

COOK Zenith[®] LP

Stéphan Haulon

G Couchet, A Felisaz,

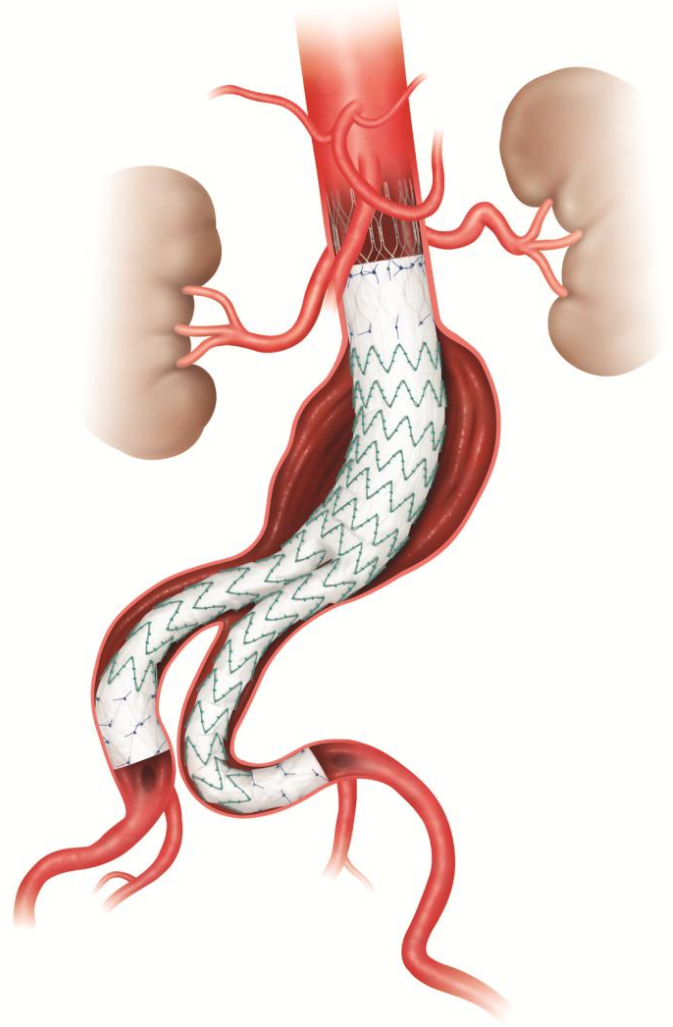
J Sobocinski, B Maurel, R Azzaoui

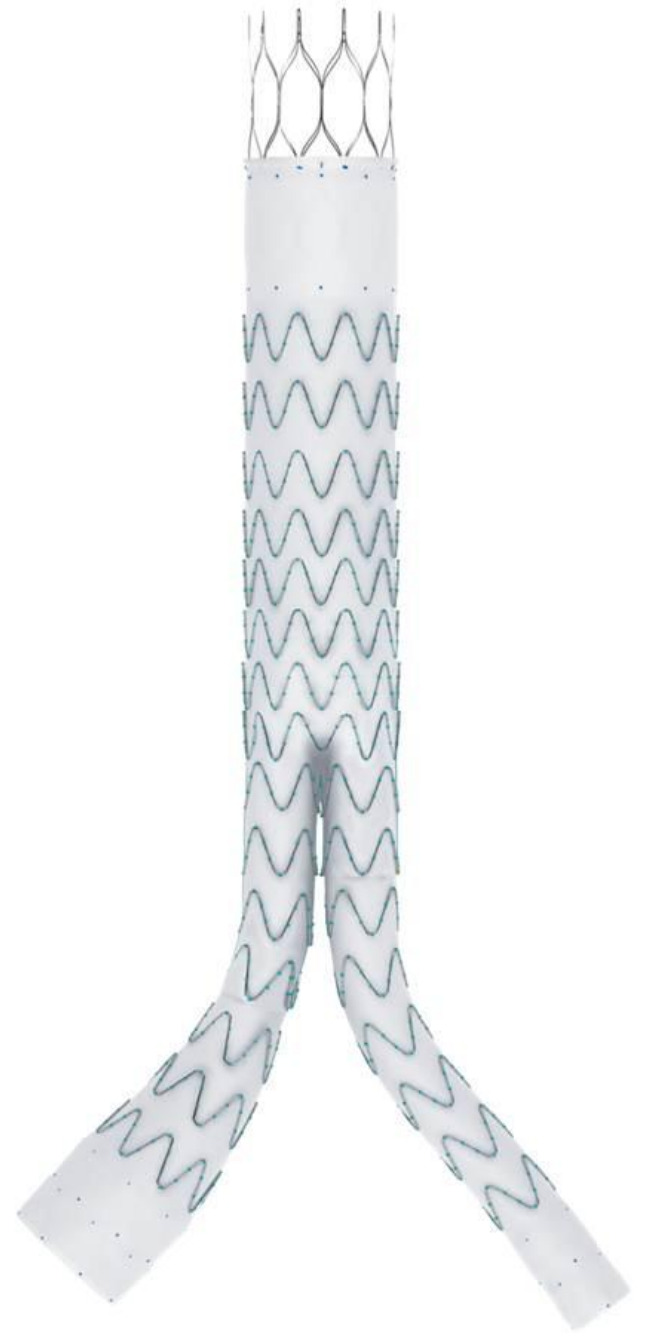
**Vascular Surgery, Lille University Hospital,
France**

