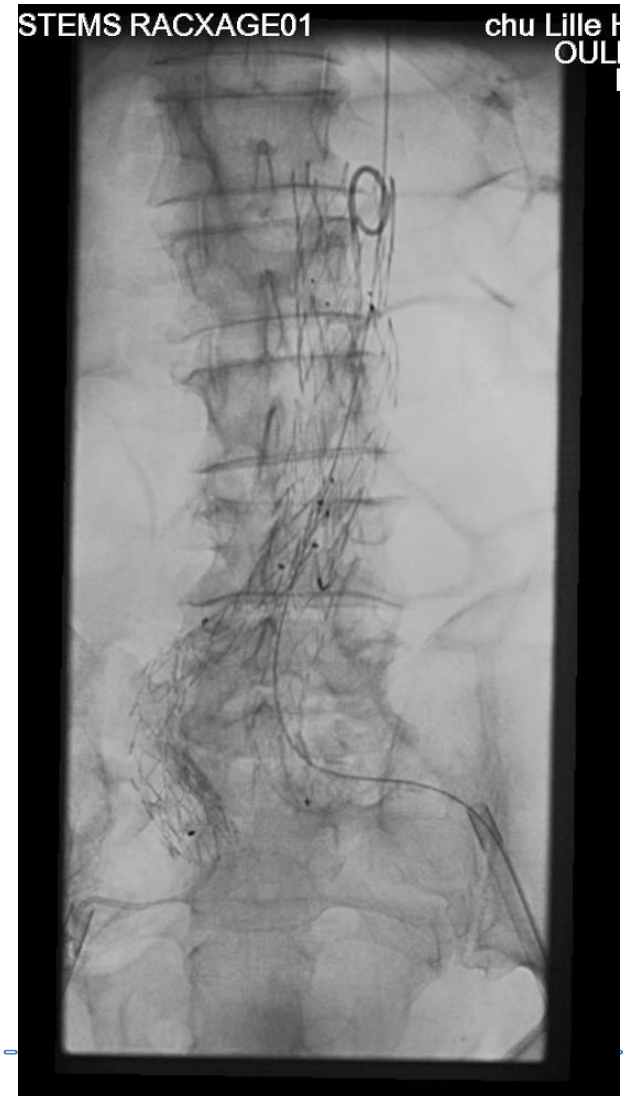

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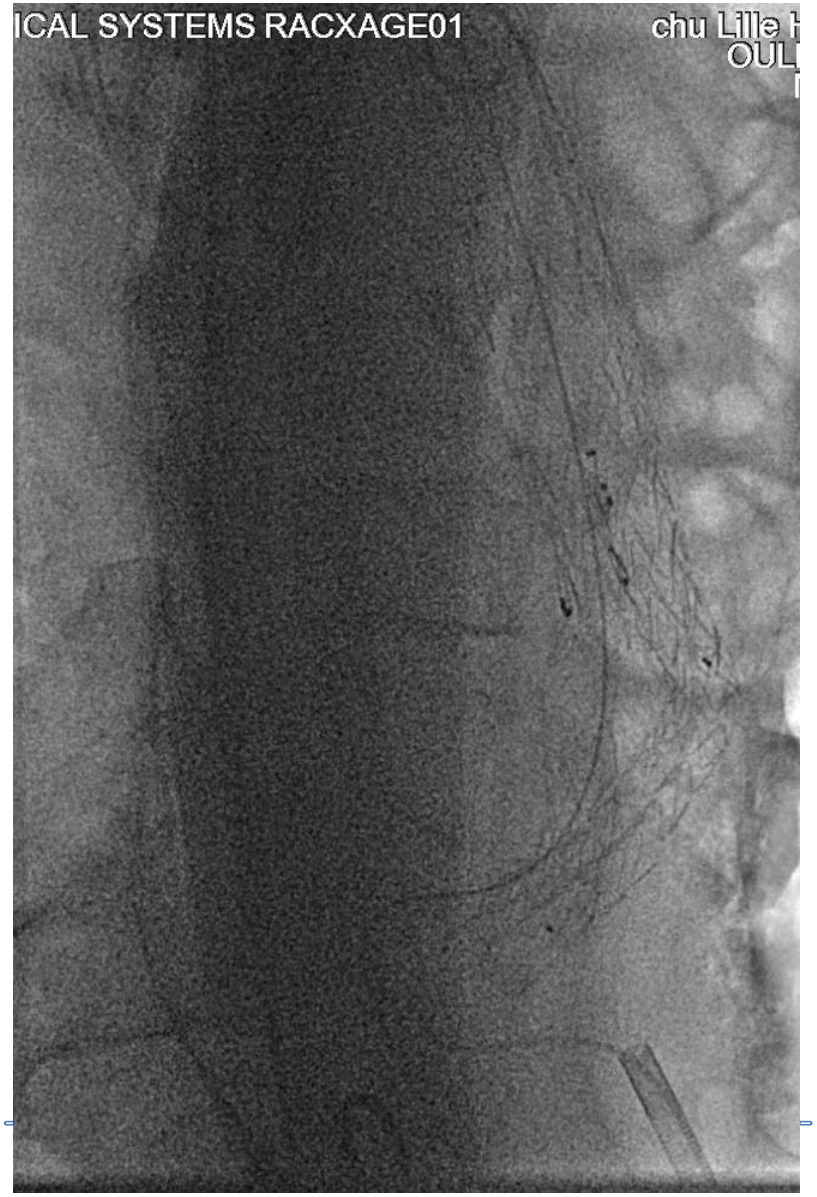

Conclusion - Abdominal Alpha Stentgrafts

- Offer valuable alternatives for patients with bad anatomies (bad access++)
- Good outcomes in this subgroup of patients – towards modification of devices' IFU?
- Easy-to-use devices

Thank you

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