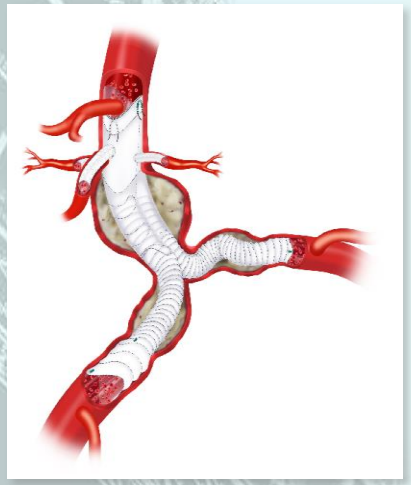
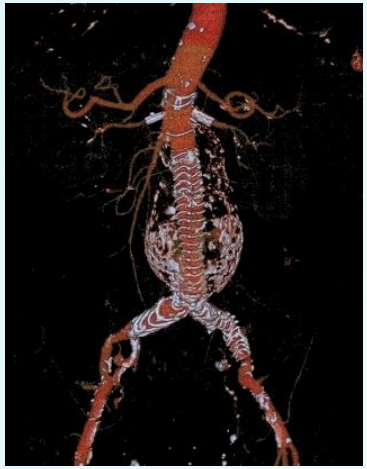
CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Results of the French multicentric study of ANACONDA™ fenestrated endografts in the treatment of complex aortic pathologies (EFEFA registry)



Dominique Midy
Caroline Caradu



Disclosure Vascutek

Consulting

Participating centers

Centers	City	Patients
CHU – HOPITAL PELLEGRIN **D MIDY**	BORDEAUX	31 (36.0)
CHU – HOPITAL HENRI MONDOR **JP BECQUEMIN**	CRETEIL	11 (12.8)
CHU – HOPITAL TROUSSEAU **R MARTINEZ**	TOURS	11 (12.8)
HOPITAL ROBERT SCHUMAN **N FRISCH**	VANTOUX	8 (9.3)
CENTRE CARDIO-THORACIQUE **C MIALHE**	MONACO	7 (8.1)
POLYCLINIQUE NOTRE-DAME **J ALBERTIN M SOSA**	DRAGUIGNAN	4 (4.7)
CHU – HOPITAL NORD **Y ALIMI**	MARSEILLE	3 (3.5)
CHU – GROUPE PITIE SALPETRIERE **F KOSKAS**	PARIS	2 (2.3)
CLINIQUE AMBROISE PARE **P BOUR**	NANCY	2 (2.3)
CENTRE MARIE-LANNELONGUE **D FABRE**	PLESSIS ROBINSON	1 (1.2)
CHU – HOPITAL PONTCHAILLOU **A CARDON**	RENNES	1 (1.2)
CHU – HOPITAL CIVIL **N CHAKFE**	STRASBOURG	1 (1.2)
CENTRE HOSPITALIER GENERAL **P PERNET**	TROYES	1 (1.2)
CENTRE HOSPITALIER REGIONAL **P SKOWRONSKI**	ORLEANS	1 (1.2)
CHU – HOPITAL BRABOIS **S MALIKOF**	NANCY	1 (1.2)
CHU – HOPITAL A. DE VILLENEUVE **L CANAUD**	MONTPELLIER	1 (1.2)
Total : 16		**86 (100)**

Aim of study

- The fenestrated Anaconda® endograft (Vascutek)

Potential advantages of complete repositioning , lack of stent material on the main aortic body for more versatility, the ability to cannulate target vessels using upper accesses

- Few data are available

- Objective : mid-term results in the treatment of complex aortic aneurysms on a consecutive series of patients treated in real conditions of use

Population

December 2010 until October 2015

86 patients were included over 16 centers

82 men, mean age 73.4 years
16 (18.6%) symptomatic aneurysms

292 target vessels mean : 3.4 vessels/patient

Group 1 45 P Renal fenestrations : valleys/scallops for the SMA
Group 2 41 P Reconstruction to the CT : valley/scallop or fenest

Perioperative Data

	GROUP 1	GROUP 2	P value
Angulation > 40 °	4,4 %	14,4 %	P=0,002
Operative time	195 mn	282 mn	P=0,0001
Fluoroscopy time	87 mn	109 mn	P=0,0001
Kerma area production	252 Gy/cm2	314 Gy/cm2	P=0,0001
Blood loos	394 ml	611 ml	P=0,0001
Contrast volume	180 ml	193 ml	NS
Repositionning	78 %	80%	NS