Disclosures

- Research support, Consulting:
 - Cook Medical, GE Healthcare









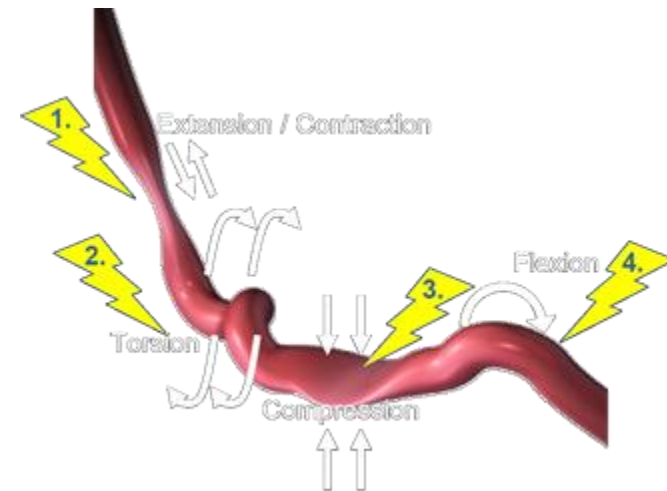
- Zenith Flex[®] AAA clinical results are unsurpassed in the marketplace
- Zenith LP was designed to have Zenith Flex AAA performance in a 16 Fr Sheath
- New graft weave – Still dacron
 - Thinner, more dense weave
- New stents - Nitinol
 - MRI Conditional
 - Low-profile while maintaining high radial force
 - **Excellent fatigue resistance**



Cook Knows Nitinol Design

- Zilver[®] stent performs in the SFA
- Cook designed the Zilver stent specifically for the SFA
- Zilver interim clinical results ⁴

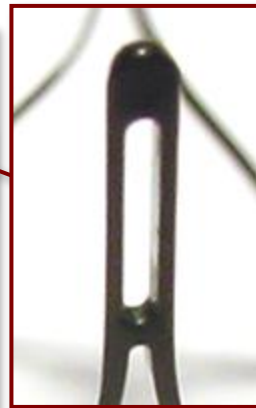
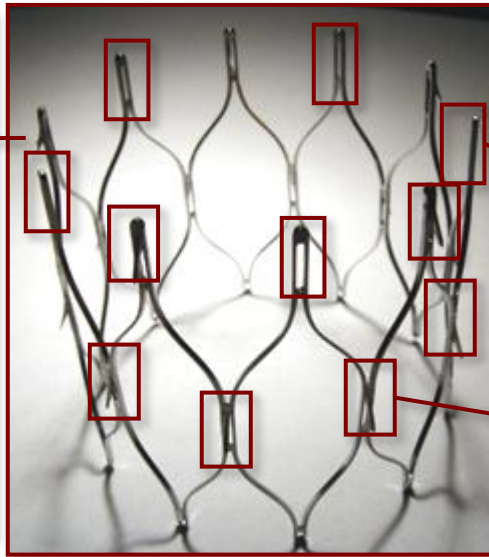
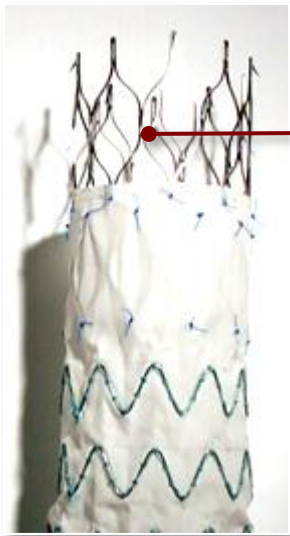
Time Period	Potential Fractures*
Procedural	0.1% (2/1551 stents)
6 months	1.4% (16/1168 stents)
12 months	1.5% (12/777 stents)



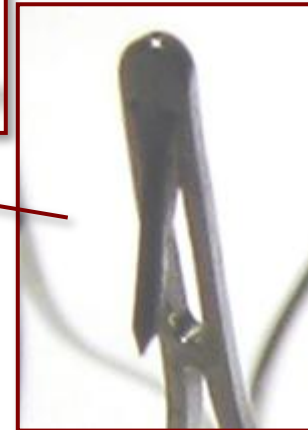
*All stents
are not
created equal!*



Zenith[®] LP Stent Design



- Trigger wire slots
- Precise deployment
- No need to dock top cap



- Integral barbs
- Located (top and midline) for maximum migration resistance

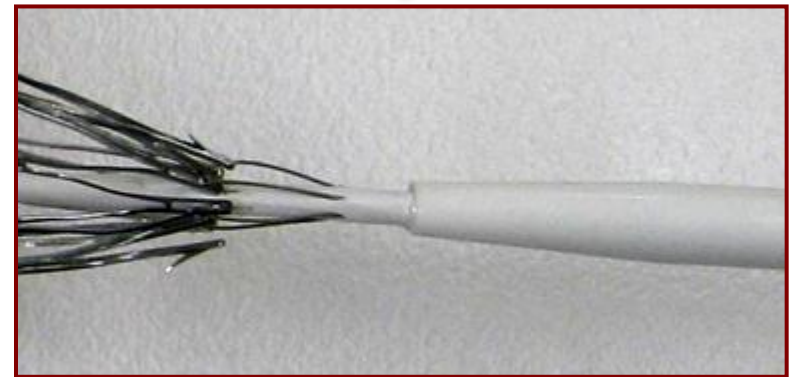


Zenith[®] LP Deployment

- Simplified, precision deployment

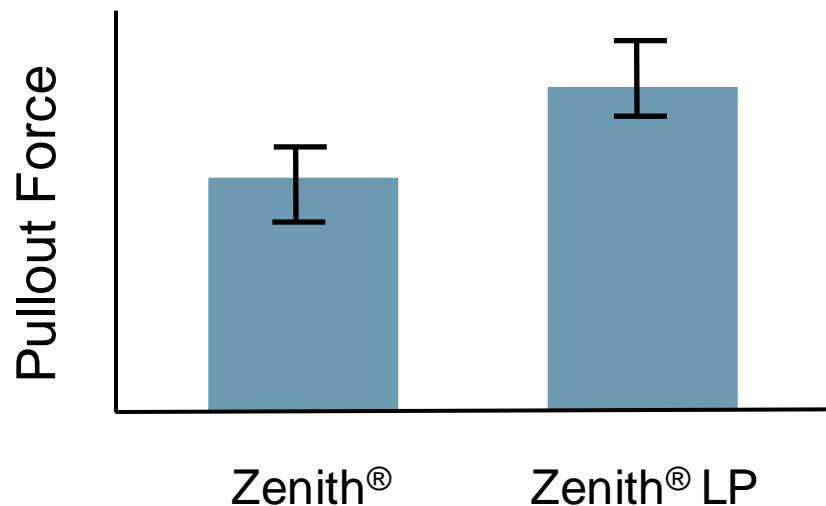


- Advantages
 - No top cap
 - No need to dock top cap
 - Smooth back taper
 - Simplified deployment



Migration Resistance

- Porcine aorta pull out
 - Greater force than Zenith Flex[®]
 - Double sutures
 - Barbs do not fracture



Zenith[®] LP Performance

Property	Engineering Test(s)	Flex	LP
Does not migrate	Porcine aorta pull-out	√	√
Durable	Stent pulsatile fatigue	√	√
	Stent longitudinal fatigue	√	√
	Graft abrasion	√	√
	Limb/leg separation	√	√
Aneurysm exclusion	Stent radial force	√	√
	Graft permeability	√	√
Deployment/Conformance	Deployment testing	√	√
	Resistance to kink	√	√
Biocompatibility	Biocompatibility	√	√
	Corrosion	√	√

Zenith LP meets the same specifications as Zenith[®]



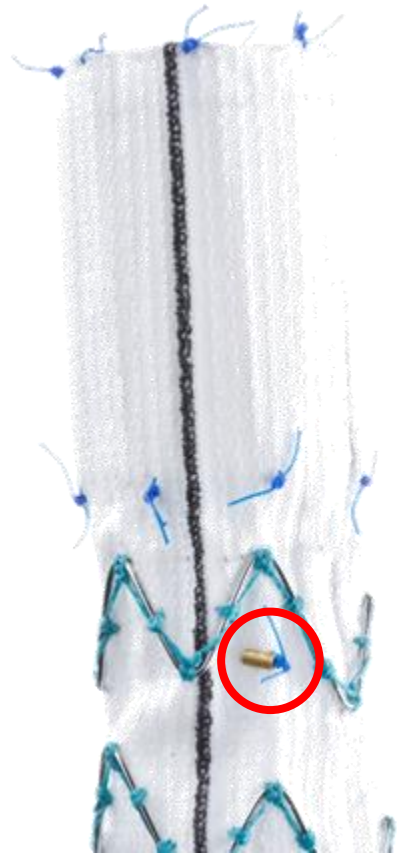
Zenith® LP – Lowest Profile

32mm Devices:	Zenith LP	Medtronic Endurant	Medtronic Talent™	Gore Excluder®	Zenith Flex®
	Inner Diameter 16 Fr	Inner Diameter N/A	Inner Diameter N/A	Inner Diameter 20 Fr	Inner Diameter 20 Fr
Outer Diameter:	18 Fr	20 Fr	24 Fr	23 Fr	23 Fr
Hydrophilic Coating:	Yes	Yes	Yes	N/A	Yes