Early results

- **Perioperative technical success 86 % (74/86 pts)**
  95,6% vs 80,5%

- **Endoleaks**

  Type I : 2 vs 3 Type III : 0 vs 2 Type II : 4 vs 10

- **Target vessels patency :99,3%** (290/292) 100% vs 98,8%

- **Post Op CTA : successful AAA's exclusion 97.6% (82/84)**
  97.7% vs 97.5%

Early results
Mortality rates

In-hospital 3.5% (3 patients) 1 group 1 vs 2 group 2

30-day 7.0% (6 patients) 2 group 1 vs 4 group 2

Related to the aortic reconstruction in 5 cases

1 acute mesenteric ischemia, 1 surgical conversion, 1 multiple organ failure, 2 hemorrhagic shocks

Related to comorbidities' decompensation in 5 cases

3 myocardial infarctions , 1 cerebral hemorrhage, 1 respiratory failure

Early results
Complications

Variables	Group 1 N = 44*	Group 2 N = 40*	Total N = 84	*p*
Myocardial infarction	2 (4.5)	0 (0.0)	2 (2.4)	*0.18*
Cerebral hemorrhage	0 (0.0)	1 (2.5)	1 (1.2)	*0.30*
Hemodynamic failure	1 (2.3)	1 (2.5)	2 (2.4)	*0.95*
AKI	3 (6.8)	3 (7.5)	6 (7.1)	*0.90*
Common femoral artery's dissection	0 (0.0)	1 (2.5)	1 (1.2)	*0.30*
Target vessel's occlusion	1 (2.3)	1 (2.5)	2 (2.4)	*0.95*
Brachial access' thrombosis	0 (0.0)	1 (2.5)	1 (1.2)	*0.30*
Mesenteric ischemia	1 (2.3)	0 (0.0)	1 (1.2)	*0.34*
Total	**8 (18.2)**	**8 (20.0)**	**16 (19.0)**	*0.83*

**One patient in each group was excluded from the count since the treatment was modified for open bypass surgery*

Reinterventions

6 early reinterventions (7.3%)