Zenith[®] LP

Clinical Experience



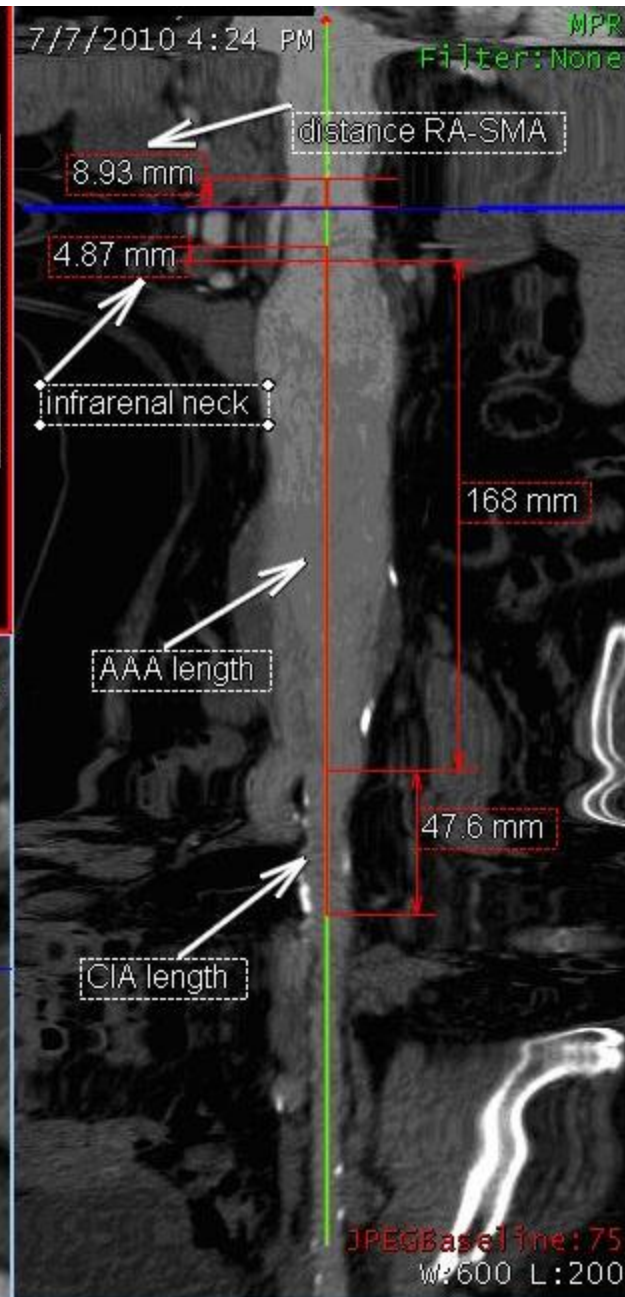
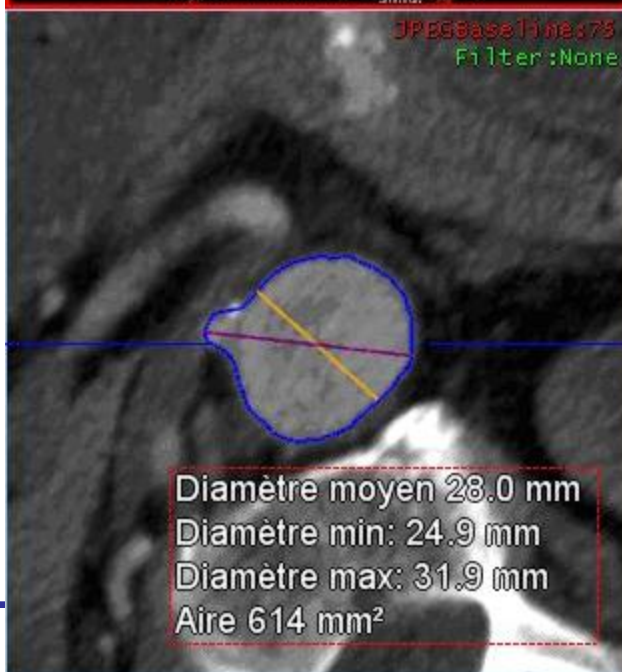
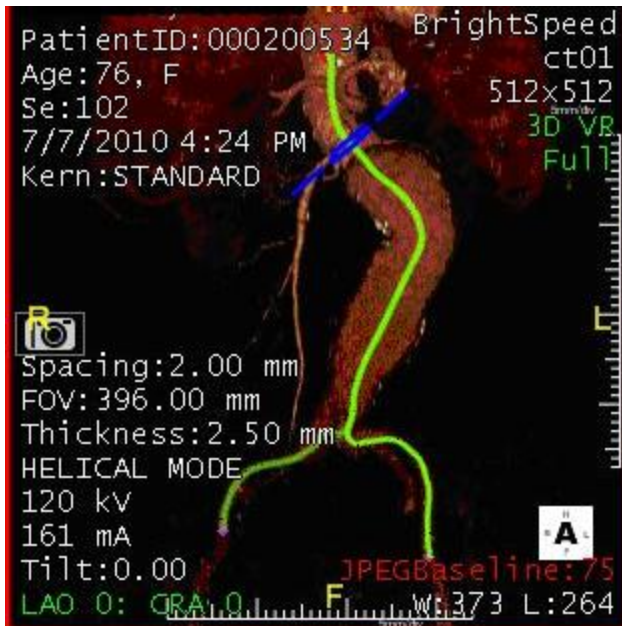