4 in group 1

1 for acute mesenteric ischemia

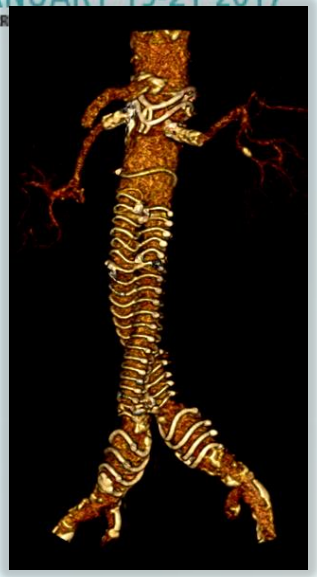
1 to correct a type I EL

2 for false aneurysms

2 in group 2

1 to correct a type I EL

1 for upper limb acute ischemia



Follow up

Mean 22 months

Mid term results 12 and 24 months

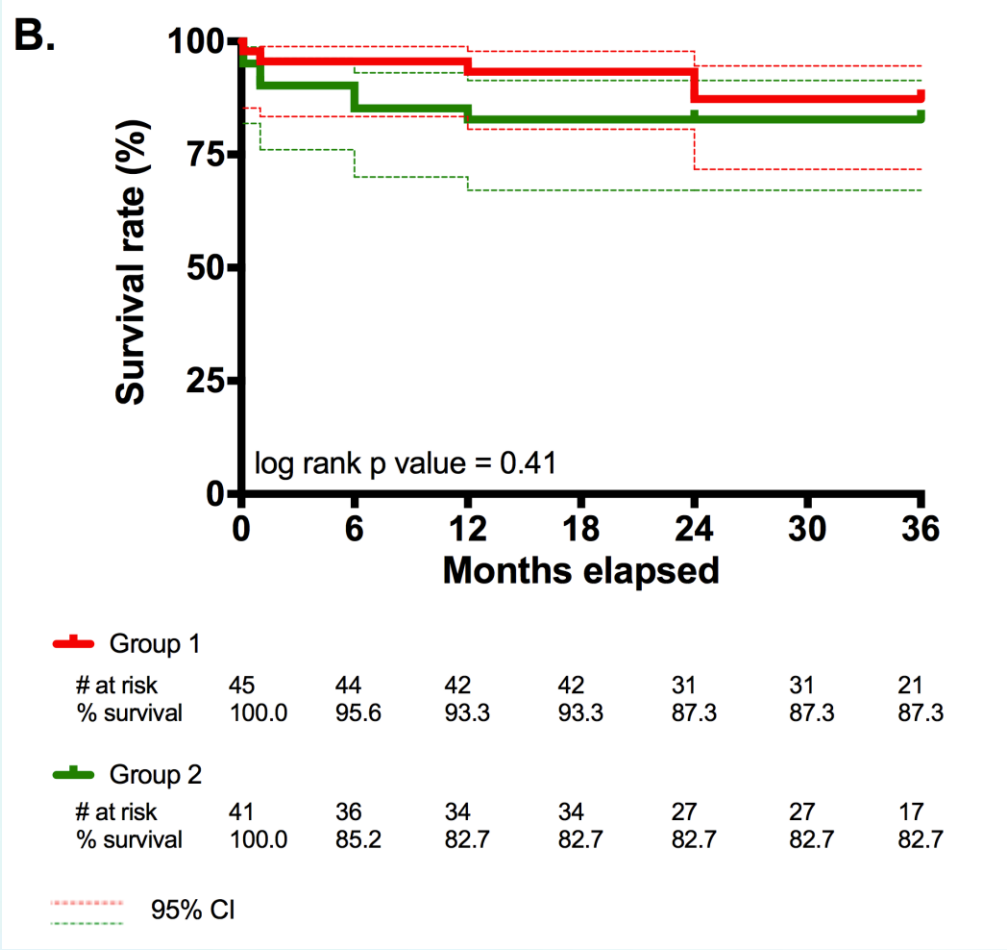
Group 1 vs Group 2

Estimated overall survival rate

12 months 88.3% (93% / 83%)

24 months 85.2% (87% / 83%)

2 deaths /cancer

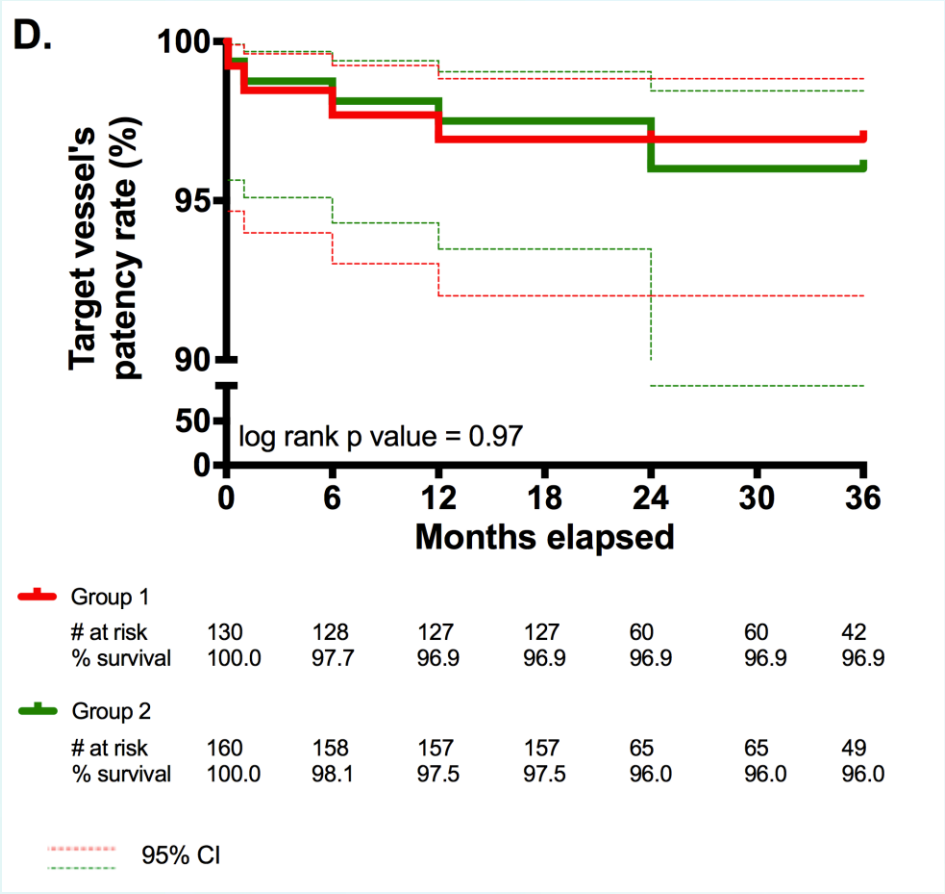


Primary patency of the target vessels

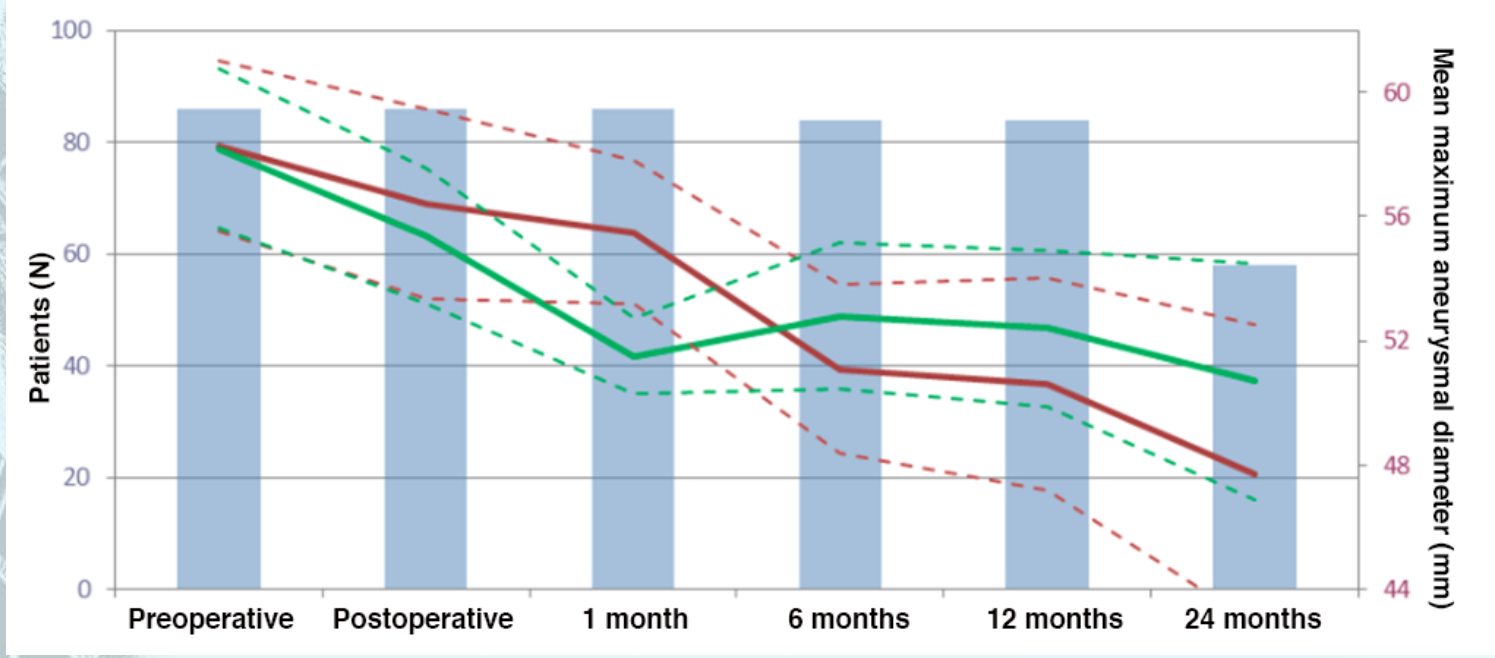
12 months 97 % (97% / 97%)

24 months 96,3 % (97% / 96%)

7 renals arteries occlusions(3/4)



Maximum aneurysmal diameter's evolution



Group 1 (95% CI)

Period	N	Mean maximal aneurysm diameter (mm)	Mean evolution at time point (%)	Overall mean evolution (%)	Standard deviation	95% CI (mm)
Preoperative	45	58.3	-	-	9.4	2.75
Postoperative	45	56.4	-3.26	-3.26	10.5	3.07
1 month	45	55.5	-1.60	-4.80	7.9	2.31
6 months	43	51.1	-7.93	-12.34	9.1	2.72
12 months	43	50.6	-0.98	-13.21	11.4	3.41
24 months	31	47.7	-5.73	-18.18	13.7	4.82

Group 2 (95% CI)