Overlap marker



Spiral-Z Leg

- Flexor delivery system
- Kink resistance



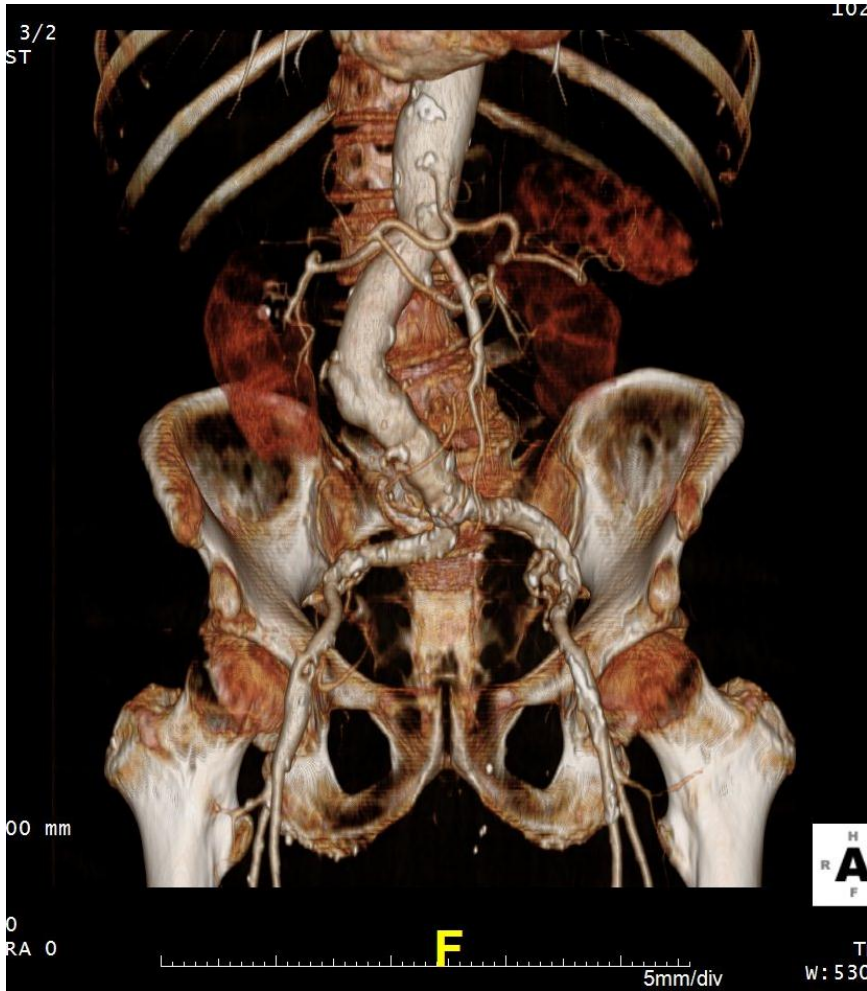


Challenging EVAR with Cook LP

Stéphane Haulon