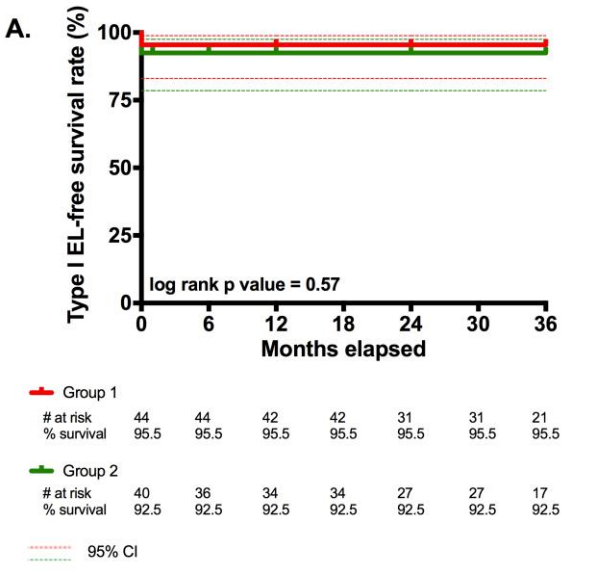
Period	N	Mean maximal aneurysm diameter (mm)	Mean evolution at time point (%)	Overall mean evolution (%)	Standard deviation	95% CI (mm)
Preoperative	41	58.2	-	-	8.4	2.57
Postoperative	41	55.4	-4.81	-4.81	7.1	2.17
1 month	41	51.5	-7.04	-11.51	4.0	1.22
6 months	41	52.8	+2.52	-9.28	7.7	2.36
12 months	41	52.4	-0.75	-9.97	8.2	2.51
24 months	27	50.7	-3.24	-12.89	10.1	3.81

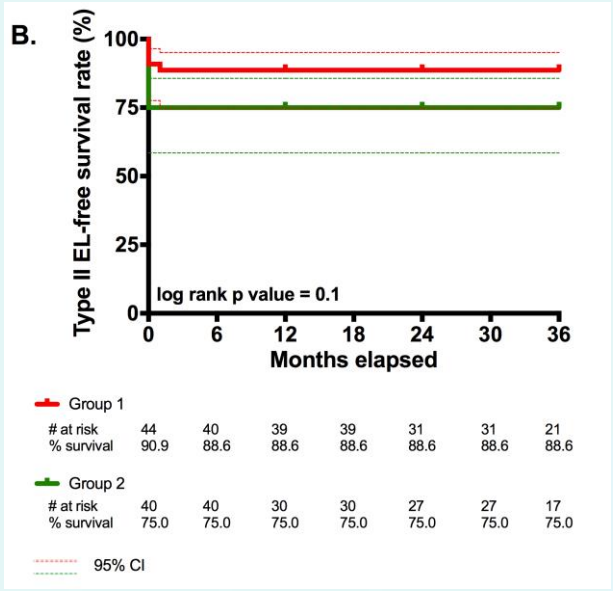
Endoleaks 13 15.5% (6 vs 7)