Case #1



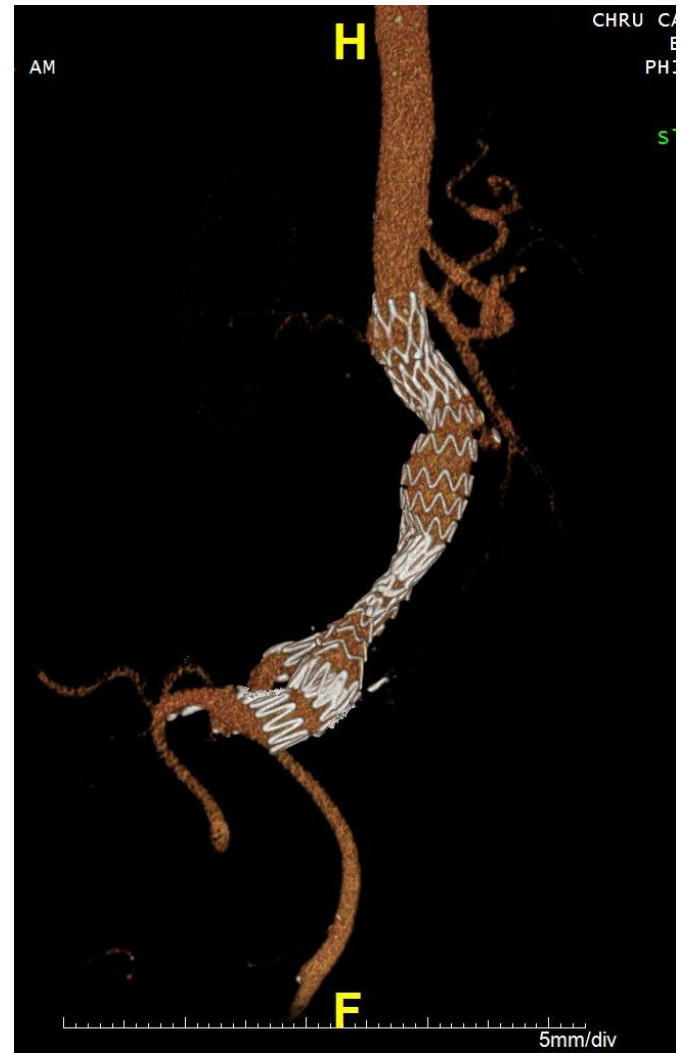
Case #1



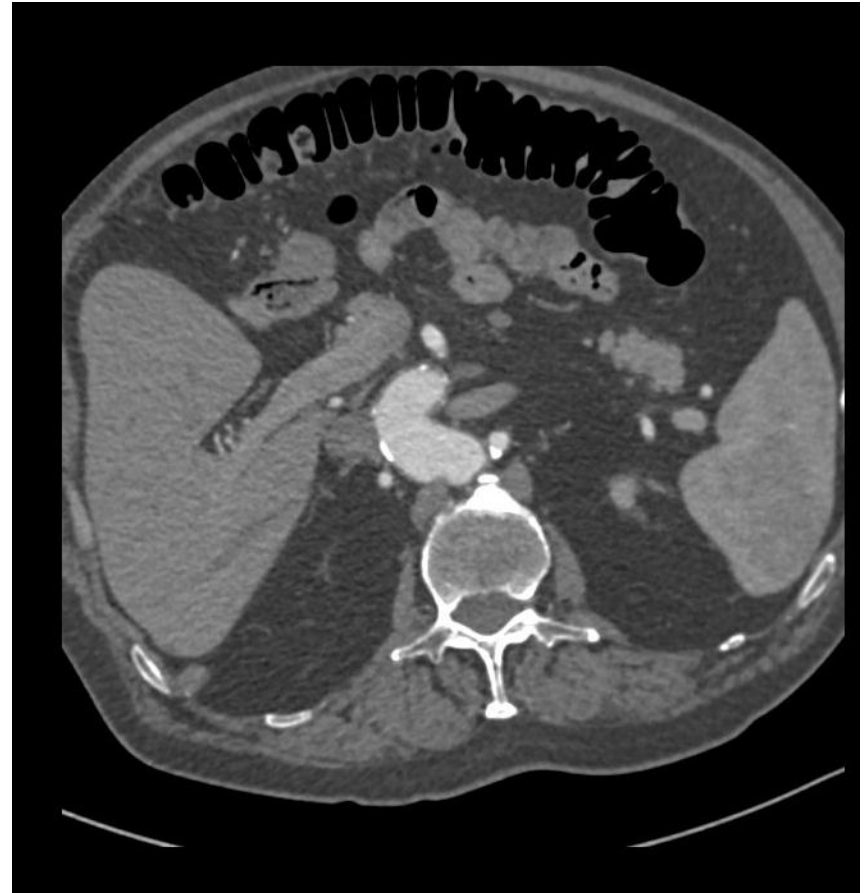
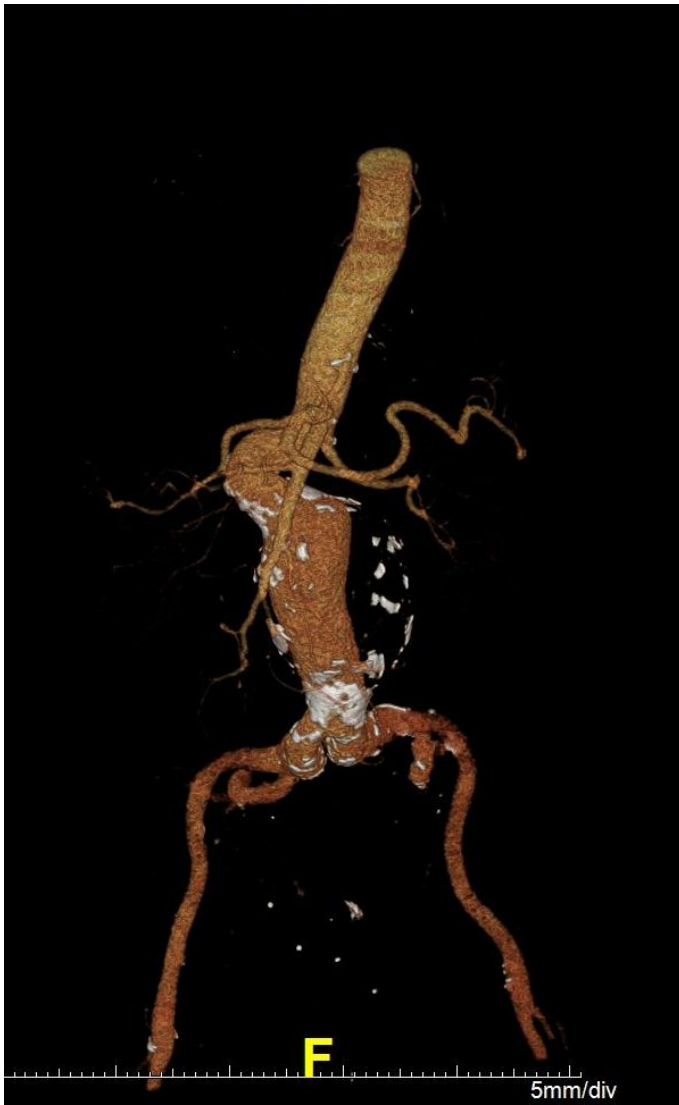
Case #2



Case #2



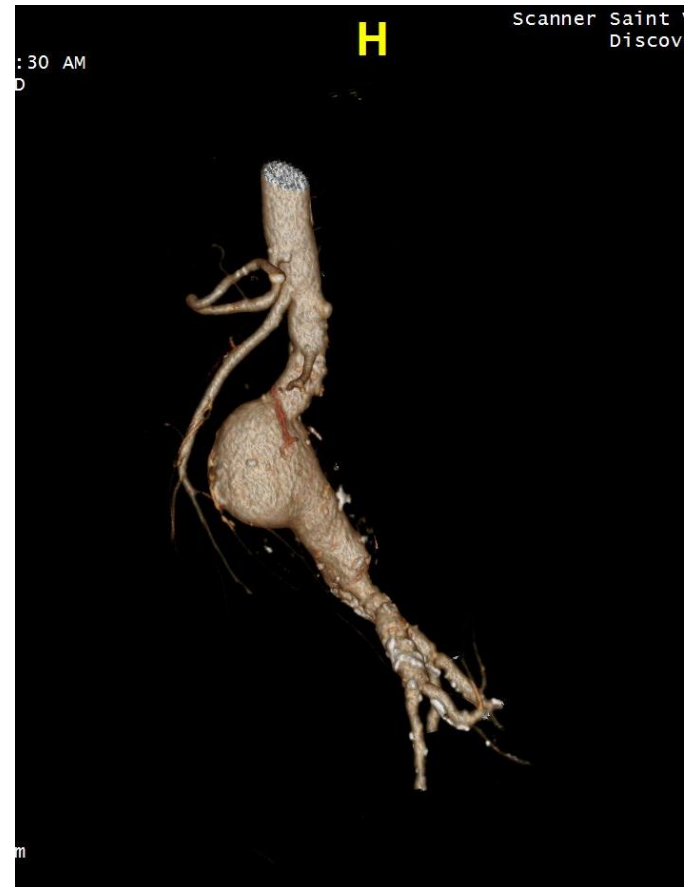
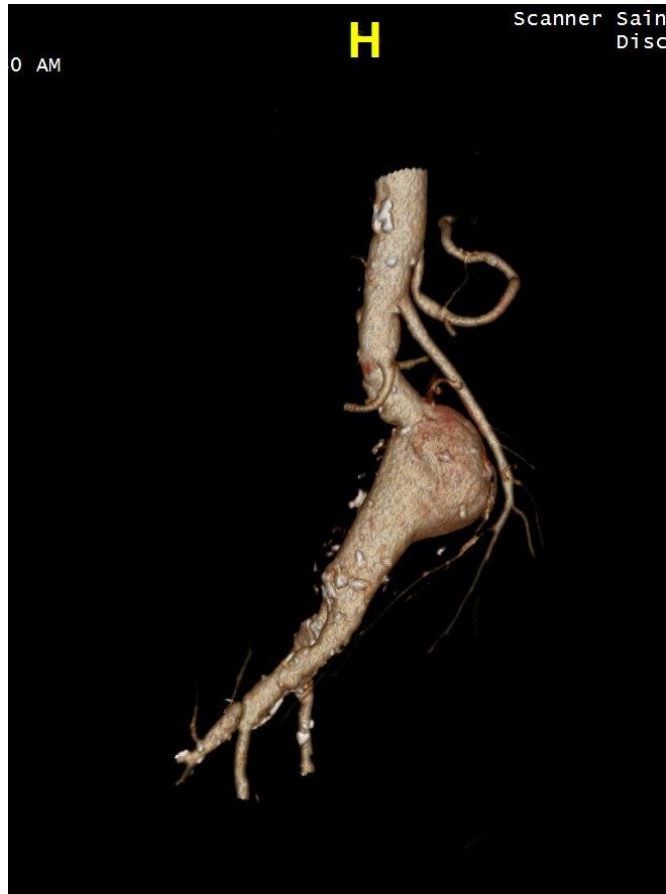
Case #3