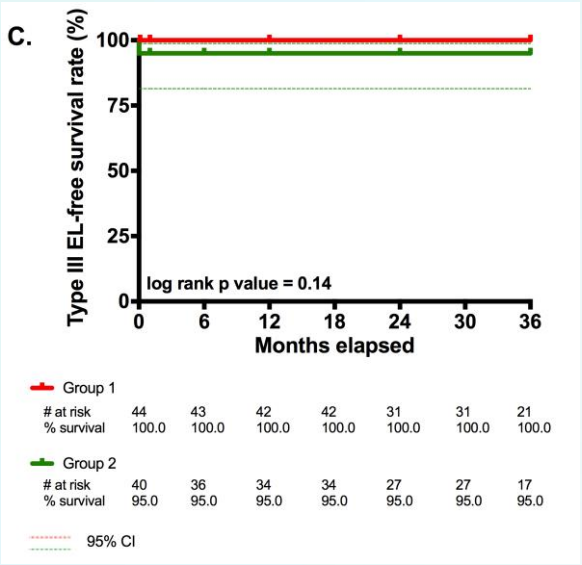
Type I : 1

Type II : 11

Type III : 1







Type I EL-free survival

Type II EL-free survival

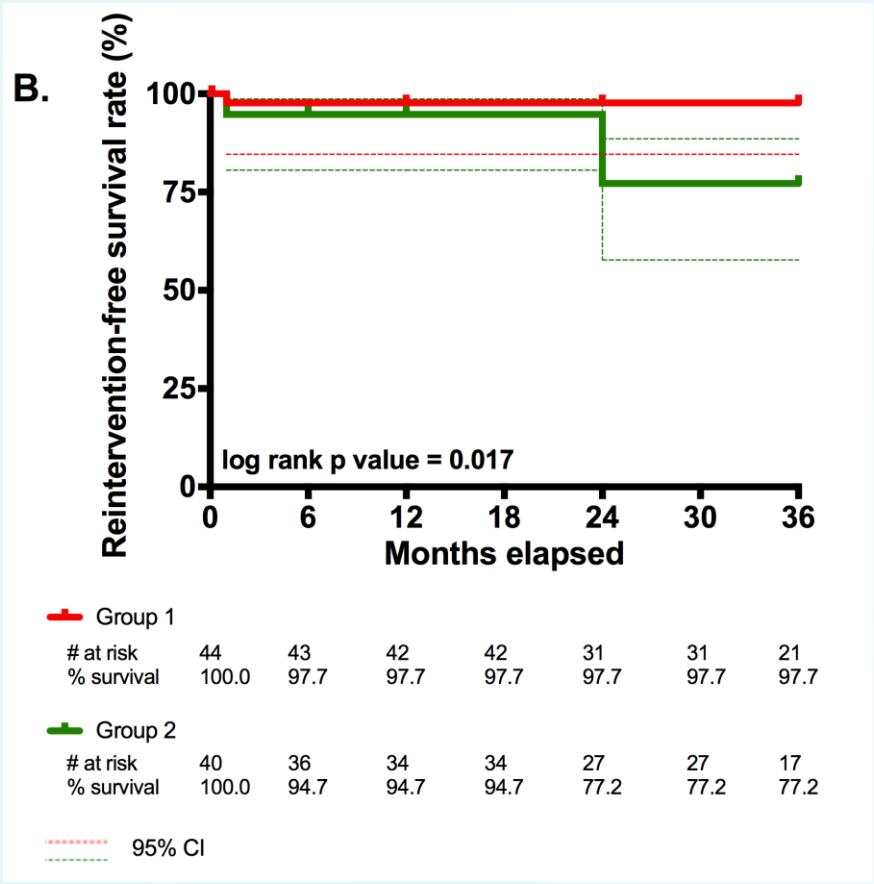
Type III EL-free survival

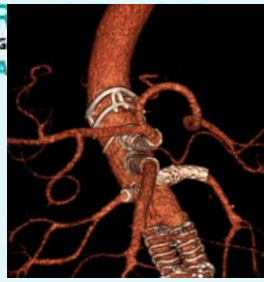
Reintervention-free survival

12 months 96.3% (97.7% vs 94.7%)
24 months 88.0% 97.7% vs 77.2%)

Majority of late reinterventions related to limb graft occlusions

6 cases (7%) group 2





Discussion

- **Outcomes correlated to the level of the proximal extent of the aneurysm :**

Subgroup 2 lower technical success rates

higher 30-day mortality

significantly higher graft limb thrombosis

- **In-hospital mortality rates 3,5 %**

WINDOWS 6.5% for juxtarenal aneurysms vs 14.3% for suprarenal and type IV TAA

Repositioning feature

High cannulation success rate (99.3%)

Blankensteijn (97.1%)

Compared to 85-95% with Zenith® fenestrated devices.

Supported by the repositioning feature and the loose fabric with missing stent wires

Potential risk of embolization

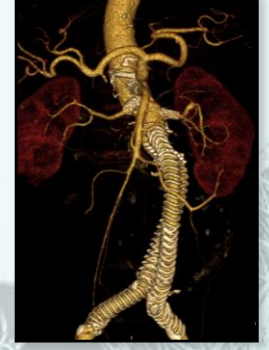
Responsible for the 2 early target vessels' occlusions (1 leading to acute mesenteric ischemia).

Occlusion

- **Shahverdan** : 15% of occlusion ?

- **Kotelis** : 39 patients follow-up of 33 months
  1 occlusion at 2 months

- **Blankensteijn** : 60 patients follow-up of 16.4 months
  1 occlusion at 17 months.



Conclusion

- The fenestrated Anaconda® stent-graft system's characteristics have the potential to increase the proportion of patients suitable for F-EVAR
- Satisfactory technical success rates as well as midterm efficacy and durability with respect to aneurysm sac regression, target vessel patency, overall mortality and reintervention rates.
- Long-term results are still awaited but until then, the rate of graft limb occlusion is of concern in case of particularly complex aortic anatomies.