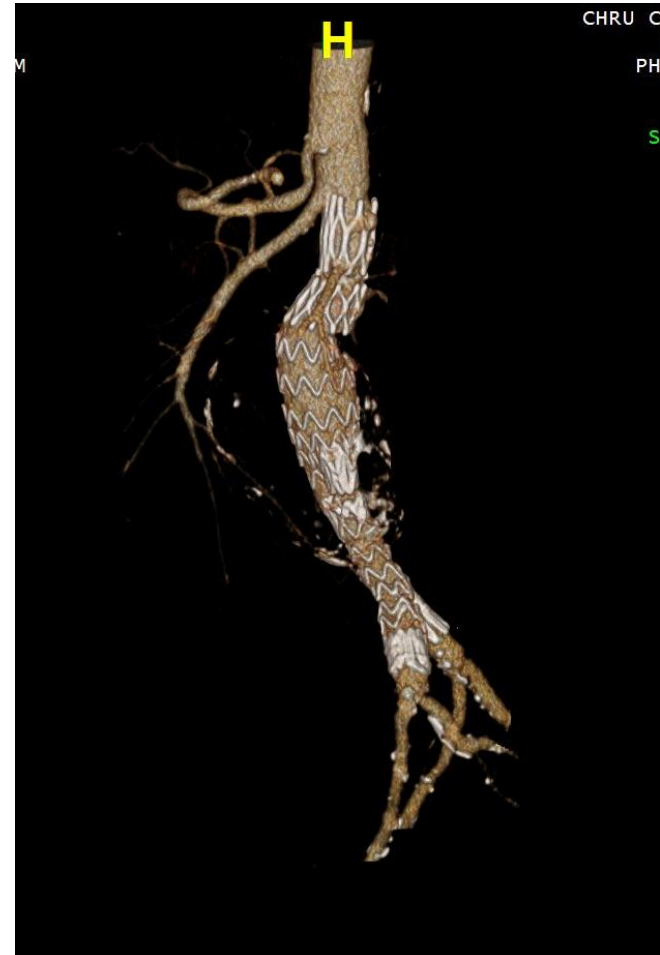
Case #3



Case #4



Case #4





RESULTS

- First 50 consecutive EVAR (January 2012)
 - LP Zenith® bifurcated body in combination with Flex Zenith® limbs (ZSLE)
 - Post operative CTA + US
 - 6-month US
-



Morphologic Data

- 46 aortic or aortoiliac aneurysm
- 4 isolated common iliac aneurysms
- Median aortic/iliac diameter:
 - 58mm [50-81] for the aortic or aortoiliac aneurysms
 - 40mm [33-48] for the isolated iliac aneurysms.



Morphologic Data

- Proximal neck diameter: 23.3 mm [17-29 mm]
- Proximal neck length: 30.5mm [12-48]
- Common iliac arteries diameter:
 - 12.4 mm [8-48 mm] on the right side
 - 13.7 mm [7-43 mm] on the left side.
- Of the 100 extern iliac access vessels, 14 had a diameter of 6 mm or lower



Results

- Implantation of the main body and both iliac limbs was successfully performed in all cases
 - Six additional procedures were planned and performed:
 - 3 embolizations of the II origin
 - 2 angioplasty-stenting (calcified aortic bif)
 - one angioplasty/stenting of a limb in a kinked iliac artery
-



Results

- Percutaneous closure system failure occurred twice on 46 percutaneous approaches (4.3%)
- A left inferior polar renal artery was deliberately covered
- No unexpected coverage of a renal artery or an intern iliac artery occurred



Results

Ultrasound Examination

- 11 endoleaks: 1 type I, 10 type II
- Femoral access: 1 thrombosis of the left external iliac artery (distal to the endograft limb).
- No secondary intervention (manual compression was performed to occlude the 2 pseudoaneurysms).



Results

- AngioCTscan analysis depicted 20 endoleaks:
 - One proximal type I (2%)
 - 19 type II (38%)



Six-month follow up

- The survival rate at six months was 96%
 - Two patients died respectively three and four months after EVAR
 - Both deaths were not aneurysm related.



Six-month follow up

- All patients underwent an aorto-iliac control ultrasound exam 6 to 12 months after EVAR
- All endografts main bodies and limbs were patent
- Five endoleaks were depicted, all were type II endoleaks (the early type Ia endoleak had sealed spontaneously; it was confirmed by an angioCT scan).



Six-month follow up

- One patient presented six months after discharge a disabling claudication of the lower limbs:
 - Ultrasonography showed a significant stenosis of the left iliac limb with a narrow (18 mm) and calcified aortic bifurcation
 - A complementary procedure (bilateral iliac angioplasty and kissing balloon stenting of the iliac limbs with balloon expandable 10mm stents) was performed
-



Conclusions

- Excellent mid term outcomes
- Enhanced delivery system
- #1 option for EVAR at our institution

